Neutral Citation Number: [2016] EWHC 1169 (Admin)

Case No: CO/2322/2015, CO/2323/2015, CO/2352/2015, CO/2601/2015 & CO/2706/2015

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION
ADMINISTRATIVE COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 19/05/2016

Before :

MR JUSTICE GREEN

- -

Between :

THE QUEEN **On the application of** **(1) BRITISH AMERICAN TOBACCO (UK) LIMITED** **(2) BRITISH AMERICAN TOBACCO (BRANDS) INC.** **(3) BRITISH AMERICAN TOBACCO (INVESTMENTS) LIMITED**	**First Claimants**
- and -	
SECRETARY OF STATE FOR HEALTH	**Defendant**

And Between : **THE QUEEN** **On the application of** **(1) PHILIP MORRIS BRANDS SARL** **(2) PHILIP MORRIS PRODUCTS SA** **(3) PHILIP MORRIS LIMITED**	**Second Claimants**
- and -	
SECRETARY OF STATE FOR HEALTH	**Defendant**

And Between : **THE QUEEN** **On the application of** **(1) JT INTERNATIONAL SA** **(2) GALLAHER LIMITED**	**Third Claimants**

- and -
SECRETARY OF STATE FOR HEALTH **Defendant**

And Between :
THE QUEEN
On the application of **Fourth**
IMPERIAL TOBACCO LIMITED **Claimant**
- and -
SECRETARY OF STATE FOR HEALTH **Defendant**

ACTION ON SMOKING AND HEALTH ("ASH") **Intervener**

- -
- -

Case No: CO/2322/2015: **NIGEL PLEMING QC, GEOFFREY HOBBS QC, DAVID SCANNELL** and **PHILIP ROBERTS** (instructed by **Herbert Smith Freehills LLP**) appeared on behalf of the **First Claimants**

Case No: CO/2323/2015: **MARIE DEMETRIOU QC** and **DANIEL PICCININ** (instructed by **Skadden, Arps, Slate, Meagher & Flom (UK) LLP**) appeared on behalf of the **Second Claimants**

Case No: CO/2352/2015: **DAVID ANDERSON QC, EMMA HIMSWORTH QC** and **JENNIFER MacLEOD** (instructed by **Freshfields Bruckhaus Deringer LLP**) appeared on behalf of the **Third Claimants**

Case No: CO/2601/2015: **DINAH ROSE QC, BRIAN KENNELLY, LINDSAY LANE, JASON POBJOY** and **MAXWELL KEAY** (instructed by **Ashurst LLP**) appeared on behalf of the **Fourth Claimant**

JAMES EADIE QC, MARTIN HOWE QC, IAN ROGERS QC, CATHERINE CALLAGHAN, JULIANNE KERR MORRISON, NIKOLAUS GRUBECK and **JAANI RIORDAN** (instructed by the **Government Legal Department**) appeared on behalf of the **Defendant** in relation to each of the above proceedings

And

PETER OLIVER and **LIGIA OSEPCIU** (instructed by **Leigh Day**) appeared on behalf of the **Intervener**

The following proceedings have also been linked to the above proceedings:

Case No: CO/2706/2015:

THE QUEEN
On the application of
TANN UK LIMITED, TANNPAPIER GMBH, BENKERT UK LIMITED, DEUTSCHE BENKERT GMBH & CO KG (Claimants)
- and -

SECRETARY OF STATE FOR HEALTH (Defendant)

KELYN BACON QC and **TIM JOHNSTON** (instructed by **Singleton Solicitors**) appeared on behalf of the **Claimants**
JAMES EADIE QC, MARTIN HOWE QC, IAN ROGERS QC, CATHERINE CALLAGHAN, JULIANNE KERR MORRISON, NIKOLAUS GRUBECK and **JAANI RIORDAN** (instructed by the **Government Legal Department**) appeared on behalf of the **Defendant**

Hearing dates: 10-11th, 14-18th December 2015

- -

Approved Judgment

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A. INTRODUCTION, SUMMARY AND CONCLUSIONS

(1) The applications for judicial review: The Regulations being challenged

1. These applications for judicial review are brought by manufacturers who represent the major part of the world's supply of tobacco products. Legislation was enacted by Parliament which conferred upon the Secretary of State[1] the power to lay before Parliament, for its consideration and promulgation, regulations which restrict the ability of the tobacco companies to advertise their brands on tobacco packaging or upon tobacco products themselves. Parliament duly promulgated The Standardised Packaging of Tobacco Products Regulations 2015 ("*the Regulations*"). These specified the 20th May 2016 as the day upon which they became effective. The Claimants challenge the Regulations as unlawful under international law, EU law and domestic common law.

(2) The international and EU context

2. The decision by Parliament to introduce the Regulations was in large measure in furtherance of the policy laid down by the World Health Organisation (WHO) in a singular treaty of 2004, the Framework Convention on Tobacco Control ("*FCTC*"). This is one of the most widely endorsed treaties in the history of the UN. In this convention the WHO has laid down a series of control measures some of which are said to be mandatory and a further series of measures which contracting states are encouraged to adopt, one of which is a prohibition on advertising on packaging and upon tobacco products. This latter measure is known as "standardised packaging". At base it involves a substantial limitation being imposed upon the ability of manufacturers to advertise or place branding upon the outer packaging or the tobacco product itself. The Regulations do not however involve all tobacco products being sold in a homogeneous, undifferentiated manner. The manufacturers can still place the brand name and variant name upon the box and in this way they can still communicate their identities to consumers and differentiate themselves from their competitors. But the manner in which the name and brand may be used is highly regulated in order, in effect, to strip away as much of the attractiveness of the branding or advertising as possible.

(3) Implementation of the Framework Convention on Tobacco Control ("FCTC")

3. The FCTC has been adhered to by 180 countries worldwide and this includes all of the Member States of the EU and the EU itself. In the EU legislation has been adopted to implement the mandatory part of the FCTC in the form of "Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC" ("*the TPD*"). The TPD requires certain restrictions to be introduced into the laws of the Member States upon, *inter*

[1] In this judgment I refer to the Secretary of State as "he" reflecting the gender of the present incumbent. I note however that Ms Jane Ellison, the Parliamentary Under-Secretary of State for Health, signed the Regulations which are in issue in these proceedings. Mr James Eadie QC, for the Secretary of State, confirmed that subject to this proviso my reference to the Defendant as "he" was correct.

alia, the labelling and packaging of tobacco products. These measures are to be implemented by 20th May 2016, the same day as the Regulations are due to become effective in the United Kingdom. In particular the TPD increases the percentage of the space on the two outer faces of a tobacco pack which must be taken up with health warnings and it introduces a series of prohibitions on different types of product presentation and appearance. However it leaves to the Member States the decision whether to go further and introduce standardised packaging.

4. The first country worldwide to introduce standardised packaging restrictions was Australia, in 2012. The Australian Government, which gave evidence to the High Court, says that the legislation is working well and the available data suggests that it is having a salutary effect upon prevalence and use of tobacco in Australia. The Government conducted a post-implementation review which was published in 2016 which was based upon a mixture of qualitative and quantitative evidence and which substantiated the view of the Government of Australia that the measures were beginning to achieve their desired objective.

5. The Regulations in this jurisdiction were introduced however by Parliament without the benefit of a full analysis having been undertaken of the Australian evidence. The view taken by Parliament was that the evidence available to it indicated that the measure would be effective and that there was a real risk to public health and welfare if there was a delay in promulgation pending some subsequent full-blown analysis of the Australian experience for purposes of comparison.

6. Many other countries worldwide are either preparing to implement equivalent standardised packaging rules or are contemplating such a course of action.

(4) A summary of the grounds of challenge

7. I refer repeatedly in this judgment to a number of key judgments. It is convenient at the outset to identify the judgments here for ease of cross-referencing. They are:

   i) *R (on the application of Lumsdon) v Legal Services Board* [2015] UKSC 41 ("*Lumsdon*");

   ii) *Bank Mellat v H M Treasury (No 2)* [2013] UKSC 39 ("*Bank Mellat")*;

   iii) Case C-547/14 *Philip Morris Brands SARL and Others* (4th May 2016) ("*Philip Morris*");

   iv) Case C-333/14 *Scotch Whisky Association et Ors v Lord Advocate, Advocate General for Scotland* (23rd December 2015) ("*Scotch Whisky*");

   v) *United States of America (and Tobacco-Free Kids Action Fund et Ors, Intervening) v Philip Morris USA Inc et al,* US District Court for the District Court of Columbia (Civil Action No. 99-2496 (GK), 17th August 2006 (*per* Judge Gladys Kessler) ("*the US Judgment*").

8. The tobacco companies have attacked the Regulations deploying the full gamut of challenges ranging from international law through EU law and human rights law right down to domestic common law. Some of their challenges prayed in aid fundamental

principles of property established in the 18th century. In order to provide some order to the complaints made by the tobacco companies I have grouped them under 17 Grounds of Challenge. Some of these grounds have multiple parts to them. In broad terms these challenges and grounds fall into 7 categories. Before addressing each category I should record that although different Claimants assumed responsibility for different and specific arguments (with some limited exceptions) they all adopted the totality of the arguments advanced.

9. The first category challenges the legality of the Regulations upon the basis that they implement the TPD, the instrument of EU law which has introduced legislation to implement the FCTC. The Claimants submit the TPD is itself illegal. A reference was made by the High Court to the Court of Justice of a series of questions raising challenges to the legality of the TPD in *Philip Morris*. On 4th May 2016 the Court of Justice handed down its judgment emphatically rejecting these challenges. The parasitic domestic law challenge thus necessarily fails. The analysis of the Court of Justice has a bearing upon a number of grounds raised in these proceedings and because of this I have addressed it at the outset of this judgment (Ground 1 – See Section E below).

10. The second ground (Ground 2 – See Section F below) raises a fundamental issue about the way in which evidence submitted by the tobacco industry should be treated. Specifically it focuses upon a challenge to the way in which the Secretary of State treated the expert evidence served by the tobacco companies during the consultation process leading up to the adoption of the Regulations. It is argued that the Government acted unlawfully because it attributed only "*limited*" weight to this evidence upon the (erroneous) basis that it lacked independence and otherwise failed to meet "best practice" standards for the preparation of evidence. The argument was advanced primarily by BAT but its arguments were adopted by the other Claimants. The position of the Secretary of State is that the generality of the evidence of the tobacco companies was indeed markedly deficient and inferior. This has given rise to two particular grounds of challenge. The first is the general complaint that it was unlawful to give only "limited" weight to the tobacco industry evidence since this unfairly discounted the probative value or worth of that evidence; the second and narrower but essentially similar argument was advanced by BAT alone and was that the specific evidence adduced by BAT had been singled out for adverse and unlawful treatment. BAT contended that its position was different to that of the other tobacco companies who participated during the consultation process because of the sheer volume and quality of the BAT evidence. The tobacco companies not only challenge the approach adopted by the Secretary of State but they also retaliate and attack the impartiality of the experts called to give responsive evidence on the side of the Secretary of State accusing them of being biased in favour of "*tobacco control*". They also attack the "best practice" standards which the Secretary of State relied upon to evaluate evidence. The issue is of very real significance. It is not only at the heart of the limited issue concerning the approach of the Secretary of State to the evidence of the Claimants during the consultation; but it is also relevant to all of the other grounds of challenge where the tobacco companies have adduced evidence though experts.

11. The next three grounds (Grounds 3-5 – See Sections G, H and I below) challenge the proportionality of the Regulations upon the basis: (a) that in the light of the now

available Australian data it can be seen that the Regulations will fail to be suitable and appropriate to achieve their stated objective and in fact will be counter-productive; (b) that in any event the Regulations are not "necessary" because there are less extreme measures which could have been adopted which would have been of equal efficacy (for example tax); and (c), that when one looks at proportionality in the round and balances the competing public and private interests the Regulations amount to an intolerable and unlawful interference with the tobacco companies' private law rights of property. These three grounds are advanced as free-standing grounds of challenge.

12. The next group of challenges (Grounds 6-8 – See Sections J, K and L below) allege a violation of the principle of respect for property. This is advanced in three different ways: (a) under Article 1 of the First Protocol of the European Convention on Human Rights (respectively "*A1P1*" and "*ECHR*"); (b) under Article 17 of the Charter of Fundamental Rights of the European Union ("*The Fundamental Charter*"); and (c) under the common law.

13. Following this the Claimants have advanced a series of technical challenges (Grounds 10, 11, 12 – See Sections N, O and P below) to the legality of the Regulations. The object of this is to establish that the Regulations are *ultra vires* either the TPD, or broader principles of EU or international law. There is no particular single unifying theme to these challenges. In broad terms they allege that the manner in which the Regulations have been adopted involve a misdirection of law, a failure to address relevant considerations, and the taking of action which exceeds the jurisdiction and competence of the United Kingdom.

14. In addition the Claimants also contend (Grounds 9 and 14 – See Sections M and R below) that the Regulations involve violations of other broad EU law provisions in particular: (a) Article 34 TFEU on the free movement of goods; and (b) Article 16 of the Fundamental Charter on freedom to trade.

15. Next BAT (alone) challenges the legality of the consultation process which is said to have been conducted in a manner which is unfair and unlawful towards it: Ground 13 – Section Q. I have already referred to the fact that BAT has alleged that both generally in relation to tobacco industry evidence and specifically in relation to *its* particular expert evidence the Secretary of State acted unlawfully by according only "limited" weight to that evidence (dealt with under Ground 2). BAT also contends that: (a) its evidence was inadequately reflected in the drafting of final submissions made by civil servants to the Secretary of State in December 2014 before he laid draft Regulations before Parliament; and (b) the civil servants unlawfully attached weight to a particular piece of evidence that had not been put out specifically to the tobacco companies for their views during the consultation. There is also a complaint that Parliament acted unlawfully in not awaiting the outcome of the reference to the Court of Justice in *Philip Morris* before promulgating the Regulations: Ground 15 at Section S below.

16. Finally, the tipping Claimants, who are the companies that manufacture, under contract from the tobacco companies, the paper for tips that fit onto cigarettes, support the submissions of the tobacco companies but also submit: (a) that properly interpreted the TPD does not allow Member States to impose restrictions upon branding or advertising upon tobacco products themselves (as opposed to the outer packaging); and (b), in any event the relevant provision (Regulation 5) within the

Regulations which addresses advertising and branding on the product is disproportionate for want of a proper supporting evidence base: See Grounds 16 and 17 – See Sections T and U below.

17. In the remaining part of this introduction I summarise, shortly, some of the central issues which arise in this litigation.

(5) The intrinsic value of the Claimants' evidence

18. A core issue in this litigation concerns the intrinsic quality of the evidence submitted during the consultation, but also in the course of this judicial review. A remarkable feature of the WHO Convention (the FCTC) is that it marks out the tobacco companies as entities which have deliberately sought to undermine national health polices and it translates this considered position into a strong recommendation to the contracting states that, in effect, they apply great circumspection when assessing evidence submitted to them by tobacco interests. The FCTC position is said to be "*evidence based*", a claim that the tobacco companies submit is "*manifestly*" absurd. The FCTC contains at its heart two propositions of real significance for the present case. The first is that tobacco use is an "*epidemic*" of global proportions which exerts a catastrophic impact upon health. The tobacco companies do not dispute or seek to undermine the universal medical consensus as to the profound harm caused by smoking. The second, and most controversial in the context of the present proceedings, is that the tobacco companies have over multiple decades set out, deliberately and knowingly, to subvert attempts by government around the world to curb tobacco use and promote public health.

19. The first proposition is the premise for most of the substantive provisions of the FCTC which set out to curb smoking and tobacco consumption. The second proposition is based upon the experience of the US courts in litigation involving the tobacco companies in the course of which the tobacco companies were, after protracted interlocutory disputes about discovery and privilege, required to divulge truly stupendous quantities of internal documentation (exceeding 50 million pages). This material has now been placed in the public domain and is searchable on-line. The WHO has produced its own practical guide to searching the material. The analysis conducted of these documents by bodies such as WHO, and by the US courts, has led to some stark and, from the perspective of public health, unpalatable conclusions: in particular that the outward facing public statements of the tobacco companies are contradicted by their own inward facing private deliberations and analyses. One instance of this concerns the claim by the tobacco companies that they do not market their products towards children. This proposition (repeated in this litigation) has been rejected in the US courts and by the WHO upon the basis, *inter alia*, of internal tobacco company documents. The FCTC requires that contracting states should exercise vigilance when dealing with the tobacco companies and should ensure that they act with accountability and transparency. The FCTC does not however spell out in detail how those principles should translate into the national laws and practices of the contracting states.

20. In these proceedings I have analysed the conclusions of the WHO and the US courts because they bear upon the dispute between the Secretary of State and the tobacco companies as to the reliability of the evidence submitted by the tobacco companies in the course of the pre-legislative consultation, but also in this litigation. Put bluntly the

Government says that the intrinsic quality of the tobacco company's evidence is inferior as not being in compliance with methodological best practice accepted worldwide by the scientific and technical research communities. These include such matters as: the importance of peer review of research results; the independence of researchers and experts from vested interests; the cross-referability of the reports of experts instructed by the tobacco companies against the internal documents of the tobacco companies themselves; the qualifications and competence of tobacco company experts to opine upon particular topics; and the practice of the tobacco company experts of ignoring or dismissing the pre-existing and adverse literature. To say that the parties disagree fundamentally about these matters is an understatement.

21. In my judgment the Government ***was*** entitled to conclude that the tobacco companies' evidence ***did*** fall below acceptable standards during the consultation. The conclusions which have arisen from the US courts about the sharp discord between what the tobacco companies think inside their own four walls and what they then say to the outside world (especially through experts), are so damning and the evidence of the discord so compelling and far reaching that it is not at all surprising that the WHO concluded that there was an *evidence base* upon which to found their recommendations to contracting states to apply vigilance and demand accountability and transparency in their dealing with the tobacco companies.

22. In coming to this conclusion I have not applied any *sui generis* rule which singles out the tobacco companies for particular and adverse treatment. The requirement that experts should act with transparency and accountability is hardly surprising. It is in fact the cornerstone of the "best practice" regimes applied by regulators worldwide when they seek to evaluate empirical evidence advanced by companies (outside the field of tobacco control) under investigation. Indeed, one of the Claimants' own experts described the principles of transparency and openness as the "*foundational tablets of the scientific enterprise"*. The approach now adopted by the international research community and by regulators represents common sense rules of evaluation which resonate strongly in a case such as the present. Further these principles are consistent with the obligations which experts and parties owe to the Court and which are required under the Civil Procedure Rules ("CPR") which govern civil litigation in this jurisdiction.

23. I have accordingly sought to apply these principles to *all* of the evidence before me, from whatever source. I have applied the sorts of methodological standards that in my judgment are world-wide norms and which make sense to apply to the present facts. As a generality, the Claimants' evidence *is* largely: not peer reviewed; frequently not tendered with a statement of truth or declaration that complies with the CPR; almost universally prepared without any reference to the internal documentation or data of the tobacco companies themselves; either ignores or airily dismisses the worldwide research and literature base which contradicts evidence tendered by the tobacco industry; and, is frequently unverifiable. I say "largely" because the quality of the evidence submitted to this Court (which included all of that tendered during the consultation) was sometimes of remarkably variable quality. Some of it was wholly untenable and resembled diatribe rather than expert opinion; but some was of high quality, albeit that I am still critical of it, for instance, because it ignores internal documents or was unverifiable.

24. It was submitted to me that the experts instructed by the tobacco companies were highly skilled and experienced professionals. Some of the work that they have produced for the purpose of this litigation (and in particular the empirical work) is indeed extraordinarily sophisticated. However, as was observed in the US Courts the simple fact that an expert has a high pedigree or is a Harvard professor or a Nobel Prize winner is not a reason not to apply to their work exactly the same rigorous standards as are applied to the work of others. The report of a Nobel Prize winner as presented to a Court might be a remarkably good piece of work but if it lacks peer review or ignores contradictory internal documents or is unverifiable, its probative value may nonetheless be substantially diminished. Nobel Prize winners should in any event be strong adherents of the very highest of international research best standards; and if they fail to live up to these standards a Court must say so and act accordingly.

25. A point referred to repeatedly by international regulators, who routinely have to address empirical analyses of great complexity authored by individuals of stature and experience and who are leaders in their fields, is that transparency, accountability and verifiability are critical. The more detailed and sophisticated the evidence tendered the greater the need for the regulator or decision maker to be able to de-construct that evidence right down to the tips of its roots in order to be able to evaluate its core structure and the assumptions upon which it is predicated and to assess them against all the available data.

26. In this case the evidence submitted by the Claimants' experts is not capable of being verified nor its underlying assumptions tested. It has been subjected to sustained criticism by the experts instructed by the Secretary of State and these criticisms extend not only to the substantive conclusions but *especially* to its methodological integrity.

27. Nonetheless, I endeavoured to conduct an exercise *for myself* in order to determine whether the *methodological* criticisms launched at the Claimants' experts were justified. This entailed taking each criticism (for instance that a piece of research was not peer reviewed, or was outside the expert's normal field of competence, or included assumptions which were not backed up with evidence, or which ignored the existing literature base, or which appeared to arrive at a conclusion which ran counter to internal documents of the tobacco companies) and checking its accuracy against the other documents in the voluminous Court file. My conclusion was that, where I was able to conduct a proper cross-check, it was a validly made criticism. It is notable that the Claimants have not materially challenged the detailed and highly particularised methodological criticisms made of their expert evidence. Rather they attack the criticism at source, contending that the "best practice" principles advocated by the Secretary of State are irrelevant, misguided or flawed and that accordingly criticisms based upon these principles simply do not strike home.

28. In my judgment the best practice principles are just that - "best" practice. They are tried and tested across the international scientific, medical, social science, legal and economic communities. These principles fall, neatly, under the broad heading of "*transparency*" referred to in the FCTC; and they are logical forensic tools to be applied by a Court to evaluate evidence. Applying these standards I have rejected the Claimants' challenge to the manner in which their evidence has been treated.

(6) Proportionality

29. Recent judgments of the Supreme Court and the Court of Justice (see at paragraph [7] above) have indicated that in relation to proportionality challenges the Courts must consider the most up to date evidence and must engage in detail with that evidence. It is accepted that the actual intensity of review may be variable and may depend upon the margin of appreciation to be accorded to the decision maker. But, nonetheless the Court must form its own conclusion about the evidence and the fact that up to date evidence is admissible means that the assessment by the Court might be of evidence that was not before the original decision maker (here Parliament). In many cases this exercise might not present particular difficulties because the new evidence may be relatively limited in compass or may be straightforward.

30. In this case however, in relation to the first part of the proportionality test (whether the measure is appropriate and suitable to meet its avowed objective), the Claimants have launched a root and branch attack upon the suitability and appropriateness of the Regulations and they have adduced a very substantial body of new expert economic, econometric and other, evidence which sought to demonstrate that in the post-implementation period in Australia, relevant data demonstrated that the standardised packaging rules were not working and in actual fact were serving to increase, not decrease, prevalence and use of tobacco. None of this evidence was adduced during the consultation process and it was hence not considered during the decision making process leading up to the promulgation of the Regulations by Parliament.

31. The Claimants submit that this new evidence is utterly compelling. The evidence relied upon by Parliament was essentially qualitative and "soft" and based upon such evidence as surveys, focus group studies, elicitation studies and a variety of soft psychological testing results. But post-Australian implementation there is now "hard" evidence of how standardised packaging will actually work in a market which is similar to that of the United Kingdom. Given that both prevalence and use can be measured with hard data, this evidence ousts the probative value of all prior "soft" evidence.

32. Put shortly it is argued that the evidence now generated in Australia proves that measures of this sort will harm but not improve public health and that accordingly the Regulations are neither suitable nor appropriate and fail the proportionality test. The Claimants advance a theory which, in very simplified terms, works like this: standardised packaging will by its very nature wipe out the attractiveness of branding. As such all tobacco packaging and products will become uniformly drab. Brand loyalties will in consequence weaken and consumers will "downtrade" to the lower priced products. In further consequence they will, on average, spend less on tobacco products than before. All things being equal if prices go down demand tends to go up so that downtrading will lead to an increase in use of tobacco. This increase will not be counterbalanced or netted off by the demand depressing effects of standardised packaging because there is no proper evidence that factors such as the increased saliency of health warnings and/or the reduction in appeal of tobacco packets and products will exert any serious demand depressing effects. As such they will not counteract the stimulant effect on demand of downtrading.

33. The Secretary of State contends to the contrary that standardised packaging will generate modest but significant reductions in prevalence. He relies upon the

substantial corpus of qualitative research worldwide conducted over more than two decades which analyses, from a wide variety of perspectives, how different consumers react to different advertising, promotional and branding techniques and he says that this type of evidence is powerful and one directional and that it remains cogent and relevant even in a world where data relating to prevalence and use from Australia is becoming available. He also relies upon quantitative regression analyses conducted by his own instructed experts and by experts instructed by the Australian Government based upon the actual experience in Australia which it is said, and notwithstanding that it is still early days, shows that standardised packaging *is* working in Australia.

34. The response of the Claimants to refute the evidence of the Secretary of State is to adopt three broad lines of attack: (i) they adduce expert evidence which challenges the worldwide qualitative evidence and research base upon the basis that it is simply illogical and adopted flawed and unreliable techniques; (ii) they adduce expert economic evidence to establish that the economic theory of downtrading leading to increased demand is logical and consistent with normal principles of market economics; and (iii), they adduce new quantitative regression analyses to establish that in actual fact their prediction that downtrading would cause demand to increase has been borne out by experience and events in Australia.

35. I have reviewed in depth all of the expert evidence in this case. I do not, by any means, refer to all of it in this judgment. I have found that the Secretary of State has adduced ample evidence to support the suitability and appropriateness of the Regulations. I accept that in accordance with internationally accepted best practice the qualitative and quantitative evidence has to be examined as a whole, and in the round. I have found that the econometric regression analyses conducted by the experts instructed by the Secretary of State is consistent and in line with the qualitative evidence and also consistent with a detailed post-implementation review conducted by the Australian Government (2016) which included new quantitative analysis. I reject the submission of the tobacco companies that their evidence is compelling; it is far from such. I accept the thrust of the methodological criticisms levelled by the Secretary of State at the Claimants' evidence, though I emphasise that my conclusion on proportionality is independent of my findings on methodological quality. My core conclusion is that the Secretary of State has simply proven his case and my conclusion about methodological flaws simply reinforces my *prima facie* conclusion.

36. I have come to similar conclusions in relation to the second and third parts of the proportionality challenge. I reject the submission that there is a less intrusive but equally effective way of addressing the Government's health concerns, namely by an increase in tax, and for this reason the Regulations are a (proverbial) sledgehammer to crack a nut when a nut cracker would have done and hence unnecessary (Ground 4). I also reject the submission that applying a "*fair balance*" test of proportionality and balancing the public and private interests the Regulations are disproportionate (Ground 5). As to this latter point the submission of the tobacco companies was that there was nothing exceptional about tobacco which was a lawfully marketed product. The companies had a powerful private interest in their property rights (mainly trade marks) which trumped the public interest arising. Counsel for the Secretary of State reformulated the argument as a claim that the tobacco companies had the right to maximise their profits for the benefit of shareholders by promoting a product that

shortened lives and caused a health epidemic of colossal proportions and which imposed upon the state a vast financial cost. If one examines the issue purely by comparing the monetary losses the tobacco industry assert that they will incur against the costs which would be saved to the public purse by the Regulations the balance comes out very clearly indeed on the side of the public purse. Yet it is wrong to view this issue purely in monetised terms alone; there is a significant moral angle which is embedded in the Regulations which is about saving children from a lifetime of addiction, and children and adults from premature death and related suffering and disease. I therefore reject the Claimants' case that the Regulations are disproportionate.

(7) The limits of judicial decision making

37. A substantial amount of expert econometric and other evidence was placed before the Court most of it focused upon the proportionality argument. I have set out in this judgment (at paragraphs [630] – [648]) my conclusions about the limits of what can properly be expected of a Court confronted with this sort of evidence. In particular this case has brought home to me that under the instruction now given to Courts hearing proportionality challenges to arrive at their own conclusions upon the basis of up to date evidence, there is a real risk that Courts will find themselves overwhelmed by highly technical and complex evidential disputes which they may not be capable of resolving. If this is so then there is a consequential risk that perfectly sound applications for judicial review on proportionality grounds will fail, where otherwise they should have succeeded, simply because the judicial process is not well suited to untangling the complexities involved. I have set out my concerns in some detail in this judgment and also suggested an approach to the way in which such evidence is handled in the future which might alleviate the problem. I have also set out my views on how the constitutional relationship between the Courts and decision makers and legislatures is affected by the task imposed upon Courts by this exercise.

(8) Violation of property rights

38. The Claimants contend that under A1P1 (Ground 6), under the Fundamental Charter (Ground 7) and under domestic common law (Ground 8) they have a property right (their intellectual property and goodwill) which has been unlawfully expropriated from them by the Regulations without compensation. I accept that their trade marks and other relevant intellectual property amount to "*possessions*" or "*property*" which in principle are capable of falling with the protective principles involved. I also accept that in principle certain types of goodwill can also amount to a protectable interest (though on the facts of the case it is not possible to form a concluded view as to the extent to which there are goodwill related rights arising). I reject the submission however that the rights have been expropriated. Title to the rights in issue remains in the hands of the tobacco companies; the Regulations curtail the *use* that can be made of those rights but they are not expropriated. Indeed, the rights remain important in the hands of the tobacco companies because the word marks can still be used on packaging and will serve their traditional function as an identifier of origin. I accept that the figurative marks cannot be used in this manner but they still have certain, admittedly very limited, vestigial uses, which the Regulations do not curtail. Further the restrictions imposed pursue a legitimate public health based interest; a conclusion not challenged by the Claimants. These two factors (retention of title and measures imposed for legitimate public interest reasons) are in large measure

sufficient to defeat in law the submission that the rights have been expropriated. But if I am wrong in this and the Claimants' rights have been expropriated I have then to decide whether compensation should be paid. The law indicates that in cases of true expropriation full compensation is payable save in "exceptional" circumstances. In my judgment it is quite obvious that the circumstances are exceptional. Tobacco usage is classified as a health evil, albeit that it remains lawful. There is no precedent where the law has provided compensation for the suppression of a property right which facilitates and furthers, quite deliberately, a health epidemic. And moreover, a health epidemic which imposes vast negative health and other costs upon the very State that is then being expected to compensate the property right holder for ceasing to facilitate the epidemic.

39. In my judgment this is not a case of expropriation but a case of curtailment of use. Where that occurs the obligation upon the State to pay compensation is governed by a "*fair balance*" test. This is, in essence, the same analysis as occurs under the component of the proportionality test which I have addressed under Ground 5. I reject the claim for compensation. It is "fair" not to compensate the tobacco companies for requiring them to cease using their property rights to facilitate a health epidemic. In my judgment it would not be right to expect the State to pay <u>any</u> compensation for the restrictions imposed upon the use of the rights in question.

(9) Challenges to the lawfulness of the Regulations

40. A variety of technical grounds were advanced by the Claimants to show that the Regulations were unlawful. These are the national counterparts of the arguments advanced by the same Claimants before the Court of Justice and which were rejected in *Philip Morris*. I have set out in this judgment why I reject these grounds. At base Parliament, both under international law relating to health (WHO) and intellectual property (e.g. in TRIPS) and under EU law, has a broad discretion to adopt on a precautionary and prospective basis measures designed to protect against health problems. And that is what the Regulations do. A number of the challenges focus upon what is said to be the essence or substance of a trade mark and upon the competence or jurisdiction of the Member States to enact legislation to regulate the use of trade marks in connection with the preservation of health. It is contended that the Regulations are unlawful or *ultra vires* if they intrude upon trade mark rights or impair those rights. These arguments operate upon the premise that a trade mark proprietor cannot be prevented from using a trade mark <u>at all</u> even when it facilitates a health epidemic. In my judgment the law is very clear: It is *no* part of international, EU or domestic common law on intellectual property that the legitimate function of a trade mark (i.e. its essence or substance) should be defined to *include* a right to *use* the mark to *harm* public health, and the Member States have a broad power to adopt health legislation even when it intrudes upon other rights belonging to manufacturers of products which cause the health problem. The technical arguments to the contrary were advanced with forensic skill but stripped down to below their respectable veneers their bare essentials are exposed as unsustainable.

(10) Challenges to other Treaty and Fundamental Charter Provisions

41. The challenges advanced under this head include a challenge to the right to conduct business under Article 16 of the Fundamental Charter which it is said the Regulations violate. As to this it is clear from case law that this is (for obvious reasons) a highly

circumscribed right and all manner of different laws and regulatory measures (tax, environmental, health and safety, etc) limit the freedom that business otherwise enjoys to do as it pleases. Indeed the express language of Article 16 confers the freedom *subject to* compliance with both EU and national laws. This ground adds nothing new to the other legal challenges. If the Claimants cannot prevail under these other grounds there is no scope for them to succeed under Article 16. A further challenge was made under Article 34 TFEU. This prohibits hindrances to the free movement of goods across borders. The Regulations do create to some degree obstacles to inter-state trade. But Article 34 TFEU is subject, *inter alia*, to overriding public health grounds (in Article 36 TFEU) and accordingly whether or not this ground succeeds is parasitic upon the success of other more specific grounds. As such it also adds nothing to the other challenges. And since no other challenge succeeds then these challenges also fail.

(11) BAT's challenges to the pre-legislative consultation exercise

42. BAT challenged, in a variety of ways, the consultative process which led up to the Secretary of State laying draft regulations before Parliament for its consideration and promulgation. There is nothing in these objections. BAT was able to submit, and did submit, a substantial volume of material during that process. The civil servants conducted an extensive consultative exercise. They received a great deal of evidence from the tobacco companies, much of it mutually supportive and directed in identical lines of travel. The civil servants summarised this evidence in detailed final submissions to the Minister. The Minister then laid draft regulations before Parliament for its independent consideration (by affirmative resolution). It is clear from the Hansard record of proceedings in Parliament that the draft regulations were subjected to vigorous debate and that many parliamentarians spoke out for the position of the tobacco companies. I can detect not a hint of unfairness in the procedure adopted towards BAT. Their arguments were summarised fairly and squarely and the short point is that Parliament made up its own mind aware of the full range of arguments on all sides of the debate, including as to the relevance of the Australian experience.

43. And moreover, even if I had concluded that there was some element of unfairness I would not have found that this was material. This is for two reasons. First, the submissions made for BAT were at a high level of generality and appeared to assume that the Secretary of State was the actual decision maker. They took no account of the fact that Parliament took its <u>own</u> independent decision after full debate. The submissions did not explain how any individual failings on the part of civil servants or Ministers could have exerted any tainting impact upon the decision subsequently made by Parliament. There is, on the evidence, simply no arguable causal nexus or connection identified and any such failing would in any event be *de minimis* and immaterial. Secondly, in so far as any such failing related to evidence going to the proportionality argument it was also BAT's argument (and that of the other tobacco companies) that what happened before Parliament was in any event irrelevant since what mattered was the position before this Court. It must follow that prior failings lost their potency when this judicial review started.

(12) The tipping manufacturers' challenges

44. The tipping manufacturers produce paper for the filter tips for cigarette sticks. They do so under contract to the tobacco manufacturers. They submit that properly construed the TPD does not allow for any sort of restriction to be imposed upon the product itself and this includes the tips. Accordingly, Regulation 5 which does just this is *ultra vires* the TPD. I reject this submission. There are three principles of construction which lead me to this conclusion. First, the TPD is not, so far as definitions of terms are concerned, comprehensive and it does not define "*packaging*". That term clearly covers the outer-packaging and any inner-packaging inside a box; but, when read purposively against the object sought to be achieved and against the international law obligations the TPD purports to implement, the phrase is capable of a wider meaning whereby "*packaging*" includes everything into which tobacco is packed or encased. This would include all that which encases or surrounds the actual tobacco and this would include the paper which constitutes the stick and the tips, as well as outer packaging and wrapping. Secondly, even if the term "packaging" is narrowly construed (as the Claimants submit) and refers only to the outer packaging then on ordinary EU law principles of construction legislatures may still take anti-avoidance measures to ensure that the effectiveness, or "*effet utile*", of the chosen measure is achieved. Indeed this point is made in the FCTC and by the WHO which identify advertising placed <u>on</u> the tobacco product itself as a way for tobacco companies to circumvent the main restrictions in the FCTC on advertising on the outer packaging. As such it is in accordance with normal rules of construction to introduce a restriction on advertising and branding placement <u>on</u> the product <u>itself</u> in order to ensure the effectiveness of the restriction upon the placing of adverts and branding on the outer packaging. Thirdly, even if the above two arguments are wrong, it is an error on the part of the Claimants to contend that the power of the Member States to introduce further legislation is limited by the terms of the TPD. That is a measure of partial harmonisation and in the gaps and interstices left by the mandatory provisions of the TPD there is ample opportunity and a right for Member States to introduce additional legislation, in particular that which is consistent with the international law obligations of the Member States and the EU under the FCTC. Regulation 5 which governs restrictions on the product itself is therefore within the competence of Parliament even if it is not covered by the TPD. I therefore reject the submission that Regulation 5 is *ultra vires*.

45. As to the submission that there is an inadequate evidence base to support the introduction of the disputed Regulation 5 on proportionality grounds, I reject this on the evidence. The Secretary of State has proven that there is an adequate evidence base to support the measure both when it was introduced and now.

(13) Conclusions

46. For the reasons set out in this judgment <u>all</u> of the applications for judicial review fail. The Regulations were lawful when they were promulgated by Parliament and they are lawful now in the light of the most up to date evidence.

B. THE FACTS

(1) The litigation/procedural matters

47. There are before the Court a series of expedited claims for judicial review. These claims were linked together and directions were made treating them as a single set of proceedings. In order to ensure that all issues could be dealt with by the Court in a manageable way a single set of directions was made governing the conduct of the case. This required considerable cooperation between the parties.[2] By the end of the case I had received in excess of 700 pages of written legal submissions from the parties. The Claimants relied upon 25 expert reports and the Defendant upon 5 expert reports. Multiple files of annexes included the evidence base behind the various expert reports. The written evidence also comprised numerous witness statements. A very substantial literature base of national and international research material was also placed before the Court. The actual hearing was divided up over 7 extended days with different Claimants' teams taking responsibility for leading the written and oral submissions on specific issues. I should record my gratitude to all counsel for the high calibre of the written and oral advocacy on the many issues arising.

48. Although I have read and absorbed the totality of the voluminous material that was before the Court it has not been necessary to record or refer to it all in this judgment. A great deal of evidence dealt with factual matters that, in the event, were not materially in dispute between the parties. I have also endeavoured to synthesise and summarise much of the expert evidence which was placed before the Court in order to make what is already a long judgment, more digestible.

49. Restrictions of a similar type to those contained in the Regulations are also under consideration in many other countries throughout the world. To date however only Australia has implemented equivalent measures. In that jurisdiction the tobacco companies challenged the introduction of standardised packaging under the Australian Constitution. The challenge was unsuccessful and was finally determined by the High Court of Australia in *JT International SA & British American Tobacco Australasia Limited v The Commonwealth of Australia* [2012] HCA 43 ("*The Australian Judgment*"). The plaintiff tobacco companies argued that the Tobacco Plain Packaging Act 2011 violated section 51(xxxi) of the Constitution which empowers Parliament to make laws with respect to: *"(xxxi) the acquisition of property on just terms from any State or person for any purpose in respect of which the Parliament has power to make laws"*. The 2011 Act imposed significant restrictions upon the colour, shape and finish of retail packaging for tobacco products and prohibited the use of trade marks on such packaging save as otherwise permitted by the Act which allowed the use of a brand, business or company name for the relevant tobacco product. It was argued that the plaintiffs' rights in the trade marks and their get-up were "property" for the purposes of section 51(xxxi) of the Constitution and that the provisions of the legislation constituted an "acquisition" of its property otherwise than on just terms. The claims failed upon the basis (as the majority held) that there was no "acquisition" albeit that the Court did accept that the Act served to strip the trade marks in issue of their real value. As such the case revolved around a narrow

[2] The directions made were in large measure agreed between the parties as a pragmatic way to enable all of the claims to be heard and determined simultaneously and within an expedited timetable. My experience was that the system adopted worked well. My caveat to this concerns the treatment of expert evidence: see Section G(16) of this judgment.

analytical pivot concerning the concept of "acquisition". Following the failure of the challenge in Australia the challenge moved to the World Trade Organisation ("WTO") in proceedings brought by Ukraine and four other countries but which, according to evidence before the Court, is sponsored by the tobacco industry.

50. The present challenge in *this* jurisdiction is the first occasion that the *full* gamut of arguments surrounding standardised packaging has been raised. These arguments range far and wide and focus (*inter alia*) upon: (a) the scope and effect of relevant international treaties and conventions; (b) the scope and effect of EU law relating to tobacco control; (c) the scope and effect of EU law relating to national and Community trade marks; (d) the jurisdictional competence of Member States of the EU to enact any legislation which adversely affects the rights of trade mark users; (e) the legality (*vires*) of the Regulations; (f) the scope and effect of international, EU and domestic laws on the expropriation of property; (g) the legality of the consultative procedure adopted by the United Kingdom leading up to the adoption by Parliament of the disputed legislation; (h) the efficacy of the chosen policy in terms of *actual* health outputs; (i) the necessity for the Regulations; (j) whether the legislation strikes a fair balance between the competing interests arising; (k) the compatibility of the Regulations with EU rules on the free movement of goods and the right to operate a business; (l) the applicability of various provisions of the Fundamental Charter; and (m) the approach to be adopted towards the assessment of expert evidence in this field both under international law and under domestic civil law. It has seemed to me that no even remotely or marginally arguable stone has been left unturned.

(2) The parties

51. The Claimants in the main proceedings all manufacture and/or supply tobacco products in particular in the form of ready-made cigarettes, and roll your own tobacco for sale in the United Kingdom. They account for the preponderant part of the world supply of tobacco products.

52. The Claimants in the connected proceedings manufacture and supply tipping paper, which is the paper which surrounds the filter on cigarettes.

53. The Defendant is the Secretary State for Health. He was responsible, following a consultation process, for exercising a statutory power to place draft legislation before Parliament under an affirmative resolution procedure. He was not the actual decision maker (that being Parliament) but he has the *locus* to act, in these proceedings, for the Crown.

54. The Intervener, "Action on Smoking and Health" ("ASH"), is a campaigning charity that works to eliminate the harm caused by tobacco products. It was established in 1971 by the Royal College of Physicians. It provides the secretariat for the All Party Parliamentary Group on Smoking and Health. It is funded largely through subventions from Cancer Research UK and the British Heart Foundation.

(3) The Standardised Packaging of Tobacco Products Regulations 2015

55. The Claimants challenge the Standardised Packaging of Tobacco Products Regulations 2015 (hereafter "*the Regulations*"). The Regulations were promulgated by Parliament on the 19th March 2015. They were made pursuant to Section 2(2) of

the European Communities Act 1972 in so far as the Regulations implement the TPD and Sections 94 and 135(2) - (3) of the Children and Families Act 2014 in relation to the other elements of the Regulations.

56. A substantial volume of material was placed before the Court as to the impact of the Regulations upon each of the individual Claimants. In large measure there is no disagreement as to the Regulations themselves or as to their broad effect. This is logical since the object behind the Regulations is to suppress the use of trade marks belonging to the Claimants as a means of advertising and promoting tobacco products manufactured and sold by the Claimants. It would therefore be surprising if there was any suggestion by the Secretary of State that the impact of the Regulations was anything less than profound and explicitly intended so to be. The Impact Assessment which accompanied the Regulations states that the object of the Regulations is to "*reduce the appeal of tobacco products*" and it must surely be common sense that so far as the Government is concerned the greater the reduction in appeal and the more dramatic the deterrent effect of the Regulations, the better.

57. The Regulations are specified to come into force on the 20th May 2016 in relation to the production of tobacco products and on the 21st May 2017 in relation to their supply. The Regulations standardise the material, shape, opening and content of the packaging of readymade cigarettes. Similar controls are applied in relation to roll your own cigarettes. The Regulations also include specific prohibitions in relation to the labelling of tobacco products. The objective of the Regulations is to introduce plain or standardised packaging and, in substantial measure, to restrict the branding permitted on tobacco packaging. The Regulations achieve this end by mandating the design elements of a package. The only permitted colour for the packaging of a tobacco product what is described as "*a drab brown with a matt finish*". The Regulations prescribe the text that may be lawfully printed on packs. Other than standardised text as to the number of cigarettes and the producer only the brand name and the variant of the cigarette is permitted. And, moreover, this is permitted only in a uniform presentation with a specified Helvetica font, case, colour, type face, orientation, and size (font size 14 for brand name and 10 for variant name). The surface of the packaging must be smooth and flat with no ridges, embossing or similar distinguishing features. The package must contain uniform lining. The appearance of the cigarettes must be plain white with a matt finish with white or imitation-cork coloured tipping paper. Permitted text must adopt a uniform presentation with a specified font, case, colour, type face, orientation and placement identifying the brand and variant name. Packaging which makes a noise, produces a smell or changes after retail sale is prohibited.

58. The Regulations are set out in Section D(9) below.

59. Whilst it is clear that the purpose of the Regulations is to strip away from manufacturers and suppliers their ability to promote the product to consumers the Regulations nonetheless (*inter alia*): (i) do not ban the sale of cigarettes altogether; (ii) permit the brand name to be placed on the package; (iii) permit new brand names to be developed and placed on packaging; (iv) permit the identity of the producer to be placed on the packet; and (v), permit promotion at the wholesale level.

(4) The Government's policy in introducing the Regulations

60. It is important (in particular for the law relating to proportionality) to be clear about the Government's policy objectives in adopting the Regulations. The legitimacy of the objective sought to be achieved by the regulation is always a relevant issue in any proportionality challenge. It does not however figure much in this litigation because it was not submitted by the Claimant tobacco companies that the pursuit of the objective of seeking to suppress tobacco consumption and use was not a legitimate objective. There are two broad strands to the objective. First, there is the general and broad health policy pursued by the Government of seeking to suppress both the supply and demand of tobacco products. Secondly there are, within this broader strategy, a number of more specific objectives. Given that the specific objectives are said to be a continuation of the broader, macro, strategy it is necessary to set out the Government case on both.

(i) General objectives – the scale of the health problem

61. At base the objective of the Government is plain and obvious and is to improve public health by suppressing the prevalence and use of tobacco. In this connection, "*prevalence*" refers to the extent to which smoking is widespread and "*use*" refers to the intensity of use by individual smokers. The expression "*consumption*" is sometimes used as an alternative to "*use*". The salient facts were set out in a witness statement prepared by Mr Jeremy Mean, who is presently the Deputy Director for Tobacco Control within the Department of Health. Additional information was set out in the evidence of the Chief Medical Officer, Professor Dame Sally Davies. None of this evidence has been challenged by the Claimants, who unequivocally accept that tobacco products are harmful. I summarise certain of the key facts below.

62. Nearly 19% of adults in the United Kingdom currently smoke and there are nearly 8 million smokers in England alone. Smoking is the primary cause of preventable morbidity and premature death, accounting each year for over 100,000 deaths in the United Kingdom. Deaths from smoking are more numerous than the next six most common causes of preventable death combined. As well as being the leading cause of preventable morbidity, smoking also causes a range of non-fatal diseases, many of which are chronic and require on-going treatment. According to the Royal College of Physicians, *"smoking has now been positively associated with over 40 diseases and the list continues to grow. For most diseases, the association with smoking is strong and viewed as causal."*

63. Smoking is a behaviour most commonly adopted in childhood or by young adolescents. Very few adults over the age of 25 start smoking. Evidence suggests that around 207,000 children aged between 11 and 15 years old start smoking every year in the United Kingdom, i.e. about 600 every day. Children whose parents or siblings smoke are 90% more likely to become smokers. Evidence suggests that if smoking is seen by young people as a normal part of life, they are much more likely to take up smoking. The impact of second-hand smoke is also a critical health issue. Smoking is highly addictive. The Royal College of Physicians has stated that the way in which nicotine causes addiction is similar to drugs such as heroin. Moreover, because of neurological immaturity children can become addicted extraordinarily quickly, literally within weeks of first smoking.

64. The majority of smokers want to quit. However, only a small percentage of quitters are successful in quitting smoking for two or more years (based upon 2008 figures).

65. Smoking has significant adverse societal costs. Quite apart from personal costs smoking also imposes costs upon the NHS and society and is one of the main causes of health inequalities. The independent review into health equalities in England concluded that:

> "Tobacco control is central to any strategy to tackle health inequalities as smoking accounts for approximately half of the difference in life expectancy between the lowest and highest income groups. Smoking-related death rates are two to three times higher in low income groups than in wealthier social groups."

66. The Claimants pay approximately £10 billion in taxes per annum to the Exchequer. However, the overall (net) economic costs of tobacco use to society have been estimated to be about £13.74 billion per annum.

67. Smoking prevalence in Great Britain has decreased from 24% in 2005 to 19% in 2013 (the latest statistics available). Nevertheless, smoking rates plateaued at around 21% and 20% between the years of 2007 and 2012, before dropping approximately 1 percentage point in 2013.

68. The overarching objective of the Regulations is therefore to reduce smoking to the maximum degree in order to improve health. This is the common objective of all tobacco policies or measures. The goal is not to reduce smoking by any particular percentage figure. The control programmes apply a mix of complementary and mutually reinforcing educational, clinical, regulatory, fiscal, economic and social strategies in the effort to reduce smoking prevalence and use. The need for states to adopt multifaceted and complementary approaches is one recognised by the WHO in the FCTC which explicitly encourages the adoption of "comprehensive" anti-smoking strategies, and is also an approach adopted by other jurisdictions across the world, such as Australia. The importance of this is that, as the FCTC reflects, there is a broad consensus at the level of international health policy that to combat smoking requires a portfolio policy approach in which the problem is treated in a variety of different ways.

69. Individual policies or measures may have their own aim or aims. Many aims are common to all or most tobacco control policies (e.g. reducing second-hand smoke). However, tobacco policies may also be targeted at reducing or removing a specific driver for demand and/or addressing a specific threat or concern identified by the Government. For example, two of the six internationally recognised strands for comprehensive tobacco control programmes are: (a) stopping the promotion of tobacco; and (b) making tobacco less affordable. Policies designed to form part of strand (a) (e.g. a ban on tobacco advertising) will have some different goals to those designed to form part of strand (b) (e.g. the imposition of a specific tax), while having common objectives such as helping or incentivising people to quit smoking. Policies directed towards preventing youths taking up smoking in the first place will, again, be different to those directed at encouraging quitting. Indeed, statistics show that most first time adopters are under the age of 25 so that policies directed at preventing take-

up or initiation are largely focused upon children and young adults. Policies directed at quitting may have a greater focus upon adults.

70. Tobacco control programmes evolve and develop in the light of new research and changing circumstances. In the absence of a continuous effort to maintain pressure on supply and demand prevalence rates increase or previous rates of decline may stagnate. The policy endorsed by the WHO thus seeks to '*future proof*' itself by urging contracting Member States to remove loopholes in new or existing policies.

(ii) Specific objectives

71. I turn now to the specific objectives behind the Regulations. These are to eradicate the attractive force of design on cigarette packaging and on the products themselves. Following the introduction over the past 20 years or so of policy measures targeting the impact of advertising, promotion and sponsorship (including the introduction of an advertising ban and display ban), the packaging of tobacco products and the appearance of the cigarettes themselves have become key promotional vehicles for tobacco manufacturers. In 2006, a spokesman for Gallaher (now part of JTI) noted that "*marketing restrictions make the pack the hero*". Branded packaging has been described as the *"silent salesman"* and the manufacturers' *"billboard"*. Tobacco companies do not divulge their internal documents and they have not done so in this litigation. But in the course of litigation elsewhere, and especially in the United States, they have been compelled to provide discovery and there is thus a large body of indicative material that gives an insight into the internal thought processes within the manufacturers. This material suggests that a cat and mouse game is employed between the companies and Governments. As the scope for promotion shrinks through successive legislative interventions so the tobacco companies focus increasingly upon the territory that is left. The importance of the present case is that the packaging and the product itself constitute virtually the last opportunity for tobacco companies to promote their product.

72. The Defendant's position is that there is clear evidence establishing a causal relationship between packaging advertising and smoking initiation, especially among the young. Psychology is critical. Brand imagery appeals to the psychological and social needs of the consumer. Over the last decade the tobacco market has seen a proliferation of tobacco brands and brand variants. Colours and branding on packaging and on cigarettes themselves are used to enhance the appeal of products, including to the young, and to communicate different messages to the consumer in relation to the strength, quality and harmfulness of the product. The market has also seen the introduction of innovative packaging intended to introduce a '*wow*' factor through, for example, 'GlideTec' packs (Imperial) which are designed to embrace the *"sociability of smoking"*. Slimmer packs are designed to appeal particularly to women, as fashion statements. Texture and lacquer are used on packs to provide a positive connection between the smoker and the packaging they handle frequently. The packaging company Vaassen said of tobacco packs:

> "… the real experience [for the smoker] begins when they are holding the pack in their hands".
>
> (Cited in Vasseen (2011) "*Optimise your brand with an inner foil lid*" Tobacco Journal International 2:115; cited in Moodie C *et al* "*Plain*

Tobacco Packaging: A Systematic Review", University of Stirling (Stirling Review)).

73. The increase in brands and brand variants entering the market in recent years coincides with the introduction of tobacco control measures restricting the ability of tobacco manufacturers to advertise and market their products. In his evidence on behalf of the Secretary of State, Mr Mean stated that this is shown by internal documents disclosed by the Claimants in the past:

> "… historic tobacco [industry] documents show … the way in which Philip Morris, in the face of marketing their products in a restrictive environment, considered product and packaging innovation as "concept areas" for development. On packaging innovation for example, in discussion of the development of an oval pack, the proposition behind the concept was identified as providing a "distinctive young masculine appearance" and noted that this idea was well received in concept study results which concluded that the "pack has tremendous appeal amongst young smokers"".

74. The packaging and appearance of cigarettes evolve continuously as tobacco manufacturers seek actively to promote their products despite other restrictions in place, and to incentivise increased purchase levels and, as a consequence, their profits.

75. The tobacco industry has sought to argue, in these proceedings and in others, that all of its marketing activity, including packaging, aims solely to persuade existing adult smokers to switch brands rather than to persuade people (including in particular children) to take up smoking. This argument is unsustainable. It is not possible to design a product to appeal to adults (over 18s) without appealing, even inadvertently, to children. A number of the tobacco companies have strenuously denied that they target their product on children or even that they are interested in the impact of tobacco on children (see paragraphs [294ff] below). But the Government medical advisers all say that, targeted or not, the lure to children remains strong and this is plain and obvious to the manufacturers.

76. In this context the Secretary of State identifies the following as the specific aims of the Regulations: (i) discouraging people from starting to use tobacco products; (ii) encouraging people to give up using tobacco products; (iii) helping people who have given up, or are trying to give up, using tobacco products not to start using them again; (iv) reducing the appeal or attractiveness of tobacco products; (v) reducing the potential for elements of the packaging of tobacco products other than health warnings to detract from the effectiveness of those warnings; (vi) reducing opportunities for the packaging of tobacco products to mislead consumers about the effects of using them; (vii) reducing opportunities for the packaging of tobacco products to create false perceptions about the nature of such products; (viii) having an effect on attitudes, beliefs, intentions and behaviours relating to the reduction in use of tobacco products; and (ix) reshaping social norms around tobacco use to promote health and wellbeing (which includes in part the '*denormalisation*' of or reshaping of social norms surrounding smoking). The aims set out above were identified during the pre-legislative consultation exercise. They are referred to in Section 94(4) Children and Families Act 2014.

(5) The commercial and economic effect of the Regulations

77. The Claimants argue that the Regulations seek, in effect, to close down the vestigial right and opportunity for manufacturers and suppliers to market their brands. They take as their starting point the pre-existing regulatory environment which, as I have already observed, in a variety of ways curtails the rights of manufacturers and suppliers to promote their products. The Claimants thus submit:

> "The production, sale, export and import of tobacco products is, and has always been, lawful in the UK. Yet manufacturers of tobacco products, including the Claimants, operate in a highly restricted environment. There is extensive regulation of tobacco products and packaging at both a domestic and European level, the substance of which is detailed in evidence before the Court. The measures taken are wide-ranging, including for example restrictions on where products can be used (tobacco products are banned from being smoked in enclosed public places), to whom they can be sold (see the raising of the minimum age to 18), how they can be purchased (see the banning of tobacco vending machines) and how they can be packaged…".

78. The Defendant exhibited to its evidence a comprehensive list of all of the measures which had been adopted in the United Kingdom from 2003 onwards. This demonstrated that over that period the Government had been involved in a multi-faceted programme to suppress supply and demand. It highlighted the numerous policies and initiatives designed, for instance, to curtail the prevalence of tobacco use by vulnerable groups such as children and young adults. The measures adopted included a series designed to limit advertising and promotion. The Claimants, for their part, also highlighted certain key legislative EU and national measures which had since the late 1980s already curtailed substantially the commercial ability of the tobacco companies to promote their products. In summary form these include:

a) The 1989 Television without Frontiers Directive, implemented by the Broadcasting Act 1990, which prohibited television advertising for tobacco products.

b) The Tobacco Advertising and Promotion Act 2002 ("TAPA 2002") which comprehensively banned (with accompanying criminal offences) the advertising of tobacco products in the UK, including prohibiting tobacco advertising on billboards and in print, and sponsorship by tobacco product manufacturers.

c) The 2003 (Second) Tobacco Advertising Directive which brought in an EU wide ban on cross-border tobacco advertising and sponsorship in media other than television.

d) The Tobacco Advertising and Promotion (Brandsharing) Regulations 2004/1824 which in essence prohibited the use of features used in tobacco branding on other products and vice versa.

e) The extension in 2006 of the TAPA 2002 ban on advertising to information society services by the Tobacco Advertising and Promotion Act 2002 etc. (Amendment) Regulations 2006/23.

f) The extension of the EU ban on television advertising by the 2007 Audiovisual Media Services Directive to all forms of audiovisual commercial communication.

g) The Tobacco Advertising and Promotion (Point of Sale) Regulations 2004/765, which revoked an exception under TAPA 2002 for the publication of an A5 advertisement at the point of sale.

h) Bans on the display of tobacco products in shops, which have been gradually introduced pursuant to the introduction of section 7A to TAPA 2002, such that now neither large nor small shops may display tobacco products other than by request or for other specific reasons.

79. The parties rely upon the regulatory history and context for different reasons.

80. The Claimants submit that because there has been so much restrictive legislation in the past the scope for them to advertise and promote their brands has perforce focused (now) predominantly upon the packaging and the actual product. It follows, and the evidence submitted by the tobacco companies bears this out, that a vast amount of thought, creativity and ingenuity has gone into packaging design. It follows that, until the adoption of the Regulations, the packaging of products and the products themselves have become the only remaining places where the Claimants may use their trade marks and they are, as it was put, "*therefore critical*".

81. The Defendant says, in effect, "*quite so*" – it is for the very reason that advertising and promotion *is* now focused almost exclusively upon the packaging and the product that this has become an area that Government must tackle if it is to succeed in making continued headway into tobacco usage and prevalence. It is precisely because advertising on packaging and on the product has become so effective that it must, in consequence, be curtailed.

82. There is another relevance to the issue of regulatory context and this is in relation to whether, for the purposes of the law relating to the expropriation of property, the Regulations deprive the owners of their property rights or merely control the use of that property. The Defendant points out that the Regulations are no more than the continuation of a long line of use restrictions and that the Claimants have never in the past objected to them as amounting to a deprivation of their actual rights; the Claimants submit that the Regulations are, in essence, the last nail in the coffin and it is these measures that now result in *de facto* deprivation of the rights themselves. The Claimants' point was made by many deponents from the tobacco industry. I cite just one (from BAT) by way of illustration:

> "Plain packaging would prevent BAT from using any of its registered trade marks and unregistered marks on its packs (consisting of stylised word marks, device marks and marks that are a combination of both device and word marks) other than non-stylised word marks, which must be used in

> prescribed font and size. In the UK market there is already an existing comprehensive ban on tobacco advertising and promotion as well as the recently introduced ban on retail displays. Against this background, the limited space on cigarette packs, and the marks used on them, are to all practical purposes the only means by which BAT can communicate the different qualities of its products to adult smokers and differentiate its brands from those of its competitors and from other brands and products within its own brand portfolios, other than on the basis of price. Plain Packaging will effectively eliminate such differentiation. This would result in the loss of the value of BAT's intellectual property rights and the goodwill attaching to those rights…".

83. The Claimants refer to "*the destructive effect*" of the Regulations on the Claimants' brands. It is said that it is self-evident that the Regulations would effectively destroy the manufacturers' brands which will in essence all look and feel the same. One expert who gave evidence on behalf of the Claimants suggested that losses to brand value could be in the region of "*billions"* of pounds and throughout this case this headline grabbing figure has been used to denote the scale of losses which would be caused by the Regulations. In relation to Philip Morris an expert instructed on its behalf estimated that the loss in brand value to the company, which holds a market share of just under 8% for ready-made cigarettes, was between £340 million and £515 million. Counsel for the tobacco companies during the hearing, whilst being chary of attributing hard valuations, nonetheless described the financial impact as "*truly immense*". It was candidly accepted that this case was about "*profits*". As I explain later in relation to the issue of valuation (See Section I(4)) I reject completely the expert evidence which postulates losses of "*billions*", but I do accept that there will be significant lost value flowing from the introduction of the Regulations.

84. As with much of the factual evidence there is not a great deal of room for dispute about broad generalities. The purpose of the Regulations is to eliminate the otherwise attractive power of the trade marks. Such rights are, in practical terms, valuable in a market place because they are attractive and they provide information to consumers which can stimulate demand for that brand both generally and for that brand to the competitive detriment of rivals. In one sense if the trade marks did not have these powerful attributes there would be no point in suppressing them.

(6) The rights in issue

85. A number of legal issues concern the analysis of the legal nature of the rights used to conduct advertising and promotion. In this section I set out some background information about the rights used by the Claimants. The principal focus of this litigation concerns trade marks and related rights. In particular the Claimants own, variously, UK national, Community trade marks, and international trade mark registrations and applications. Two of the Claimants (Imperial and BAT) also rely upon relevant copyright, patents and design rights, registrations and applications.

86. It is an obvious point to make that trade marks represent an important weapon in a trader's armoury designed to promote the sales of that trader's products both generally and in competition with those of rivals. In their various witness statements the

Claimants emphasise the commercial function of trade marks: "*The collective impact of these individual features is to present a recognisable brand which is familiar to consumers and easy to identify*"; "*... a brand enables consumers to clearly and quickly identify, distinguish and differentiate products, including from other brands or brand variants*"; "*… for manufacturers, brands provide an important means of competition, distinguishing one brand or product from another*"; "*… brands are extremely valuable intangible assets*".

87. There was a significant amount of evidence before the Court on the commercial breadth and strength of the different Claimants' trade mark portfolios. Once again there is no need to set out, *in extenso,* the evidence for me to be able to accept the basic proposition that the trade marks owned by the Claimants comprise substantial and valuable portfolios of intellectual property rights, and that the Claimants' brands may have value both individually and collectively (the sum is greater than the individual parts). For instance JT International owns in excess of one hundred registrations of tobacco products sold in the UK and some of those trade marks are of a long standing nature. The first Benson and Hedges trade mark in the United Kingdom was applied for in 1883 and the Gold pack has been protected by registered trade mark for in excess of 50 years. The Claimants' registered trade marks come in a variety of forms including: device or design marks; pack-front marks; background pack-front marks; names in distinctive typefaces; combinations of marks; colours claimed as an element of the trade mark; and word marks.

88. In addition to trade marks a number of Claimants rely upon other property rights. In particular various Claimants rely upon goodwill in the sense of the goodwill which attaches to (in essence) registered trade marks: see by way of description *Boehringer Ingelheim Ltd v VetPlus* Ltd [2007] Bus LR 1456 paragraphs [36] – [37]. Once again a considerable body of evidence was placed before the Court to establish that there can be goodwill attached to the trade marks and other intellectual property rights. I accept that proposition which to me seems self-evident. The evidence, for instance, refers to various illustrative corporate transactions entailing the licence and sale of brands where a major component of the consideration paid was said to be attributable to goodwill.

89. It is also said that substantial resources are invested in the development and building up of goodwill. One relevance of this in the present case is that it is contended that the goodwill amounts to "property" which is protected by the law of passing off and/or where registered, trade mark infringement and, it is submitted, that the Regulations unlawfully deprive the Claimants of the goodwill attached to their marks by "*cutting them off from the heritage with which they are associated*". The Claimants point out that such goodwill is distinct from goodwill in the business arising independently of the trade marks as the Courts have recognised: e.g. *Mertrux Ltd v HMRC* [2013] EWCA Civ 821 paragraph [40]. Imperial and BAT also rely upon patents, design rights and copyright. All of this is for the purpose of categorising these rights as "personal property" which falls within the definition of "*possessions*" for the purpose of the submission relating to the law concerning the deprivation of property rights without compensation (cf. Grounds 6, 7 and 8).

C. THE CONSULTATION PROCESS LEADING UP TO THE PROMULGATION OF THE REGULATIONS

(1) The identity of the decision maker: Parliament

90. I turn now to the process which led to the adoption of the Regulations. This is relevant to those Grounds which challenge the consultation process but it also provides background information relevant to the Grounds relating to proportionality and property rights (Grounds 3-8). It is important to remember that the ultimate decision maker was Parliament and that the process of promulgation was by affirmative resolution which thereby necessitated Parliament addressing itself specifically to the measures to be adopted. It is abundantly clear from Hansard that Parliament engaged in depth with the merits and de-merits of the arguments; it cannot on any view be said that Parliament rubber stamped the legislation.

91. Accordingly, the consultation process that preceded the laying before Parliament of the draft Regulations was for the purpose of a Ministerial decision as to the form of draft regulations to be laid before Parliament for its consideration.

92. I set out below a summary of the main stages that the legislation went through from consultation to promulgation.

(2) The Stirling Review

93. The Stirling Review was commissioned in 2011 by the Department of Health led by researchers at the University of Stirling. It examined the evidence examining the proposed benefits of standardised packaging. It considered several measures of appeal and in particular perceptions (the attractiveness of standardised packages; the quality of cigarettes in standardised packages; smoker identity and personality attributes associated with standardised packages). The investigation also examined whether standardised packaging increased the salience of health warnings (the ability of a person to notice and recall health warnings on packages, or the seriousness or believability of the warnings). In addition the review considered whether and how perceptions of the harmfulness and strength of standardised packages differed from branded packs (and how different kinds of plain packages differed in this regard). It also looked at whether and how standardised packages impacted upon smoking related attitudes and beliefs, perceived impact on others, and perceived impact on own smoking-related intentions and behaviours.

94. The review examined and reviewed 37 pre-existing studies. The authors concluded that there was strong evidence to support three contentions. These have been described as "intermediate effects" and are encapsulated under the headings: (a) reduction in appeal; (b) increasing the salience of health warnings; and (c) increasing perceptions of harm:

> "Plain packaging has been shown to: A. reduce pack and product appeal, by making packs appear less attractive and of lower quality, and by weakening the positive smoker identity and personality attributes associated with branded products B. increase the salience of health warning, in terms of improving the recall and perceived seriousness and believability of

> warnings, and C. reduce the confusion about product harm that can result from branded packs".

95. A Research Update produced independently by researchers at the University of Stirling, and by essentially the same team, in September 2013 looked at 17 further published studies and concluded that in sum this added weight to the earlier findings. They excluded from their review unpublished (non peer-reviewed) work. Notably, a greater proportion of the studies featured in the Research Update were UK-based than in the 2011 review.

96. A number of limitations in the evidence base were recognised in the Stirling Review: (i) there were no randomised controlled trials of standardised packaging; (ii) many studies exhibited significant methodological flaws; and (iii), the studies often examined hypothetical situations and attitudes which affected their predictive value. However, the point was made that the individual limitations were mitigated by the fact that, overall, the research was consistent in its conclusions. In the (subsequent) Chantler Review (discussed below), Sir Cyril Chantler endorsed the findings of the Stirling Review and expressly observed that the failure by the tobacco companies to disclose internal research put into context their criticisms of the Stirling conclusions:

> "4.8 Contrary to the criticisms made, the authors rightly place emphasis on the overall consistency of results collected through multiple study designs and across several countries (and the absence of evidence pointing in the other direction). This is a commonplace of research analysis which involves determining the direction of effect and, where possible, effect size. *In my view, it does not seem to be a fair criticism that drawing studies from peer reviewed journals with a public health orientation represents a biased approach. There has been ample opportunity for the tobacco industry to present the undoubtedly extensive results of its own internal market research, for example focus group research exploring brand switching, but to date this has not been forthcoming other than as a result of litigation in the United States*."
>
> (Emphasis added)

(3) The 2012 Consultation

97. On 9th March 2011, the Government published *Healthy Lives, Healthy People: A Tobacco Control Plan for England.* This set out 6 different types of measure for the control of tobacco over a five year time horizon. The document foreshadowed a consultation on standardised packaging. On 16th April 2012 a *Consultation on Standardised Packaging of Tobacco Products* (the "2012 Consultation") was published. The then Minister for Health stated:

> "The Government have an open mind at this stage about introducing standardised packaging. Through the consultation, we want to understand whether there is evidence to demonstrate that standardised packaging of tobacco products

> would have an additional public health benefit over and above existing tobacco control initiatives."

98. Consultees were invited to respond to three options: (a) *"do nothing"*; (b) introduce standardised packaging; and (c) adopt *"[a] different approach to tobacco packaging to improve public health"*. The Department did not rule out considering additional alternative ways to reduce the promotional impact of tobacco packaging upon smoking.

99. The 2012 Consultation sought responses to 27 questions. A link to the Stirling Review was provided. Paragraph 1.3 of the 2012 Consultation stated: "*... Any decisions to take further policy action on tobacco packaging will be taken only after full consideration is given to consultation responses*". There has been no suggestion that any of the times ultimately permitted for consultation responses was too short or in any way inadequate. In excess of 2,400 detailed responses and nearly 666,000 campaign responses were received. They were reviewed with the assistance of external consultants.

(4) The introduction of plain packaging rules in Australia

100. In October 2012, Australia's plain packaging legislation came into force, with full (albeit staged) implementation required by December 2012.

(5) The February 2013 submission

101. A submission was provided to Ministers by civil servants dated 12 February 2013. This was accompanied by 20 Appendices (the "February 2013 Submission"). This provided an assessment of the evidence available at that time. It put four options to the Minister. It did not contain a recommendation. Two of the options were: (a) to defer a decision until the Australian experience had been evaluated; and (b), to decide not to proceed with the policy at all.

(6) The Summary Report: July 2013 / the position in relation to Australia

102. On 12th July 2013 the Government published a summary report on the 2012 Consultation responses. On the same date, the Secretary of State made a statement to Parliament. He noted that the views expressed in response to the consultation were polarised. Then the Minister stated:

> "Having carefully considered these differing views, the Government has decided to wait until the emerging impact of the decision in Australia can be measured before making a final decision on this policy. Currently, only Australia has introduced standardised packaging, although the Governments of New Zealand and the Republic of Ireland have committed to introduce similar policies. Standardised packaging, therefore, remains a policy under consideration…".

103. Although it was considered appropriate to wait for further information about the Australian position there was no formal commitment to wait for 'actual' data that 'proved' the success or failure of the policy there. As the chronology demonstrates,

the view that the final decision should await the Australian experience was not in the event adhered to. Although this change in position was criticised by the Claimants no one has suggested that the Government was bound to follow its initial view or was, otherwise, not entitled to change its mind.

(7) The setting up of the Chantler Review

104. The decision to defer sparked considerable Parliamentary activity and this led to the enactment of section 94 of the Children and Families Act 2014 which empowered the Secretary of State to lay draft regulations before Parliament. Even though the policy remained under active consideration by the Department, many parliamentarians wished further progress to be made on the issue because of the important public health benefits it was expected to bring about. The enactment of section 94 thus prompted the Government to appoint Sir Cyril Chantler to review not only the evidence considered in preparing the February 2013 Submission but any new evidence.

105. The review was announced on 28 November 2013. The Minister stated that the Government would introduce standardised packaging if, following the review and consideration of wider issues, the Government was *"satisfied that there are sufficient grounds to proceed, including public health benefit".*

106. Sir Cyril Chantler ("Chantler") is a paediatrician and medical researcher. He was informally recommended to the Department by the independent Chief Medical Officer. Upon the basis of the evidence before the Court, I am satisfied that he was appointed upon the basis of his qualifications and reputation and because he was accepted as a neutral expert competent to provide impartial advice to the Government. As the Chief Medical Officer explained, in a highly polarised field such as tobacco control, having an independent expert to assess the weight of the evidence was desirable.

(8) The Chantler Review Report

107. The Chantler Review Report was dated 31st March 2014 and was published on 3 April 2014. The Report summarised the arguments for and against standardised packaging. The review did not repeat the exercise conducted in 2012 (the Stirling Review) but sought to build upon it.

108. Chantler set out a description of the methodology he used. This included reviewing existing evidence and new submissions, meeting with experts on all sides of the debate (including experts commissioned by the Tobacco Claimants whose evidence submitted to Chantler was also before the Court). He also considered the evidence then existing from Australia and he went to Australia to meet relevant officials and experts. In relation to the firmness of any final conclusion he made the important point (at paragraph [1.19] – set out below) that given the multifaceted nature of the regulatory restrictions imposed it was "*difficult*" both at the time and in the future ("*in due course*") to separate the effect of plain packaging from other measures. He also highlighted the problem faced by researchers which was that they could not conduct double blind randomised control trials (such as were routine in drug trials). His conclusion (at paragraph [1.20] – see below) was that, viewed in the round, there was, nonetheless, a "*considerable volume*" of relevant evidence to evaluate:

"The Review's methodology

1.8 On 16 December 2013 I published a Method Statement which set out the method I intended to adopt in carrying out my review (see Annex A).

1.9 In accordance with the Method Statement, the Review Team and I began by considering the existing evidence relevant to the public health issue I had been asked to consider. This involved giving careful consideration to the Summary Report of the Department of Health's 2012 consultation, reviewing full text versions of a range of detailed responses to that consultation from the main stakeholders and both the Stirling Review and subsequent Research Update published in September 2013.

1.10 Following publication of the Method Statement, some 50 new submissions were received, which brought to light several new papers, including some "in press" or in the process of peer review. The submissions also included a number of organisation's member opinion surveys, and the views of, amongst others, packaging businesses.

1.11 All submissions to the Review were read and key points of argument and supporting evidence identified for follow-up. In several cases I contacted experts who had articulated what appeared to be the key arguments and/or summation of evidence, and arranged face to face meetings with them to explore their views in greater detail. This included meetings with experts such as Professors Devinney and Steinberg, who had produced detailed critiques of the Stirling Review and the drivers of smoking initiation respectively.

1.12 In addition to meeting with experts, in accordance with my Method Statement I held two main meetings to discuss the views of the principal bodies representing each side of this polarised debate. Accordingly, I met with representatives of the Smokefree Action Coalition on 27 January 2014 and the Tobacco Manufacturers Association on 29 January 2014 in order to better understand and explore their respective views. I also met with representatives of Philip Morris Ltd on 29 January 2014 as they are not a member of the Tobacco Manufacturers Association. I am publishing the transcripts of these meetings.

1.13 A number of papers referenced in the tobacco industry's submissions were considered in detail after identification of those that appeared most relevant to the task. The voluminous literature on tobacco control was also scrutinised to the extent time allowed, including material sourced from references in submissions, published papers and previous reviews.

1.14 As anticipated in my Method Statement, I also commissioned some further expert advice to assist me in the analysis of the key evidence. In particular, I commissioned two specific pieces of independent analysis on the qualitative and quantitative studies in the Stirling Review (and the subsequent Research Update) using Critical Appraisal Skills Programme assessment tools. These were undertaken by academics at Southampton University and Kings College London respectively.

1.15 Finally, I also sought to take account of the emerging evidence relating to the implementation of plain packaging in Australia. In particular, I met with a range of stakeholders in Australia during March 2014, including representatives of the tobacco industry, leading public health academics, and key departments of the Australian Commonwealth Government.

1.16 A list of all published evidence considered by the Review will be made available separately, together with copies of the submissions sent in response to the Method Statement and further evidence sent to the Review which generally arose in follow-up to questions posed in meetings or in response to specific requests.

1.17 I have not sought to distinguish between different types of tobacco products for the purposes of this Review but have looked at tobacco in general. All tobacco products are dangerous in their health effects. The Review has, however, focused on cigarettes and roll-your-own tobacco in view of their overall prevalence and particularly their use by children and young people. I note in this regard the approach, taken in the revised European Tobacco Products Directive (mentioned further below) in relation to these products which differs from that taken for more mainstream products but preserves power to intervene further as necessary. I see the scope of any standardised packaging scheme as one matter for policy makers to consider further in the event of a decision to introduce such a scheme.

1.18 Given my terms of reference, much of the Review's time was spent considering the likely impact of standardised packaging on young people. For clarity, in this report references to "children" are generally used to refer to those under 18 years of age (who are unable legally to purchase tobacco), and references to "young adults" are to 18-24 year olds. In practice however, I considered it necessary to consider the effects of standardised packaging across the age range as a continuum. This is because addiction to smoking can involve a number of stages after first initiation, including prolonged progression through occasional use and later consolidation to becoming a habitual smoker. Coupled with the fact that once

> established, giving up smoking is extraordinarily difficult, there is a clear rationale for targeting anti-smoking efforts at children and young people whenever possible.
>
> The nature of the evidence
>
> 1.19 I have been asked whether the evidence shows that it is *likely* that there would be a public health impact. This is clearly not an issue which is capable of scientific proof in the manner one might apply, for example, to the efficacy of a new drug. There have been no double blind randomised controlled trials of standardised packaging and none could conceivably be undertaken. The most direct experiment to test the efficacy of standardised packaging might be to compare the uptake of smoking in non-smoking children with cigarettes in branded packaging and to see which group smoked more. But given the highly addictive and harmful nature of smoking, such an experiment could, rightly, never receive ethical approval. In any case such an experiment would need to be conducted over a long period and within a large population in which other variables were held constant. Indeed in Australia it will be difficult in due course to separate the effect of plain packaging from other factors such as changes in pack sizes introduced by the manufacturers, and price and tax increases.
>
> 1.20 However there is a considerable volume of other evidence from interested parties on all sides of the debate, augmented by further tobacco control publications, internal tobacco industry documents, wider marketing literature and practice, all of which I have taken into account in arriving at a considered view of likely effects, grounded in the best available evidence".

The Secretary of State points out that the Chantler Review represented a form of peer review of the conclusions of the Stirling review which itself was a peer review of the extant material in the public domain in particular that which was peer reviewed.

109. **Intermediate outcomes**: Chantler accepted that it was "*entirely compatible with known risk factors for smoking uptake such as peer pressure and parental smoking*" (ibid paragraph [4.22]) for the three main "*intermediate*" outcomes said in the Stirling Review (see paragraph [94] above) to lead in due course to reduced tobacco consumption, in fact to do so. These were:

a) Reduction in appeal: Branded packaging alone or with novel/innovative design features, appeals to target consumer groups and conveys the qualities of the product. Standardised packaging removes that lure or appeal making smoking aesthetically unappealing via a package design intended to "*conjure up the most negative associations instead of positive ones*". In consequence consumers feel more negative about the taste of the cigarettes and they find the pack ugly and want to conceal it. This leads to the long-term denormalisation of smoking.

b) Increasing the salience of health warnings: The juxtaposition of health warnings with attractive branding is confusing and distracting and diminishes the credibility of the health warning. As such people discount the health warnings believing that if it was dangerous as suggested, it would not be legal. Standardised packages remove the distraction from the health warnings making them more credible, memorable and effective. Standardised packaging entails large graphical (i.e. pictorial) health warnings combined with text selected for its hard-hitting negative visual impact.

c) Increasing perceptions of harm: Colours and descriptors confuse smokers into perceiving significant differences between the relative harmfulness of different brands notwithstanding that there is no material health difference between different branded products. Potential quitters sometimes decide instead to smoke lighter cigarettes in the false belief that they are less harmful rather than attempting to quit.

110. **The need for a multifaceted approach to regulation**: Chantler concluded that the regulation of smoking necessitated a multifaceted approach incorporating a variety of regulatory approaches:

> "I am struck by the emphasis in the published literature, and in oral evidence from experts, that the nature of tobacco control measures is rarely about single, one-off solutions. Given the extraordinary difficulty of quitting smoking, it would be surprising if this were not the case. This is summed up by the Royal College of Physicians Tobacco Advisory Group, who have said:
>
> > "*It is important that policies continue to be developed, improved and innovated to retain initiative and impact with smokers and the general public. It is also important to consider that the individual components of tobacco control policy typically have modest effects. It is their collective impact in the context of a comprehensive range of policies that becomes substantial*"".

111. **Extent of health benefit**: Chantler accepted that the conclusions of the Stirling review were modest and that the evidence base had its limitation but he nonetheless formed the judgment that the evidence was all in one direction and that the so-called "intermediate outcomes" (reduction in appeal, increased salience of health warnings, reduction in confusion, etc) were to be categorised as health benefits which would reduce smoking in the long term:

> "6.2. The specific evidence base, centred on the Stirling Review and update, is relatively modest, and put forward in awareness of its limitations due in particular to constraints on study design. But it points in a single direction, and I am not aware of any convincing evidence pointing the other way. It strongly supports the intermediate outcomes identified, and, taking into account the wider evidence around marketing, and

> drawing on modern behavioural psychology, there is a clear plausible link to behaviour. Whilst standardised packaging may have a *modest* effect, it is the nature of public health measures that small effects mount up at a population level.
>
> 6.3 The "intermediate outcomes" are debatably public health benefits in themselves. For people to be less confused about the harms of smoking is a good thing even if it does not immediately result in them smoking less. It is hard to see how the clearly documented intermediate effects could possibly *increase* smoking, and easy to see to how, over time they could *reduce* it".

112. **The intrinsic quality of the evidence**: Chantler also addressed an issue which has loomed large in all debate over impending legislation between the state and the tobacco industry, namely bias and perceptions of bias. He rejected the criticism made by the tobacco companies that those that advised the Government were biased against the industry. Conversely, he articulated scepticism about the methodological efficacy of research results generated by the tobacco companies. He also criticised the tobacco companies for adopting unrealistic criticisms of the output of existing researchers (see e.g. paragraphs [4.13] and [4.14]). He cited with apparent approval an article by Ulucanlar S, Fooks GJ, Hatchard JL and Gilmore[3]:

> "4.15. In a recently published article Ulucanlar (et al) argue that the tobacco companies' evidence was "underpinned by three complementary techniques that misrepresented the evidence base. First, published studies were repeatedly misquoted, distorting the main messages. Second, 'mimicked scientific critique' was used to undermine evidence; this form of critique insisted on methodological perfection, rejected methodological pluralism, adopted a litigation (not scientific) model, and was not rigorous. Third, tobacco companies engaged in 'evidential landscaping', promoting a parallel evidence base to deflect attention from standardised packaging and excluding company-held evidence relevant to standardised packaging".

113. The point is a significant one. It is an issue that I address fully in relation to Ground 2 in this judgment. Chantler referred to an important judgment in the US given by Judge Kessler (the *US Judgment* - see paragraph [7] above). He said this:

> "6.9 It is always possible to confuse passionate interest with bias. In this regard I note the opinion of Judge Kessler at the conclusion of a seven-year lawsuit involving scrutiny of thousands of documents and examination of many expert witnesses. Namely that: "Much of the Defendants' criticisms of Government witnesses focused on the fact that [they] had been

[3] Ulucanlar S, Fooks GJ, Hatchard JL and Gilmore AB, (2014) "How transnational tobacco companies misuse scientific evidence: a review of tobacco industry submissions to the UK government consultation on standardised packaging." *PLoS Med* 11(3): e1001629.

> long-time, devoted members of "the public health community." To suggest that they were presenting inaccurate, untruthful, or unreliable testimony because they had spent their professional lives trying to improve the public health of this country is patently absurd."[4]
>
> 6.10 My overall findings are not dissimilar to those of previous reviews that have looked at this issue. For example, the findings of the study by RAND Europe undertaken for the European Commission in the context of revision of the European Tobacco Products Directive:
>
> > "While there is still some debate about the feasibility of implementing this measure and about the evidence base for the impact on tobacco consumption, the types of studies presented […] provide evidence of the role and importance of cigarette packaging design in attracting consumers (both current smokers and aspiring smokers) to tobacco products. Thus, given the importance of product attractiveness in product purchasing decisions and evidence that such packaging detracts from the health warning currently placed on such products, it is apparent that plain packaging would have some deterrent impact (albeit difficult to quantify) on the consumption of tobacco products. It might also be envisaged that this impact could be greater in deterring consumers who are non-smokers and therefore not yet addicted to nicotine from taking up smoking. Also, given the evidence on cigarette design attractiveness to different target populations, the impact of plain packaging could also have a particularly positive effect on these groups, encouraging them to reduce their cigarette consumption and uptake".

114. **The impact upon children and youth**: Chantler also firmly rejected the submission of the tobacco companies that standardised packaging could produce a perverse *appeal* (as opposed to a deterrent effect) for children. He noted that this view originated from a 2008 consultation on the future of tobacco control which sought views on plain packaging, and the adverse impact of advertising upon children was listed there as a "*potential disadvantage*". The text continued to say however that "*the Department of Health is not aware of any research evidence that supports such concerns*". Chantler was of the view that the concern expressed by the tobacco companies was speculative and lacking in supporting evidence. He was not aware of any suggestions that this effect has been seen to date in Australia. He stated: "*Whilst not entirely lacking plausibility, at least for a subset of young people, the lack of*

[4] United States District Court for the District of Columbia, (filed: 09/08/2006). *United States of America, Tobacco-Free Kids Action Fund, American Cancer Society, American Heart Association, American Lung Association, Americans for Nonsmokers' Rights and National African American Tobacco Prevention Network v Philip Morris USA Inc. et al*. Civil Action No. 99-2496 (GK). I address this judgment at paragraphs [306] – [310].

evidence suggests that this effect, if manifested at all, would not overturn the broader effect on appeal described above." (ibid paragraph [4.23]).

115. **Ultimate effect of standardised packaging would enhance public health**: The final conclusion of Chantler was that standardised packaging would, on balance, advance public health:

> "6.11 In conclusion research cannot prove conclusively that a single intervention such as standardised packaging of tobacco products will reduce smoking prevalence. For various reasons as cited it is not possible to carry out a randomised controlled trial. Even if it was possible it would be extremely difficult to control for all the various confounding factors which are known to affect smoking. However after a careful review of all of the relevant evidence before me I am satisfied there is sufficient evidence derived from independent sources that the introduction of standardised packaging as part of a comprehensive policy of tobacco control measures would be very likely over time to contribute to a modest but important reduction in smoking prevalence especially in children and young adults. Given the dangers of smoking, the suffering that it causes, the highly addictive nature of nicotine, the fact that most smokers become addicted when they are children or young adults and the overall cost to society, the importance of such a reduction should not be underestimated".

116. **The conclusions of the independent economist**: The tobacco companies argue strongly that standardised packaging will lead to "downtrading" which, all things being equal, would lead to an increase in demand. This is an issue which is addressed at length in relation to Ground 3 below. Chantler decided to test the issue of the price effects of standardised packaging by instructing an independent economist to review the issue. The conclusions were set out in Annex C to the Report. In relation to demand for tobacco the economists concluded that standardised packaging would have two effects. First it would make tobacco products less desirable; and secondly, consumers would therefore be willing to pay less for tobacco than hitherto:

> "In so far as consumers value branded packaging, then a move to standardised packaging reduces the desirability of tobacco products. This is a reduction in demand, or 'willingness to pay' that, under standard economic theory, can be expected to lead to both a fall in price *and* a fall in consumption. In this respect, whilst the magnitude of effect of standardised packaging can be debated, the *direction* of effect from the initial demand change will almost certainly be to reduce consumption of tobacco.
>
> One of the consequences of changing demand is likely to be trading down towards lower cost products. This is because consumers no longer value premium products as highly after desirable packaging is removed. These effects are reported in research produced for Phillip Morris International (PMI) and for Japan Tobacco International (JTI). However, existing

> smokers display extremely high brand loyalty and will have been exposed over their lives to many thousands of branding images prior to the introduction of standardised packaging, so their brand memory will be strong. In Australia, there is some evidence that an existing trend for 'down-trading' towards value brands may have accelerated since the introduction of plain packaging. However, much of this effect is likely to be the result of the significant tax increases that have also been introduced.
>
> *Overall, if standardised packaging was working, a degree of down-trading would be expected to occur, especially in the long-term. This reflects that tobacco in standardised packaging becomes less desirable than it was in branded packaging and therefore the amount consumers are willing to pay for tobacco products is reduced".*
>
> (Emphasis added)

(9) Position of the Chief Medical Officer in the light of Chantler

117. In response to the Review (having received an early copy), the independent Chief Medical Officer, Professor Dame Sally Davies, wrote to the Minister endorsing the Review. She also commissioned internal reports from the Deputy Senior Medical Officers which corroborated her conclusion and that of Chantler.

(10) The response of the Government to the Chantler Review: April 2014

118. On 4 April 2014, the Parliamentary Under Secretary for Public Health announced the Government's response to the Chantler Report:

> "In light of [Sir Cyril Chantler's] report and the responses to the previous consultation in 2012 I am therefore currently minded to proceed with introducing regulations to provide for standardised packaging. However, before reaching a final decision and in order to ensure that that decision is properly and fully informed, I intend to publish the draft regulations, so that it is crystal clear what is intended, alongside a final, short consultation, in which I will ask, in particular, for views on anything new since the last full public consultation that is relevant to a final decision on this policy. I will announce the details about the content and timing of that very shortly but would invite those with an interest to start considering any responses they might wish to make now".

(11) The 2014 Consultation

119. The 2014 Consultation document was published six weeks after the announcement of 4th April 2014. Paragraph [1.1] of the 2014 Consultation document explained that:

> "The Government has not yet made a final decision on whether to introduce standardised packaging of tobacco products. This consultation will inform decision making by the Department of Health and Devolved Administrations on whether to introduce standardised packaging. We want to hear the views of interested people, businesses and organisations. We particularly seek new, or additional, information relevant to standardised packaging that has arisen since the 2012 consultation".

120. Draft regulations were also provided with the 2014 Consultation document so that consultees could understand how the policy would work in practice. All of the Claimants responded to the 2014 Consultation. In total, the Department received a further 1,307 detailed responses and 136,404 campaign responses.

(12) Contingency planning and notification to the European Commission

121. I turn now to the procedure adopted by the Secretary of State in notifying the draft Regulations to the European Commission. Contingency steps were taken in relation to the adoption of the Regulations because of the looming of the 2015 General Election and the onset of *purdah*. As part of these contingency plans on 29th August 2014 the United Kingdom notified the draft regulations to the European Commission in accordance with Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 (the *"Technical Standards Directive*") and Article 24(2) TPD. Article 24 TPD is set out at paragraph [238] below.

122. The decision to notify was taken independently of the final substantive decision whether or not actually to introduce standardised packaging. The Defendant thus explained in his written submissions to the Court:

> "As it was anticipated that the notification would attract detailed comment from other Member States, and thus that the usual three-month standstill period would need to be extended by a further three months, it was decided that the notification should be made before the final policy decision was reached so that if the decision was to enact the Regulations, this would still be viable before the end of the Parliamentary session. BAT and Imperial attach significance to the fact that in response to the notification certain Member States served detailed opinions objecting to the draft Regulations. However, many Member States did not. Moreover, BAT and Imperial do not refer to the fact that a number of other countries support the introduction of standardised packaging (other than Australia), including Ireland, New Zealand, France, and Norway. As set out above, the Guidelines to the FCTC recommend that all members of this important WHO Treaty consider introducing the policy".

123. The TPD is promulgated pursuant to Article 114 TFEU. It provides:

> "Article 114

1. Save where otherwise provided in the Treaties, the following provisions shall apply for the achievement of the objectives set out in Article 26. The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.

2. Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons.

3. The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

4. If, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 36, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

5. Moreover, without prejudice to paragraph 4, if, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

6. The Commission shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

> In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved.
>
> When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.
>
> 7. When, pursuant to paragraph 6, a Member State is authorised to maintain or introduce national provisions derogating from a harmonisation measure, the Commission shall immediately examine whether to propose an adaptation to that measure.
>
> 8. When a Member State raises a specific problem on public health in a field which has been the subject of prior harmonisation measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council.
>
> 9. By way of derogation from the procedure laid down in Articles 258 and 259, the Commission and any Member State may bring the matter directly before the Court of Justice of the European Union if it considers that another Member State is making improper use of the powers provided for in this Article.
>
> 10. The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 36, provisional measures subject to a Union control procedure".

124. It will be seen that under Article 114(5) Member States are empowered to "introduce" measures in the field of "*protection of the environment or the working environment*" and a notification procedure is laid down. It has not been suggested by the Defendant that the power to adopt the Regulations emanated from this provision; but rather that it comes from Article 24(2) TPD which is broader and includes in particular public health grounds. The Commission responded on 10th November 2015 and indicated that it had assessed the evidence submitted in the context of "*...the free movement of goods*" but chose to offer no opinion under the Technical Standards Directive. The Commission stated that it would monitor "*implementation*" and, significantly, would follow international developments "*...particularly at the level of the World Health Organisation*".

(13) The December 2014 Submission

125. On 16th December 2014 a submission (the "*December 2014 Submission*") was placed before Ministers seeking directions on how to proceed with policy development on standardised packaging. The submission set out the relevant evidence to enable ministerial decision making and followed analysis of the responses to the 2014

Consultation and preparation of an impact assessment (see below). The submission sought directions on two policy options which were: (a) to proceed with standardised packaging of tobacco products; or (b) not to proceed with standardised packaging.

126. The basis upon which Ministers were invited to take this decision was that they concluded that there were "*sufficient grounds to do so*". Ministers were made explicitly aware that if they decided in favour of proceeding with the proposal this would involve the laying before Parliament of Regulations. They were advised of the fact that the timetable would be "*extremely tight*" given the need to ensure "*proper Parliamentary scrutiny*" before Parliament rose ahead of the upcoming election. The submission comprises an 81 paragraph summary of the relevant issues and of the positions of the opposing parties to the debate. It comprised 14 annexes which set out further detail on each of the main areas of consideration and it also included a "*reference folder*" which contained the key documents referred to in the submission. The submission as a whole submitted to Ministers was a comprehensive document.

127. A number of features of the submission are relevant to the grounds of challenge. In particular, one such ground (Ground 13) alleges that the Claimants' evidence, and in particular the expert evidence, was insufficiently and unfairly summarised in the submission. As to this the submission provides a summary of the criticisms made of the Chantler Report and in particular it records the tobacco companies' objection that Chantler contained an insufficient evidential basis upon which to introduce legislation, that the Report relied upon unsound and hypothetical evidence and incorrectly concluded that branded packaging contributed to increased tobacco consumption. The submission also sets out the complaint that the Chantler Report was not independent, relying upon expert opinions from tobacco control advocates and those with conflicts of interest and that it unfairly dismissed evidence which did not support the policy (i.e. Chantler was guilty of predetermination). The submission also records the complaint of the tobacco industry that Chantler relied too heavily upon the Stirling Review and paid insufficient attention to data available from Australia. For example, it is recorded that the tobacco companies were of the view that Chantler had ignored a KPMG report upon illicit tobacco markets in Australia. They also referred to a report from London Economics submitted by PMI which concluded that the data from Australia did not demonstrate a change in smoking prevalence following the introduction of plain packaging.

128. Paragraph [22] of the December 2014 Submission lists the principal points advanced by the tobacco industry:

> "22. The main issues raised in response to the consultations by opponents to the policy were:
>
> - In relation to the evidence base – 1) It would not be effective in reducing smoking prevalence since tobacco packaging is not a relevant factor in people's decisions to smoke or quit and, 2) given the lack of evidence the government has not demonstrated that the benefits would outweigh the adverse consequences.
>
> - It would increase the illicit tobacco trade in the UK.

- It would have other significant adverse unintended consequences such as lowering prices and thereby increasing smoking, reducing government revenue, and harming small businesses.

- It creates a further burden on retailers, as it would be more difficult to manage stock and increase transaction times for selling of tobacco.

- It would cause UK job losses in tobacco manufacturing and packaging industries.

- It is unlawful as it would breach UK, EU and international laws and agreements and be an expropriation of intellectual property rights, requiring payment of compensation by the Government.

- There a number of alternative evidence-based options that are proportionate, effective, workable and can achieve public health objectives".

129. The submission also recognised, explicitly, that the evidence base supporting public health benefits of standardised packaging had limitations. These limitations were said to be unavoidable and were a direct result of the nature of the question and the fact that only one country had implemented the policy to date, and had done so only relatively recently. It recorded the objections of the tobacco industry as being "*vocal*" regarding the limitations and gaps in the evidence base. In Annex C to the Submission a detailed, 52 paragraph, analysis of the strengths and weaknesses of the evidence in support of the introduction of advertising restrictions is set out. This Annex acknowledges the limitations inherent in the research base in support of legislation. It also sets out the criticisms advanced by the tobacco companies of that research base and examines those criticisms. It is notable that nowhere in either the Submission or in the Annexes is it said that the evidence supplied by the tobacco companies is to be given discounted weight relative to that advanced in support of restrictive measures by reason of methodological flaws contained within the tobacco companies' evidence.

130. It is right to record that the document came to the conclusion that, on balance, the existing evidence base supported the introduction of restrictive advertising measures.

131. In relation to the risks of "downtrading" (which forms a central basis for the Claimants' submissions under Ground 3) the December 2014 Submission accepts that there "*may be*" increased price competition whereby in time smokers would downtrade from premium to lower priced brands. And it is recorded that the Department accepted that some downtrading "*may occur*" if standardised packaging was introduced into the United Kingdom. The Submission stated that some support for this conclusion could be found in the Australian data but that the results may be due to tax increases introduced there. The Department was of the view that insofar as downtrading did occur the impact of any price reduction could be mitigated by HMT through increased taxation.

132. In relation to illicit trade the Department took the advice of HMRC. A summary of the conclusions of HMRC was set out at Annex K to the submission. It recorded that the tobacco industry had identified an increase in illicit tobacco as a possible unintended consequence of the introduction of the Regulations. The conclusion of HMRC was that there was no evidence to suggest that the introduction of standardised packaging would have a significant impact upon the size of the illicit market or would prompt a step-change in the activity of organised crime gangs. HMRC did anticipate that it might prompt some change in the mechanics of fraud and to the composition of the illicit market but that this could be mitigated and managed through modifications or extensions to existing intervention methodologies. In Annex L further analysis was provided of the risk that the introduction of standardised packaging would increase illicit trade. This took greater account of evidence emanating from Australia. It provided a summary of the conclusions in the KPMG April 2014 Report "Illicit tobacco in Australia: 2013 Full Year Report". This report, prepared on behalf of the tobacco industry, was provided to Ministers in the reference folder which accompanied the actual submission. The Annex provides the view of HMRC on the KPMG Report. The view was that the evidence from Australia was still emerging and that the picture was complex and incomplete. In paragraph [28] of Annex L the following is stated:

> "The KPMG Report indicates a rise in the illicit tobacco market in Australia. However, this Report is funded by tobacco companies and KPMG itself has said that it is a misrepresentation of the Report "*to suggest it supports the contention that plain paper packaging could lead of itself to an increase in tobacco smuggling and duty avoidance*"".

133. In relation to data generated by the Australian Government (the Australian Customs and Border Protection Services Data) the Annex reported that this showed an increase in confiscation of cigarettes in 2012/2013 but observed that it was unclear whether this reflected the general variation of figures from year to year, increased enforcement activity or an increase in illicit trade. The Annex then stated:

> "It is worth noting that there are significant differences between the markets in the UK and Australia, particularly in terms of the proximity to other countries, so the lessons learnt from the introduction of standardised packaging in Australia may not necessarily translate to the UK".

The view of the authors of the December 2014 Submission was that the HMRC assessment was the most comprehensive and reliable information available and that HMRC was the department "*best placed to judge the impact upon the illicit tobacco market in the UK*". Reliance upon the HMRC assessment was appropriate given the potential limitations of evidence emerging from Australia and the differences between that jurisdiction and the United Kingdom. In paragraph [30] the following was stated:

> "Even if it were to transpire that the HMRC assessment underestimates the impact on the illicit market, the final impact assessment for standardised packaging…considers that the benefits of introducing standardised packaging are so large that "21% of the UK duty paid market would need to transfer to the

> UK duty unpaid market, and 21% of those who would otherwise have quit smoking need to divert to the UK duty unpaid market for this policy not to have a positive NPV".

134. The Minister was provided with a further impact assessment (see below). This was ultimately published on 10th February 2015. This included a rebuttal of the key arguments advanced by the Claimants and others who opposed standardised packaging. It is the most detailed analysis of the conclusions arrived at during the consultation process and it can fairly be said to represent the most up to date analysis put to Ministers. Although it cannot be said *necessarily* to reflect Parliament's thinking it can, nonetheless, be said to represent the most comprehensive justification extant at the time of promulgation of the Regulations.

(14) The 2014 Impact Assessment

135. The impact assessment (the "2014 Impact Assessment") considered, in the light of previous Ministerial decisions, three options: (a) to do nothing and await the introduction of the TPD; (b) to adopt standardised packaging; or (c) to defer the decision (again). A detailed cost/benefit analysis was conducted.

136. The conclusion in the 2014 Impact Assessment was that the expected societal benefits from reduced smoking prevalence and the resultant lives saved would be materially larger than the expected costs to society from reduced taxation revenue and costs to businesses. The assessment was published on 10th February 2015. The total quantified benefits were put at £30 billion with the total quantified costs of £5.2 billion and therefore a net benefit to the public interest of circa £25 billion.

137. I set out below paragraphs [1] – [38] of the assessment. These represent, in summary form, the most comprehensive statement of reasons which it might fairly be said reflected the view of the Secretary of State when laying draft regulations before Parliament and it can also, I believe fairly, be said to reflect the reasons upon which Parliament acted. It is important to be precise as to the objects behind the Regulations. These were set out in the assessment. They take their cue from the FCTC. They can be summarised simply:

- Introducing standardised packaging is one part of the Government's wider comprehensive tobacco control strategies to improve public health by reducing tobacco use.
- Standardised packaging will reduce the appeal of cigarettes (including hand rolling tobacco), packs and brands and increase the salience of health warnings.
- It will make perceptions of product harm and strength more accurate and reshape smoking-related attitudes, beliefs, intentions and behaviour.
- It will have a positive impact on reducing youth uptake of smoking and will encourage and support quitting amongst smokers who wish to quit.
- The Regulations are not intended to exert a dramatic effect in reducing prevalence but will contribute as part of a wider package of measures to curb demand.

138. Paragraphs [1]-[38] are important and are as follows:

"What is the problem under consideration? Why is government intervention necessary?

1. Tobacco use remains one of the most significant challenges to public health across the United Kingdom and is the leading cause of premature death in the UK. The Government remains concerned about the take up of smoking by young people, the difficulty that adult smokers have in quitting smoking, high levels of relapse of those smokers that do attempt to quit and the consequences for the health of others from exposure to second hand smoke (SHS). Tobacco use also contributes significantly to health inequalities.

2. The Government has a policy to stop the promotion of tobacco. Action to stop the promotion of tobacco has been taken over many years. The Tobacco Advertising and Promotion Act 2002 (TAPA) prohibits tobacco advertising. The Health Act 2009 requires the end of tobacco displays in England (in large stores from 2012 and all other tobacco retailers in 2015). A Cancer Research UK report on plain packaging says that tobacco packaging serves multiple functions for tobacco manufactures. It is used to promote the product using the same strategies employed by other manufacturers of consumer goods, specifically packaging innovation, design and value packaging. Packaging is viewed as a key marketing tool for tobacco companies, according to both their own internal documents and also the retail press. Packaging has a wider reach than advertising and is the most explicit link between the company and the consumer. Tobacco packaging and branding is a key element of tobacco marketing and promotion in the UK today.

3. Evidence suggests that the majority of existing smokers would prefer not to smoke. Almost 7 smokers in 10 say they would like to quit, yet only half actually make a quit attempt. Furthermore, less than 3% of smokers successfully quit each year. The smoker who wishes to give up smoking faces many obstacles, particularly the psychological and physiological components of addiction. Out of the smokers who do attempt to quit, approximately half do so without any assistance. These unassisted quit attempts are associated with the highest rates of relapse. In general, attempts to stop smoking are accompanied by powerful urges to smoke/cravings which are a major source of relapse and occur despite the individual concerned wanting to remain abstinent. Cravings overpower and undermine resolve to remain abstinent. These problems present examples of the difference between what smokers would prefer to do and what they are actually able to do with respect to tobacco consumption. The policy objectives include supporting smokers who want to quit and helping those who have quit avoiding

relapse into smoking. In doing so, they will be better able to exercise their free choice in consumption decisions.

4. Introducing standardised packaging represents a policy option for the Department of Health in England and for the Devolved Administrations in Scotland, Wales and Northern Ireland, as part of their wider comprehensive tobacco control strategies, to improve public health by reducing tobacco use. Research evidence suggests that standardised packaging of tobacco products would contribute to the Government's public health policy objectives by reducing the appeal of cigarettes (including hand rolling tobacco), packs and brands, increasing the salience of health warnings, making perceptions of product harm and strength more accurate and reshaping smoking-related attitudes, beliefs, intentions and behaviour.

5. Tobacco control policy across the UK aims to reduce youth uptake of smoking, and to encourage and support quitting amongst smokers who wish to quit; standardised packaging is expected to have a positive impact on both.

6. Smoking rates are today broadly the same among men and women. Around two-thirds of smokers say that they started smoking regularly before the age of 18. In 2009, the Public Health Research Consortium (PHRC) published a review of young people and smoking in England. The review found that the onset of smoking is a function of individual factors (e.g. self-image), social and community factors (e.g. family circumstances) and societal factors (e.g. tobacco marketing). Moodie et al. (2008) summarise the different research undertaken on tobacco advertising and smoking uptake by young people, and has found that:

> *Research has consistently revealed that tobacco advertising and promotion increases the likelihood that adolescents will start to smoke, whether employing cross-sectional research, prospective research, time series studies or systematic reviews. The cumulative evidence indicates that there is a dose-response relationship, where greater exposure to advertising and promotion results in higher risk, even when controlling for known causative factors such as low socioeconomic status, parental and peer smoking… Furthermore, we know that tobacco branding is continuing to drive UK teen smoking even after TAPA (2008).*

7. Of particular concern is the impact of tobacco packaging on young people who might not yet be in a position to make properly informed or considered adult lifestyle choices. Growing up in homes where smoking by adults is the norm, children are more likely to become smokers themselves and to take up smoking at an earlier age, perpetuating smoking into

new generations. Pupils who live in a household where someone else smoked are more likely to smoke than those who do not live with any smokers, and, in England, 37% of pupils live with someone who smokes.

8. The impact of tobacco marketing (including branding) may be a key factor in youth smoking uptake. The British Medical Association says:

> *Young people are greatly influenced by their sense of what is normal and attractive; and this in turn is affected by the messages and imagery attached to different behaviours. Thus, particular fashions, music styles and forms of recreation become more or less popular over time. Young people's smoking is susceptible to these same forces, but in this case the associated imagery seems, for some young people at least, to remain consistently positive. This capacity to remain 'forever cool' belies the reality: smoking continues to be the leading cause of ill health and premature death in the UK.*
>
> *Pro-smoking imagery originates from three overlapping sources.*
>
> *First, it is part of the social milieu: young people see others – parents, peers and public figures – smoking and this reinforces the normalcy of the habit. In Great Britain, smoking still has around 10 million role models. The detritus of smoking also provides a reminder of the apparent normalcy of the behaviour.*
>
> *Second, entertainment media depict smoking on a regular basis. Images of smoking are commonplace in films, television shows and magazines, and can influence the attitudes and behaviours of young people. Other forms of media such as the internet represent a growing concern in this respect.*
>
> *Third, young people are exposed to the positive images of smoking generated by tobacco industry marketing. The ban on tobacco advertising in the UK has greatly restricted the more traditional forms of marketing (e.g. billboards); however, ubiquitous distribution, increasingly elaborate point-of-sale displays, attractive pack liveries and evocative brand imagery continue to provide key marketing opportunities that influence young people.*

9. Research suggests that standardised packaging would help to *re-shape* social norms around the use of tobacco products, assisting people to understand that tobacco use is highly addictive and can be hugely damaging to health. According to

an article in the *Bulletin of the World Health Organisation,* 'for decades, the tobacco industry has taken advantage of the package as a venue for creating positive associations for their product'.

10. While smoking prevalence has fallen steadily in England since its peak in the mid-20th century, smoking rates are today higher than average among particular groups meaning that smoking has emerged as one of the most significant contributors to health inequalities in England. The association between smoking and inequalities is today apparent from evidence of who smokes. Smoking is most common among those who earn the least, and least common among those who earn the most. In 2010, smoking prevalence was more than twice as high among people in routine and manual occupations compared with managerial and professional occupations. Smoking rates are high in particular ethnic and social groups. Smoking rates among people with mental health problems is significantly higher than among the general population.

11. The difference in smoking between social groups widens throughout adulthood as people from more affluent groups are more able to quit, for a variety of reasons. Differences in motivation do not account for the differences in smoking rates between social groups, as desire to quit remains broadly the same. There is likely to be a number of reasons why people from less affluent backgrounds are less successfully able to quit, including levels of addiction and the socially reinforcing nature of smoking in groups and communities where smoking rates are high.

12. Smoking is the main cause of differences in illness and death between the poor and wealthy. The Government's Healthy Lives, Healthy People White Paper published in 2010 sets out that one of the Government's key objectives will be to improve the healthy life expectancy of the population, improving the health of the poorest, fastest. The independent review into health inequalities in England, 'Fair Society, Healthy Lives', proposed 'the most effective evidence-based strategies for reducing health inequalities in England' and made the following recommendation: *Tobacco control is central to any strategy to tackle health inequalities as smoking accounts for approximately half of the difference in life expectancy between the lowest and highest income groups. Smoking-related death rates are two to three times higher in low-income groups than in wealthier social groups*.

13. In England and Wales, at least half of the excess risk of death observed in unskilled manual workers by comparison with professionals is attributable to smoking. Similar effects of smoking on health inequalities were also seen in the United

States, Canada and Poland. A 28-year cohort study in Scotland examined the impact of smoking on survival between social classes, and found that the differences in survival between smokers and never smokers are much greater than those between smokers in different social positions.

14. The total cost of treating childhood disease caused by second hand smoke has been estimated at £23m per annum in the UK. We expect this to reduce if legislation to make private vehicles carrying children smokefree is introduced. We would expect this cost to be reduced in proportion to any reduction in parental smoking which might result from a standardised tobacco packaging policy. But, as in previous IAs related to tobacco control policies, we have not otherwise included an impact on NHS costs for the treatment of smoking-related diseases. Although recent research has claimed that quitting may lead to reduced lifetime healthcare costs, the required modelling of cost consequences of deferred mortality requires further development.

Summary and Conclusion of Tobacco Standardised Packaging Impact Assessment

15. There is a substantial body of evidence regarding the factors associated with the uptake of smoking by young people and the factors that can inhibit smokers who wish to quit and induce relapse among smokers who have tried to quit. This evidence strongly suggests that the implementation of standardised packaging ("the intervention") could both reduce the uptake of smoking by young people and create a more supportive environment for those who wish to quit. Recent research has considered the impact specifically of tobacco packaging and branding (including standardised packaging) on the self-image of smokers and on the likelihood of quitting, and has confirmed that introducing standardised packaging could bring substantial benefits for public health.

16. Quantification of the likely scale of the impact on smoking take up and prevalence is difficult. There is, however, experience in the UK and internationally of other tobacco control interventions, particularly those involving tobacco advertising, promotion and marketing, to provide insight into expected impacts of introducing standardised packaging. Researchers who have specialised in tobacco control are in an informed and experienced position to integrate existing policy experience with the research studies on tobacco packaging. Independent academic research was commissioned by DH to gather an expert view on the likely scale of impact of standardised packaging from a range of tobacco control experts from around the world. The consensus (based on the median of

reported views) of these experts is that the intervention would be expected to generate after two years:

- a decline in the proportion of 11-15 year olds who have ever smoked of 3 percentage points (the proportion of this population who have ever smoked was 27% at the time of the research, so the 3 percentage points would represent a fall of 11% (3 in 27)); and

- a decline in adult smoking prevalence of 1 percentage point (the proportion of this population smoking was 21% at the time of the research, so would represent a 4.8% (1 in 21) fall), as more people find themselves able to quit.

17. The benefits and costs in this IA are assessed on the basis of additional benefits and costs that would be likely to accrue over and above existing tobacco control measures and anticipated measures in place at the time of standardised packaging implementation. This includes the benefits and costs of recently commenced legislation in England to end tobacco sales from vending machines, ending the open public display of tobacco products in shops by April 2015, and the benefits and costs arising due to the revised TPD.

18. Based upon the European Tobacco Product Directive (TPD) Impact Assessment we estimate around a 1.9% reduction in the number of smokers might plausibly be achieved by TPD without standardised packaging, including a 1% reduction due to packaging and labelling aspects. We account for TPD within Option 1 (our "Do Nothing" option), so only the incremental gain of standardised packaging provides our central estimates (i.e. the 11% and 4.8% figures in the above bullet points become a net reduction of 10% and 3.8% to prevent double-counting)

19. At this time it is difficult to conclude what the impact of standardised packaging on Australian smoking prevalence has been, due to confounding issues of changes to tobacco prices. There are also general difficulties of sample size when investigating impacts that are expected to be relatively small. Also the policy is at an early stage and data on medium and longer term trends do not exist yet. However the evidence that is available is consistent with a hypothesis such as the consensus one above that the policy would contribute to a modest decrease in prevalence.

20. With the intervention sustained for ten years following the policy implementation date (the standard policy appraisal period), such shifts in smoking behaviour would generate very large health benefits – estimated in total at 0.49m life years

(discounted). These health gains, using standard DH methodology (based upon surveys of citizens' willingness to pay for mitigation of health risks), are valued at £29bn.

21. There is considered to be lost economic productivity due to smoking breaks and tobacco-related absenteeism, therefore this policy is expected to decrease this loss and provide productivity gains of £0.9bn (discounted over the lifetime of those who exhibit behaviour change in the 10 years following policy implementation).

22. We estimate a cost saving associated with the production of simpler standardised rather than branded packs, of £0.23bn (discounted over 10 years). Only a small portion of this will accrue to the UK.

23. There are other benefits discussed but not quantified and not included in the Net Present Value calculations. When considering consumer surplus the orthodox approach is based on rational consumer behaviour. However, for addictive goods, this theory is not a plausible approach. For addictive goods, branding may act as a cue that stimulates craving. Removing the cue helps the addict to realise their true preferences. Any reduction in consumption due to standardised packaging might therefore be taken to reflect true preferences. The approach leaves the analyst with the task of assessing both the costs and the benefits realised by those who, in the wake of reduced branding, either do not become smokers or are enabled to quit. In addition to the health benefits listed above, there is pecuniary gain from reduced spending by quitters of around £5.7bn. However, there are offsetting withdrawal pains that quitters endure and any loss of any pleasure associated with smoking. There are also pecuniary gains for those who do not take up smoking, of £880m. These children are not addicted and hence have no offsetting withdrawal pains, but they do lose smoking related pleasures. As the assumptions that would be required to calculate non-health net gains would be relatively unconventional at this time, and were not included in the consultation IA, so they are not included in the NPV.

24. There are also expected to be benefits in terms of reduced morbidity and mortality due to second hand smoke exposure. There would be reduced costs to local authorities, and to businesses, for litter collection due to fewer discarded cigarette butts.

25. We also expect there to be a reduction in health inequalities. In 2010, 13% of the managerial and professional group were smokers compared with 27% of the routine and manual group. If display of branded packets induces take-up within the home and explains the link between parental

smoking and take-up, standardised packaging may be helpful in tackling the differences in acculturation to smoking across socio-economic groups.

26. We consider the possibility that standardised tobacco packaging would be easier and cheaper to copy, so increasing the supply of counterfeit tobacco in standardised packs. We also consider the possibility that smokers may be more likely to seek out branded products in a standardised packaging environment. There are also counter arguments to these possibilities as well as the mitigation factors and options, and evidence from Australia in relation to these risks. We conclude that there is a sizeable likelihood that there will be no discernible increase in the illicit market or cross border shopping (CBS), but there is a chance of an increase. A reasonable statistical expectation is of a 0.4% transfer from the UK duty paid market to UK duty unpaid market (both illicit and CBS are part of the UK duty unpaid market), would imply a £31m UK loss to tobacco manufacturers, wholesalers and retailers.

27. There are also expected losses to the exchequer of £5.0bn. These losses mainly come from the reduction in tobacco consumption. They also come about if smokers downtrade from higher price brands to lower price brands (which are taxed less).There is also a contribution from a potential increase in cross border shopping and illicit trade.

28. In general we assume that normal profits lost due to reduced tobacco sales will be offset by sales of non-tobacco within the economy. However, some of the value of these sales is due to the value of brands that have already been created, and whose value is diminished by the intervention. This diminution of value needs to be reckoned as a one-off cost of the policy. With standardised packaging we expect a more rapid decline in sales of high price than of low price brands because of a greater likelihood of quitting among smokers of high price brands and due to downtrading from high price to low price brands among those who continue to smoke. The impact on returns to UK business (tobacco manufacturers, wholesalers and retailers) attributed to the reduction in brand value is estimated to have a present value of £190m.

29. The impact on small and micro businesses is uncertain, but the small and micro business sector may have relatively higher transitional losses compared to larger businesses due to lost footfall-related sales.

30. Standardised packaging may encourage printing to switch from gravure printing to cheaper offset lithography so some gravure machines may become redundant. In any case the value

of the produce of packaging manufacturers will drop, diminishing the profit stream associated with this business. An estimate of this impact is the expected drop in the economic value of the capital stock which might be affected. We estimate that £10-£15m worth of machinery may become redundant and use this as an estimate of the lost profit stream to packaging manufacturers.

31. We expect there to be a very short lived increase in serving time whilst shop assistants familiarise themselves with the new system and customers become aware of the change in appearance. We value this loss of time to tobacco retailers and those purchasing tobacco at £0.80m.

32. The Direct impact upon all UK based business for One In Two Out (OITO) purposes is set out in the OITO section of the IA.

33. We need to consider not only the consumer surplus associated with smoking (discussed above) but that associated specifically with branded products, the loss of the ability of those who continue to smoke to gain the intangible benefit associated with smoking a particular brand that only the packaging of that brand, as it is currently available, can produce.

34. It is hard to assess how many of the 9.9 million or so people expected to continue smoking would suffer any felt loss from the absence of this particular avenue of self-expression, and to quantify the loss. Personal branding might be substituted by purchase of other branded goods. There is some further evidence that such branding carries a positional good externality i.e. the positive branding associated with premium brands inspires embarrassment and hostility in others not able to afford such self-branding. For these reasons, we have not quantified the loss of consumer surplus from branding.

35. Those who continue to smoke may also feel as though they have suffered a restriction in freedom. However, from a societal perspective, there is reason to discount the importance of this loss of freedom. For individuals to carry and personally to display branded packets of cigarettes may contribute to encouraging others, including children, to take up smoking and to deter quitting by those who wish to quit. Tobacco packaging and branding plays a promotional role and helps to shape social norms around smoking. The freedom to have branded tobacco, therefore, carries a cost to others; and society arguably need not accord value to a freedom that involves inflicting harm on others.

36. One unquantified cost is a reduction in the ability of tobacco companies to compete through product differentiation because of different packaging.

37. The gross gain of standardised packaging (that could be valued) before considering costs or unquantified impacts is assessed as £30bn. The gross costs of standardised packaging (that could be valued) are assessed as £5.2bn. This gives a net gain of around £25bn. Since the benefits are estimated to be much larger than the costs, the risk of the policy having a net loss is considered small. Furthermore, if the policy had a smaller impact than expected on smoking prevalence then although the benefits would decrease, so would the largest element of cost (that to the exchequer).

38. The intervention is worth pursuing now, notwithstanding these costs and risks. We believe that the cost of delaying a decision on whether to implement the intervention (Option 3) is too great in public health terms, particularly in view of the following considerations:

- we can already benefit from the experience of Australia in determining the detail of any legislation and in implementing the intervention;

- the potential health gains are very substantial and dramatically outweigh quantified costs;

- the deferral of such gains would adversely affect the life expectancy of large cohorts of children and adult would-be quitters in every year of deferral;

- if the true impact of standardised packaging is substantially smaller than assumed in this IA (but not zero) it would still be net beneficial to act now;

- evidence from Australia is valuable, but there are considerable uncertainties that will remain;

- if standardised packaging is implemented, monitoring of extent of impacts, such as any impact on cross-border shopping or the size of the illicit market would identify where mitigating action is needed; the information conveyed by such monitoring is likely to be much more directly pertinent to the policy context in the UK than that which can be gathered from other countries that have implemented the intervention (such as Australia)".

(15) The Pechey Elicitation Study (2013)

139. In the context of the 2014 Impact Assessment it is necessary to backtrack slightly and consider a 2013 elicitation study conducted by Pechey *et ors*. This was relied upon in the 2014 Impact Assessment in relation to the quantification of potential costs and benefits. Researchers were commissioned to conduct an elicitation study whereby experts were interviewed to test their reactions to certain premises[5]. This was a study regarding the likely impact on smoking rates in adults and children of plain packaging of tobacco products. Thirty-three tobacco control experts were recruited from the UK (14), Australia (12) and North America (7). Their views were elicited via telephone interviews, and then pooled on a linear basis. Elicited estimates consisted of (1) the most likely, (2) the highest possible, and (3) the lowest possible, value for the percentage of (a) adult smokers and (b) children trying smoking, two years after the introduction of plain packaging (all other things being constant) in a target country in the expert's region of residence.

140. The median estimate for the impact on adult smoking prevalence was a 1 percentage point decline (99% range 2.25 to 0), and for the percentage of children trying smoking the median estimate was a 3 percentage point decline (99% range 6.1 to 0), the latter estimated impact being larger than the former ($P < 0.001$, sign test). There were no differences in either estimate by region but there was considerable variability between experts' estimates within regions. The study showed that tobacco control experts felt the most likely outcomes would be a reduction in smoking prevalence in adults, and a greater reduction in the numbers of children trying smoking. The results did however reveal a significant variability in the estimated size of these impacts. No expert estimated an increase in smoking as a likely outcome.

141. The Pechey Study authors record the concerns expressed by some of the experts as to the absence of hard data upon which they were asked to base their views and the views of these experts, however skilled they were, were only best estimates. The authors recommend that in future a comparison of the experts' views with "actual impact" evidence would be helpful in verifying the experts' conclusions. The Pechey review was peer reviewed and was conducted by independent researchers. The procedure adopted for the study was described in the following way:

> "Procedure
>
> A semi-structured telephone interview was used to elicit subjective judgments for the impact of plain packaging on (a) the prevalence of smoking in adults and (b) the percentage of children trying smoking. The script was developed by the authors from those used in similar studies. Prior to interview participants were sent a copy of a recent systematic review on the impact of plain packaging of tobacco products to ensure that all participants had the same summary of the most recent evidence relating to plain packaging. This did not provide numerical estimates of the likely impact of plain packaging

[5] Pechey, R, Spiegelhalter D Marteau T (2013) "Impact of plain packaging of tobacco products on smoking adults and children: an elicitation of international experts' estimates", BMC Public Health 13:18-24.

> policies on the two outcomes of interest in this study. During the interview, the interviewer provided the prevalence rates for the two outcomes of interest and asked participants to estimate the expected values of these two years after the introduction of plain packaging in their region, and the lowest and highest likely values, holding all other relevant factors constant (e.g. with current controls regarding the sale of tobacco still being in force, and the price and current prevalence levels being stable over the two year period). Subsidiary questions were used to explore the range of plausible values provided, to ensure that experts felt they would be extremely surprised if the actual values fell outside the range they had provided ('extremely' was described as a 1% chance), given the tendency of individuals to provide too narrow a range in these types of study. Finally, participants were asked to outline the reasoning behind the estimates they provided".

142. The consensus opinion of the experts was a decline in the proportion of 11-15 year olds who had ever smoked of 3%. The percentage of this population who had ever smoked was 27% at the time of the research so the 3% represents a fall from 27% of the population to 24% of the population which, itself, represented a prevalence fall of 11%. So far as adults were concerned a decline in smoking prevalence of 1% point was estimated. The proportion of this population that was smoking was 21% at the time so this represented a fall in prevalence of 4.8% estimated (i.e. 1 in 21). The variations in the estimates given by the various experts was also taken into account in the sensitivity analyses conducted as part of the 2014 Impact Assessment.

(16) The Ministerial decision to lay draft regulations before Parliament

143. Upon receipt of the December 2014 Submission and further advice from the Chief Medical Officer the Minister made the final decision to lay draft standardised packaging regulations before Parliament. This decision was announced on 21st January 2015. Subsequently, on 12th February 2015, the Department published a summary report "Consultation upon Introducing Regulations for Standardised Packaging of Tobacco Products". It also published the 2014 Impact Assessment which had been approved as "fit-for-purpose" from the Government's Regulatory Policy Committee, a final Equalities Analysis, and, the assessment conducted by HMRC of the "Potential Impact on the Illicit Market".

144. On 18th February 2015 the Department made a submission to the Minister setting out the response of the UK to the detailed opinions served by other Member States pursuant to the Technical Standards Directive. A copy of the submissions made to the European Commission were before the Court. In its response to the Commission the United Kingdom summarised the evidence which had led to the Ministerial Decision. The submission included an analysis of potential other alternative measures. The submission stated of the suggestion that there were alternative means of combating tobacco usage:

> "We have looked carefully at those suggestions. Many of the suggestions presented as "alternatives" have been or are being implemented as part of the UK comprehensive tobacco control

> policies. They are not alternative ways of combating the promotional impact of tobacco packaging in a meaningful way, as effectively or to the same extent. In the context of a comprehensive policy, they may be considered as complementary, rather than as alternative to standardised packaging. Packaging is the last major promotional avenue for tobacco products, which is why this action is important".

145. The Government also set out its position on potential risks to illicit trade, and to the risk of downtrading. In relation to reduction in tax revenue the Government stated:

> "The UK Government accepts that there will be a loss of tax revenue from tobacco products as a result of tobacco control policies. Whilst tax revenues need to be taken into account, it is not possible to make a proper comparison between the benefit to health and wellbeing that comes from helping smokers to quit and any loss in tax revenues".

146. In particular, the Government relied upon the fact that in the FCTC contracting States were under obligations to meet the treaty objective to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke through the implementation of "*comprehensive tobacco control strategies*". The Government stated that since it became a party to the treaty in 2004 it had taken its international obligations very seriously. The Government recognised that the FCTC guidelines were not binding. However, the fact that the contracting parties had agreed that the guidelines reflected their "*consolidated view of a desirable means of fulfilling their FCTC obligations*" was important.

147. In relation to the suggestion advanced by a number of other Member States that the UK should await the legal proceedings brought against Australia before the World Trade Organisation, the Government stated:

> "The case for action in the UK is clear. If all countries were to wait for the results of all the various actions against Australia this would delay the long term process of changing social norms about smoking, and mean that some children and young people would not be prevented from taking up smoking, and adult smokers would not be supported to the same degree in their efforts to quit. The sooner we act, the sooner the health benefits will accrue".

148. The conclusion of the Government was in the following terms:

> "Standardised packaging is a proportionate and justified response to the significant harm caused by tobacco. For the good of public health, we aspire to a smoke free future".

(17) The promulgation of the Regulations by affirmative resolution

149. The draft Regulations were laid before Parliament on 23 February 2015 for approval by way of affirmative resolution and were adopted following the normal process of

scrutiny and after debate in the Delegated Legislation Committee and in the House of Lords. The Regulations were signed by the Minister on 19 March 2015. The affirmative resolution procedure enabled Parliament to consider the proposed regulations and form its own view after appraisal. The Supreme Court has held that whether a measure has been subjected to an affirmative resolution procedure is a consideration which is pertinent to the margin of appreciation which a Court accords the decision maker: See *R (on the application of SG & Ors) v Secretary of State for Work and Pensions (SWWP)* [2015] UKSC 16 at paragraphs [92] and [93] per Lord Reed:

> "94. As I have explained, the Regulations were considered and approved by affirmative resolution of both Houses of Parliament. As Lord Sumption observed in Bank Mellat v H M Treasury (No 2) [2013] UKSC 39; [2014] AC 700, para 44:
>
> > "When a statutory instrument has been reviewed by Parliament, respect for Parliament's constitutional function calls for considerable caution before the courts will hold it to be unlawful on some ground (such as irrationality) which is within the ambit of Parliament's review. This applies with special force to legislative instruments founded on considerations of general policy"".

D. THE RELEVANT LEGISLATIVE FRAMEWORK

(1) Introduction

150. Many of the issues of law raised in the present case involve a close analysis of a large number of international, EU and domestic legislative provisions. In this section I have set out the relevant material where relevant setting out my conclusions on issues of construction and effect which arise.

(2) The Framework Convention on Tobacco Control ("FCTC")

(i) Signatories/relevance

151. The starting point is the FCTC. This is important for a wide variety of reasons. First, it is a Convention signed by 180 states including all of the Member States of the EU and by the EU itself. Second, it is a basis for the relevant EU legislation (the TPD). Third, it has been accepted by the European Court of Human Rights as a legitimate basis upon which States may, in principle, derogate from property rights within the confines of the rules regulating the expropriation or control of property rights (*in casu* A1P1). Fourth, it is referred to as one of the principal reasons leading the Secretary of State to lay the Regulations before Parliament. Fifth, the Court of Justice in long established case law has attached considerable weight to policies adopted by the WHO. Sixth, the response to the notification of the Regulations by the European Commission was to the effect that it would monitor implementation and take account of developments at the level of the WHO, i.e. under the FCTC: See paragraph [124] above. Seventh, it is the basis for the principle that FCTC contracting states should ensure that evidence submitted by tobacco companies should meet high standards of transparency and accountability.

152. The Convention was adopted by the World Health Organisation ("WHO"). It opened for signature on 16 June to 22 June 2003 in Geneva, and thereafter at the United Nations Headquarters in New York, the depositary of the Treaty, from 30 June 2003 to 29 June 2004. The Convention is now closed for signature. It is one of the most widely endorsed treaties in UN history. States wishing to become a party, but who did not sign the Convention by 29 June 2004, may still do so by means of accession, which is a one-step process equivalent to ratification.

(ii) Status as a guide to interpretation

153. The FCTC has a high status in EU law. EU legislation in the field of tobacco advertising must be construed in the light of the FCTC. The TPD expressly refers in Article 1 to the TPD as being an instrument intended to meet the EU's obligations under the FCTC. In *Philip Morris* such was the importance of the FCTC that even the Guidelines to the Convention were treated as of "*particularly high evidential value*" (ibid paragraph [175]).

154. EU legislation must as a general principle be interpreted in accordance with source international law obligations. In Case C-61/94 *Commission v Germany* [1996] ECR I-3989 at paragraph [52] the Court considered an argument that provisions of an EU regulation (on inward processing) excluded the operation of an agreement concluded under the GATT. The EU regulation did not refer to the international agreement but the Court held that this was not significant. It held:

> "52. When the wording of secondary Community legislation is open to more than one interpretation, preference should be given as far as possible to the interpretation which renders the provision consistent with the Treaty. Likewise, an implementing regulation must, if possible, be given an interpretation consistent with the basic regulation. Similarly, the primacy of international agreements concluded by the Community over provisions of secondary Community legislation means that such provisions must, so far as is possible, be interpreted in a manner that is consistent with those agreements".

155. In case T-237/08 *Retuerta v Office for Harmonisation in the Internal Market (Trade marks and Designs) (OHIM)* [2010] ECR II-1583 the Court of First Instance addressed the relationship between an EU regulation and the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS"). This was in the context of a judicial review of a decision relating to trade marks for wines containing geographical indications. The Court held:

> "63. The fourth recital in the preamble to Regulation No 3288/94 states that 'Article 23(2) of the TRIPs Agreement provides for the refusal or invalidation of trade marks which contain or consist of false geographical indications for wines and spirits without the condition that they are of such a nature as to deceive the public, and that 'a new subparagraph (j) has to be added to Article 7(1) of Regulation (EC) No 40/94.

> 64. It should be recalled that, since the Community is a party to the TRIPS Agreement, it is required to interpret its trade mark legislation, as far as possible, in the light of the wording and purpose of that agreement (see *Anheuser Busch*, paragraph 21 above, paragraph 42 and the case law cited).
>
> 65. It is settled case-law that a provision of an agreement entered into by the Community with non-member countries must be regarded as being directly applicable when, regard being had to the wording, purpose and nature of the agreement, it may be concluded that the provision contains a clear, precise and unconditional obligation which is not subject, in its implementation or effects, to the adoption of any subsequent measure (Joined Cases C-300/98 and C-392/98 *Dior and Others* [2000] ECR I-11307, paragraph 42).
>
> 66. The Court has however already held that, first, having regard to their nature and structure, the WTO Agreement and the annexes thereto are not in principle among the rules in the light of which the Court is to review measures of the Community institutions in the context of an action for annulment (*Dior and Others*, paragraph 65 above, paragraph 43) and, second, the provisions of the TRIPS Agreement, an annex to the WTO Agreement, are not such as to create rights upon which individuals may rely directly before the courts by virtue of Community law (*Dior and Others*, paragraph 65 above, paragraph 44).
>
> 67. It follows that, although the provisions of the TRIPS Agreement do not have direct effect, it is nevertheless true that the trade mark legislation, that is to say, in the present case, Article 7(1)(j) of Regulation No 40/94, must, as far as possible, be interpreted in the light of the wording and purpose of that agreement".

156. A similar conclusion was arrived at in relation to the scope of protection accorded to patents under Article 9 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, in the light of Articles 27 and 30 of TRIPS. In Case C-428/08 *Monsanto v Cefetra et ors* (6th July 2010) the Court having held that Article 9 contained an exhaustive definition of the scope of the rights in question (ibid, paragraphs [51]-[63]) held:

> "70. By its fourth question, the national court asks, essentially, whether Articles 27 and 30 of the TRIPS Agreement affect the interpretation given of Article 9 of the Directive.
>
> 71. In that regard, it should be borne in mind that the provisions of the TRIPS Agreement are not such as to create rights upon which individuals may rely directly before the courts by virtue of European Union law (Joined Cases C-300/98 and C-392/98 *Dior and Others* [2000] ECR I'11307, paragraph 44).

> 72. If it should be found that there are European Union rules in the sphere in question, European Union law will apply, which will mean that it is necessary, as far as may be possible, to supply an interpretation in keeping with the TRIPS Agreement, although no direct effect may be given to the provision of that agreement at issue (Case C-431/05 *Merck Genéricos - Produtos Farmacêuticos* [2007] ECR I'7001, paragraph 35).
>
> 73. Since the Directive constitutes European Union rules in the sphere of patents, it must therefore, as far as may be possible, be interpreted in such a manner.
>
> 74. It is clear that the interpretation given in the present judgment of Article 9 of the Directive does not run counter to that obligation".

(iii) The stated objectives of the FCTC

157. The FCTC entered into force on 27 February 2005. It is stated by WHO to be an evidence-based treaty that reaffirms the right of all people to the highest standard of health and representing a "*paradigm shift in developing a regulatory strategy to address addictive substances*". It focuses upon demand reduction strategies as well as supply issues. The foreword to the FCTC describes tobacco use as an "*epidemic*" and points out that advertising contributes to that adverse consequence:

> "The WHO FCTC was developed in response to the globalization of the tobacco epidemic. The spread of the tobacco epidemic is facilitated through a variety of complex factors with cross-border effects, including trade liberalization and direct foreign investment. Other factors such as global marketing, transnational tobacco advertising, promotion and sponsorship, and the international movement of contraband and counterfeit cigarettes have also contributed to the explosive increase in tobacco use".

158. The preamble to the FCTC sets out the policy which underlies its substantive provisions. Although the recitals are not numbered in the original I have numbered them below for ease of cross-reference. It is worth setting the preamble out in full:

> "The Parties to this Convention,
>
> 1. *Determined* to give priority to their right to protect public health,
>
> 2. *Recognizing* that the spread of the tobacco epidemic is a global problem with serious consequences for public health that calls for the widest possible international cooperation and the participation of all countries in an effective, appropriate and comprehensive international response,

3. *Reflecting* the concern of the international community about the devastating worldwide health, social, economic and environmental consequences of tobacco consumption and exposure to tobacco smoke,

4. *Seriously concerned* about the increase in the worldwide consumption and production of cigarettes and other tobacco products, particularly in developing countries, as well as about the burden this places on families, on the poor, and on national health systems,

5. *Recognizing* that scientific evidence has unequivocally established that tobacco consumption and exposure to tobacco smoke cause death, disease and disability, and that there is a time lag between the exposure to smoking and the other uses of tobacco products and the onset of tobacco-related diseases,

6. *Recognizing also* that cigarettes and some other products containing tobacco are highly engineered so as to create and maintain dependence, and that many of the compounds they contain and the smoke they produce are pharmacologically active, toxic, mutagenic and carcinogenic, and that tobacco dependence is separately classified as a disorder in major international classifications of diseases,

7. *Acknowledging* that there is clear scientific evidence that prenatal exposure to tobacco smoke causes adverse health and developmental conditions for children,

8. *Deeply concerned* about the escalation in smoking and other forms of tobacco consumption by children and adolescents worldwide, particularly smoking at increasingly early ages,

9. *Alarmed* by the increase in smoking and other forms of tobacco consumption by women and young girls worldwide and keeping in mind the need for full participation of women at all levels of policy-making and implementation and the need for gender-specific tobacco control strategies,

10. *Deeply concerned* about the high levels of smoking and other forms of tobacco consumption by indigenous peoples,

11. *Seriously concerned* about the impact of all forms of advertising, promotion and sponsorship aimed at encouraging the use of tobacco products,

12. *Recognizing* that cooperative action is necessary to eliminate all forms of illicit trade in cigarettes and other tobacco products, including smuggling, illicit manufacturing and counterfeiting,

13. *Acknowledging* that tobacco control at all levels and particularly in developing countries and in countries with economies in transition requires sufficient financial and technical resources commensurate with the current and projected need for tobacco control activities,

14. *Recognizing* the need to develop appropriate mechanisms to address the long-term social and economic implications of successful tobacco demand reduction strategies,

15. *Mindful* of the social and economic difficulties that tobacco control programmes may engender in the medium and long term in some developing countries and countries with economies in transition, and recognizing their need for technical and financial assistance in the context of nationally developed strategies for sustainable development,

16. *Conscious* of the valuable work being conducted by many States on tobacco control and commending the leadership of the World Health Organization as well as the efforts of other organizations and bodies of the United Nations system and other international and regional intergovernmental organizations in developing measures on tobacco control,

17. *Emphasizing* the special contribution of nongovernmental organizations and other members of civil society not affiliated with the tobacco industry, including health professional bodies, women's, youth, environmental and consumer groups, and academic and health care institutions, to tobacco control efforts nationally and internationally and the vital importance of their participation in national and international tobacco control efforts,

18. *Recognizing* the need to be alert to any efforts by the tobacco industry to undermine or subvert tobacco control efforts and the need to be informed of activities of the tobacco industry that have a negative impact on tobacco control efforts,

19. *Recalling* Article 12 of the International Covenant on Economic, Social and Cultural Rights, adopted by the United Nations General Assembly on 16 December 1966, which states that it is the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,

20. *Recalling also* the preamble to the Constitution of the World Health Organization, which states that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition,

> 21. *Determined* to promote measures of tobacco control based on current and relevant scientific, technical and economic considerations,
>
> 22. *Recalling* that the Convention on the Elimination of All Forms of Discrimination against Women, adopted by the United Nations General Assembly on 18 December 1979, provides that States Parties to that Convention shall take appropriate measures to eliminate discrimination against women in the field of health care,
>
> 23. *Recalling further* that the Convention on the Rights of the Child, adopted by the United Nations General Assembly on 20 November 1989, provides that States Parties to that Convention recognize the right of the child to the enjoyment of the highest attainable standard of health,
>
> *Have agreed*, as follows…".

159. Recitals 7, 8, 9 and 20 highlight the need to protect children from the effects of tobacco. Recital 18 highlights the need for contracting States to be "*alert*" to efforts by the tobacco industry to "*subvert*" control efforts. The 19th recital makes clear that the Convention incorporates the principles set out in Article 12 of the International Covenant on Economic, Social and Cultural Rights ("ICESCR"), adopted by the United Nations General Assembly on 16 December 1966. This refers to a "*right of everyone to the enjoyment of the highest attainable standard of physical and mental health*". This is a "*right*" which can quite properly be classified as a human or fundamental right. Article 12 ICESCR explicitly embodies this "*right*" and is in the following terms:

> "Article 12
>
> 1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
>
> 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
>
> (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
>
> (b) The improvement of all aspects of environmental and industrial hygiene;
>
> (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
>
> (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness".

(iv) The prohibition on advertising in the FCTC

160. Article 1(c) defines advertising and promotion in the following very broad and sweeping terms:

> "'*tobacco advertising and promotion'* means any form of commercial communication, recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly…".

161. Article 2 makes clear that the measures laid down in the FCTC represent *minimum* requirements and do not preclude the adoption of stricter measures provided they are consistent with the Convention and with international law:

> "1. In order to better protect human health, Parties are encouraged to implement measures beyond those required by this Convention and its protocols, and nothing in these instruments shall prevent a Party from imposing stricter requirements that are consistent with their provisions and are in accordance with international law".

162. The central objective of the FCTC is set out in Article 3; it condemns tobacco products in ringing terms:

> "*Article 3*
>
> Objective
>
> The objective of this Convention and its protocols is to protect present and future generations from the devastating health, social, environmental and economic consequences of tobacco consumption and exposure to tobacco smoke by providing a framework for tobacco control measures to be implemented by the Parties at the national, regional and international levels in order to reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke".

163. Article 4 sets out a long list of principles which contracting states are to pursue in fulfilment of this overarching objective. Article 4(1) starts with an iteration of the threats posed by tobacco products:

> "Every person should be informed of the health consequences, addictive nature and mortal threat posed by tobacco consumption and exposure to tobacco smoke and effective legislative, executive, administrative or other measures should be contemplated at the appropriate governmental level to protect all persons from exposure to tobacco smoke".

164. Article 4(2) provides, so far as relevant:

> "Strong political commitment is necessary to develop and support, at the national, regional and international levels,

> comprehensive multisectoral measures and coordinated responses, taking into consideration:
>
> (a) the need to take measures to protect all persons from exposure to tobacco smoke;
>
> (b) the need to take measures to prevent the initiation, to promote and support cessation, and to decrease the consumption of tobacco products in any form;
>
> …".

165. In the Chapter dedicated to measures designed to reduce demand there is a specific article focusing upon packaging and labelling of tobacco products. This identifies all of the ways in which tobacco might be promoted and requires the prohibition of advertising in relation to such matters. So, for instance, it identifies any advertising or promotion that might convey erroneous impressions about health effects or hazards or emissions (Article 11(1)(a)). It obligates contracting States to require health warnings to be included on packaging (Article 11(1)(b)).

166. The 11th recital expresses serious concern at "*all*" forms of advertising. Specifically with regard to tobacco advertising, promotion and sponsorship Article 13 imposes an obligation or duty on contracting states to impose prohibitions on all advertising where consistent with constitutional principles:

> *"Article 13*
>
> Tobacco advertising, promotion and sponsorship
>
> 1. Parties recognize that a comprehensive ban on advertising, promotion and sponsorship would reduce the consumption of tobacco products.
>
> 2. Each Party shall, in accordance with its constitution or constitutional principles, undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship. This shall include, subject to the legal environment and technical means available to that Party, a comprehensive ban on cross-border advertising, promotion and sponsorship originating from its territory. In this respect, within the period of five years after entry into force of this Convention for that Party, each Party shall undertake appropriate legislative, executive, administrative and/or other measures and report accordingly in conformity with Article 21.
>
> 3. A Party that is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles shall apply restrictions on all tobacco advertising, promotion and sponsorship. This shall include, subject to the legal environment and technical means available to that Party, restrictions or a comprehensive ban on advertising, promotion

and sponsorship originating from its territory with cross-border effects. In this respect, each Party shall undertake appropriate legislative, executive, administrative and/or other measures and report accordingly in conformity with Article 21.

4. As a minimum, and in accordance with its constitution or constitutional principles, each Party shall:

(a) prohibit all forms of tobacco advertising, promotion and sponsorship that promote a tobacco product by any means that are false, misleading or deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions;

(b) require that health or other appropriate warnings or messages accompany all tobacco advertising and, as appropriate, promotion and sponsorship;

(c) restrict the use of direct or indirect incentives that encourage the purchase of tobacco products by the public;

(d) require, if it does not have a comprehensive ban, the disclosure to relevant governmental authorities of expenditures by the tobacco industry on advertising, promotion and sponsorship not yet prohibited. Those authorities may decide to make those figures available, subject to national law, to the public and to the Conference of the Parties, pursuant to Article 21;

(e) undertake a comprehensive ban or, in the case of a Party that is not in a position to undertake a comprehensive ban due to its constitution or constitutional principles, restrict tobacco advertising, promotion and sponsorship on radio, television, print media and, as appropriate, other media, such as the internet, within a period of five years; and

(f) prohibit, or in the case of a Party that is not in a position to prohibit due to its constitution or constitutional principles restrict, tobacco sponsorship of international events, activities and/or participants therein.

5. Parties are encouraged to implement measures beyond the obligations set out in paragraph 4.

6. Parties shall cooperate in the development of technologies and other means necessary to facilitate the elimination of cross-border advertising.

7. Parties which have a ban on certain forms of tobacco advertising, promotion and sponsorship have the sovereign right to ban those forms of cross-border tobacco advertising,

> promotion and sponsorship entering their territory and to impose equal penalties as those applicable to domestic advertising, promotion and sponsorship originating from their territory in accordance with their national law. This paragraph does not endorse or approve of any particular penalty.
>
> 8. Parties shall consider the elaboration of a protocol setting out appropriate measures that require international collaboration for a comprehensive ban on cross-border advertising, promotion and sponsorship".

(v) Guidelines on Article 13 FCTC

167. Guidelines adopted by the WHO on Article 13 (entitled "Guidelines for implementation of Article 13: Tobacco advertising, promotion and sponsorship") emphasise the need for a comprehensive, all embracing, and multifaceted approach to curbing advertising. Paragraphs [4] – [24] of the Guidelines set out to describe the myriad ways in which tobacco advertising can occur. For present purposes it is necessary only to focus upon those specific provisions which are the *locus classicus* of the TPD. However, it is important to bear in mind that these particular provisions are intended under the FCTC to be but one part of a much wider, prohibitive jigsaw. Paragraphs [15] – [17] address the way in which manufacturers use attractive designs on packaging to promote their products and it explicitly endorses and encourages the use of plain design in relation to both the outer pack and the product itself:

> "Packaging and product features
>
> 15. Packaging is an important element of advertising and promotion. Tobacco pack or product features are used in various ways to attract consumers, to promote products and to cultivate and promote brand identity, for example by using logos, colours, fonts, pictures, shapes and materials on or in packs or on individual cigarettes or other tobacco products.
>
> 16. The effect of advertising or promotion on packaging can be eliminated by requiring plain packaging: black and white or two other contrasting colours, as prescribed by national authorities; nothing other than a brand name, a product name and/or manufacturer's name, contact details and the quantity of product in the packaging, without any logos or other features apart from health warnings, tax stamps and other government-mandated information or markings; prescribed font style and size; and standardized shape, size and materials. There should be no advertising or promotion inside or attached to the package or on individual cigarettes or other tobacco products.
>
> 17. If plain packaging is not yet mandated, the restriction should cover as many as possible of the design features that make tobacco products more attractive to consumers such as animal or other figures, "fun" phrases, coloured cigarette papers, attractive smells, novelty or seasonal packs.

> Recommendation
>
> Packaging and product design are important elements of advertising and promotion. Parties should consider adopting plain packaging requirements to eliminate the effects of advertising or promotion on packaging. Packaging, individual cigarettes or other tobacco products should carry no advertising or promotion, including design features that make products attractive".

(vi) The protection of national health policies from vested tobacco interests: Article 5(3)

168. An important, and indeed singular, provision of the Convention which is relevant to issues arising in this case is Article 5(3). This is a remarkable provision which operates upon the express premise that government is the victim of attempts to undermine it by the tobacco industry. It requires contracting states to "*protect*" their health policies from the "*vested interests of the tobacco industry*":

> "Article 5
>
> General obligations
>
> 1. Each Party shall develop, implement, periodically update and review comprehensive multisectoral national tobacco control strategies, plans and programmes in accordance with this Convention and the protocols to which it is a Party.
>
> 2. Towards this end, each Party shall, in accordance with its capabilities: (a) establish or reinforce and finance a national coordinating mechanism or focal points for tobacco control; and (b) adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke.
>
> 3. In setting and implementing their public health policies with respect to tobacco control, *Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law*".
>
> (Emphasis added)

169. This follows on from the 18th recital to the Convention (see paragraph [158] above) which extols contracting states to be "*alert*" to "*efforts by the tobacco industry to undermine or subvert tobacco control efforts*".

(vii) Guidelines on Article 5(3)

170. The Guidelines on Article 5.3 (entitled "Guidelines for implementation of Article 5.3 – Protection of public health policies with respect to tobacco control from commercial

and other vested interests of the tobacco industry") take as their starting point what may fairly be described as an expression of profound distrust about the motives of the tobacco industry in their submissions to Government about health and environmental issues relating to tobacco. The provision assumes a history of deliberate subversion by the industry of governmental health policies:

> "1. World Health Assembly resolution WHA54.18 on transparency in tobacco control process, citing the findings of the Committee of Experts on Tobacco Industry Documents, states that "*the tobacco industry has operated for years with the express intention of subverting the role of governments and of WHO in implementing public health policies to combat the tobacco epidemic*".
>
> 2. The Preamble of the WHO Framework Convention on Tobacco Control recognized the Parties' "*need to be alert to any efforts by the tobacco industry to undermine or subvert tobacco control efforts and the need to be informed of activities of the tobacco industry that have a negative impact on tobacco control efforts*".

171. A significant part of the basis for this conclusion is the inferences drawn by WHO from the internal documents disclosed by the tobacco companies in US litigation. The implications of this are examined in relation to Ground 2 below.

172. Paragraph 5 encourages contracting states to implement these guidelines to the greatest extent possible within their national laws. Paragraph 11 explains that these concerns are evidence based:

> "11. The broad array of strategies and tactics used by the tobacco industry to interfere with the setting and implementing of tobacco control measures, such as those that Parties to the Convention are required to implement, *is documented by a vast body of evidence*. The measures recommended in these guidelines aim at protecting against interference not only by the tobacco industry but also, as appropriate, by organizations and individuals that work to further the interests of the tobacco industry".

(Emphasis added)

173. Paragraph 7 explains that contracting states must ensure that efforts to protect tobacco control from commercial and other vested interests are comprehensive and effective. Parties should implement measures in all branches of government that may have an interest in affecting, or the capacity to affect, public health policies with respect to tobacco control.

(viii) The principle of transparency

174. An important recommendation is to: "*Require that information provided by the tobacco industry be transparent and accurate*." Paragraphs [24] and [25] elaborate upon this and then set out practical recommendations to be followed:

> "24. To take effective measures preventing interference of the tobacco industry with public health policies, Parties need information about its activities and practices, thus ensuring that the industry operates in a transparent manner. Article 12 of the Convention requires Parties to promote public access to such information in accordance with national law.
>
> 25. Article 20.4 of the Convention requires, inter alia, Parties to promote and facilitate exchanges of information about tobacco industry practices and the cultivation of tobacco. In accordance with Article 20.4(c) of the Convention, each Party should endeavour to cooperate with competent international organizations to establish progressively and maintain a global system to regularly collect and disseminate information on tobacco production and manufacture and activities of the tobacco industry which have an impact on the Convention or national tobacco control activities.
>
> *Recommendations*
>
> 5.1 Parties should introduce and apply measures to ensure that all operations and activities of the tobacco industry are transparent.
>
> 5.2 Parties should require the tobacco industry and those working to further its interests to periodically submit information on tobacco production, manufacture, market share, marketing expenditures, revenues and any other activity, including lobbying, philanthropy, political contributions and all other activities not prohibited or not yet prohibited under Article 13 of the Convention.
>
> 5.3 Parties should require rules for the disclosure or registration of the tobacco industry entities, affiliated organizations and individuals acting on their behalf, including lobbyists.
>
> 5.4 Parties should impose mandatory penalties on the tobacco industry in case of the provision of false or misleading information in accordance with national law.
>
> 5.5 Parties should adopt and implement effective legislative, executive, administrative and other measures to ensure public access, in accordance with Article 12(c) of the Convention, to a wide range of information on tobacco industry activities as

> relevant to the objectives of the Convention, such as in a public repository".

175. I return later, in the context of the analysis under Ground 2 (cf. Section F of the Judgment), to the implications of this for judicial proceedings where tobacco companies adduce evidence.

(3) The Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS")

(i) TRIPS

176. I turn now to summarise the second international law instrument which is important to the legal analysis arising. TRIPS is an international agreement administered by the World Trade Organization (WTO). It lays down minimum standards for various forms of intellectual property regulation as applied to nationals of other WTO members. It was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994. TRIPS introduced intellectual property law into the international trading system for the first time.

(ii) The basic rights conferred by a trade mark/the distinction between the right to exclude and the right to use: Article 16

177. Article 16 identifies the rights conferred. The rights are expressed to be in the negative, namely "*the exclusive right to prevent*". However the Article makes clear that it is not inconsistent with TRIPS for contracting states *"...making rights available on the basis of use*". Article 16 thus creates a floor right and leaves it to the contracting states to expand rights to include use. But TRIPS does not itself do that: See italicised text below. Article 16(1) is in the following terms:

"*Article 16*

Rights Conferred

> 1. The owner of a registered trade mark *shall have the exclusive right to prevent all third parties not having the owner's consent from using* in the course of trade identical or similar signs for goods or services which are identical or similar to those in respect of which the trade mark is registered where such use would result in a likelihood of confusion. In case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed. The rights described above shall not prejudice any existing prior rights, *nor shall they affect the possibility of Members making rights available on the basis of use*".

(Emphasis added)

(iii) Public health limitations on trade mark rights: Articles 7 and 8

178. The interrelationship between trade marks and other, *superior,* public policies is an important issue in this litigation and forms a part of a number of the Claimants'

submissions. Trade marks are qualified rights and they do not under TRIPS have a fixed or uniform content or substance because they may be subjected to limitations imposed in national law justified by reference to overriding public policy. The combined effect of Articles 7, 8 and 17 makes this clear. Article 7 makes the important point that intellectual property must serve but not subvert the public interest. In particular usage must be reconciled with "*social and economic welfare"* and *"a balance of rights and obligations*":

"*Article 7*

Objectives

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge *and in a manner conducive to social and economic welfare, and to a balance of rights and obligations*".

(Emphasis added)

179. Article 8 confers on contracting states the right to introduce exceptions to trade mark use rights based upon the protection of "... *public health and nutrition*":

"*Article 8*

Principles

> 1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect *public health and nutrition*, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
>
> 2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology".

(Emphasis added)

180. The WTO Ministerial Conference has adopted a declaration which elaborates upon the importance of public health as a proper reason to derogate from intellectual property rights. This declaration is, on ordinary principles of international law, relevant in interpreting TRIPS. Article 31 of the *Vienna Convention* states that a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose. This includes: "(a) *any agreement relating to the treaty which was made between all the parties in connexion with the conclusion of the treaty; (b) Any instrument which*

was made by one or more parties in connexion with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty." Further there is to be taken into account "*...any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions*".

181. The DOHA Declaration was adopted by the WTO Ministerial Conference of 2001 (14th November 2001). It states, *inter alia*, that *"the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health"*[6]. The Declaration was primarily focused upon the conflict between intellectual property (patents) and the price of pharmaceuticals to national health services. However, it was deliberately drafted in much broader terms:

> "1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
>
> 2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
>
> 3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
>
> 4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.
>
> 5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:
>
> a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

[6] (WTO Doc WT/MIN(01)/DEC/2 (20 November 2001)

> b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
>
> c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
>
> d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4".

182. It is significant that in the FCTC the prevalence and use of tobacco is described as an "*epidemic*" which is the term used in Paragraph 1 of the Declaration. It is also significant that in EU trade mark regulations the relevance and validity of this Declaration is acknowledged (See Recital 21 of the amended, recast, TMD – see paragraphs [198] – [199] below).

(iv) Additional powers to introduce legislation derogating from trade mark rights: Article 17

183. Article 17 recognises that other limited exceptions can be made to trade mark rights provided these are balanced against the proprietor's "*legitimate interests*". It follows, *a fortiori*, that some proprietary interests are not "*legitimat*e":

> "*Article 17*
>
> Exceptions
>
> Members may provide limited exceptions to the rights conferred by a trade mark, such as fair use of descriptive terms, provided that such exceptions take account of the legitimate interests of the owner of the trade mark and of third parties".

(v) Justified encumbrances on use rights

184. Article 20 also implicitly acknowledges that the use of trade marks may be *"encumbered by special requirements*" but only subject to a test of justification:

> "*Article 20*
>
> Other Requirements
>
> The use of a trade mark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trade mark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or

> services of one undertaking from those of other undertakings. This will not preclude a requirement prescribing the use of the trade mark identifying the undertaking producing the goods or services along with, but without linking it to, the trade mark distinguishing the specific goods or services in question of that undertaking".
>
> (Emphasis added)

(vi) Restrictions on licensing practices due to competition law: Article 40

185. TRIPS also creates exceptions to usage rights where they collide with competition law. Article 40 provides:

> "*Article 40*
>
> 1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.
>
> 2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.
>
> 3. Each Member shall enter, upon request, into consultations with any other Member which has cause to believe that an intellectual property right owner that is a national or domiciliary of the Member to which the request for consultations has been addressed is undertaking practices in violation of the requesting Member's laws and regulations on the subject matter of this Section, and which wishes to secure compliance with such legislation, without prejudice to any action under the law and to the full freedom of an ultimate decision of either Member. The Member addressed shall accord full and sympathetic consideration to, and shall afford adequate opportunity for, consultations with the requesting Member, and shall cooperate through supply of publicly available non-confidential information of relevance to the matter in question and of other information available to the Member, subject to domestic law and to the conclusion of mutually satisfactory agreements concerning the safeguarding of its confidentiality by the requesting Member.

> 4. A Member whose nationals or domiciliaries are subject to proceedings in another Member concerning alleged violation of that other Member's laws and regulations on the subject matter of this Section shall, upon request, be granted an opportunity for consultations by the other Member under the same conditions as those foreseen in paragraph 3".

(vii) FCTC and TRIPS

186. It is plain from the above that intellectual property rights are not absolute and must be balanced against other competing public interests. In particular the right to use a trade mark can, under national law, yield to limitations imposed in the pursuit of superior public policy considerations. There is no canonical list of the public interests that may or may not be resorted to on the part of contracting states to limit intellectual property rights and a good deal of discretion is accorded to the signatories. What *is* however clear is that intellectual property rights can be derogated from in the name of public health since this is one of the few public interests which is explicitly identified. It is a point I return to later but it is worth emphasising here: For all the above reasons TRIPS and the FCTC can be read together without any risk of them colliding or being mutually inconsistent.

(4) Directive 2008/95/EC of the European Parliament and of the Council of 22 October 2008 to approximate the laws of the Member States relating to trade marks (the "TMD")

(i) The TMD is not intended to be exhaustive of trade mark rights

187. The TMD lays down minimum rights which are to be implemented into national law relating to trade marks. A new, recast, directive was adopted in 2015. To the extent relevant I address this at paragraphs [195ff] below. The recitals to the TMD make clear that it is not intended to be exhaustive of all of the laws capable of affecting trade marks. In particular it is exclusive of neither international law nor domestic law on other (non-trade mark) matters:

> "Whereas this Directive does not exclude the application to trade marks of provisions of law of the Member States other than trade mark law, such as the provisions relating to unfair competition, civil liability or consumer protection".

(ii) The interpretation of EU subordinate legislation: Always subject to superior rules and principles

188. Article 7 TMD seeks to implement the rules on free movement of goods contained within the TFEU and encapsulates the well known principle of the exhaustion of rights:

> "Exhaustion of the rights conferred by a trade mark
>
> 1. The trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in

> the Community under that trade mark by the proprietor or with his consent.
>
> 2. Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialization of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market".

189. An issue in the present case (under Ground 10) concerns the extent to which a directive can in principle exhaustively and definitively define the rights conferred on proprietors of intellectual property rights. I set out below the principles of law which govern the interpretation of directives. These show that the rights conferred by directives on proprietors cannot be taken as exhaustive. Directives are species of subordinate legislation and cannot depart from the superior rights and obligations set out in the Treaties themselves. For this reason the Court of Justice has repeatedly made clear that whilst a trade mark serves important functions, including those set out in relevant trade mark legislation, it is nonetheless subject to *further* limits imposed by the Treaty.

190. By way of illustration this was made clear in Case C-348/04 *Boehringer Ingelheim KG Boehringer Ingelheim Pharma GmbH & Co. KG Glaxo Group Ltd v Swingward* Ltd [2007] ECR I-3391 (26th April 2007) ("*Boehringer*") where the issue related to whether a proprietor could use a trade mark to hinder parallel imports of pharmaceutical products because of the trade marks being used on the imported packaging. As to this it has been long settled that rights conferred by specific trade mark legislation cannot oust the more fundamental rights of free movement contained within the Treaties.

191. Advocate General Sharpston usefully summarised the position. She explained how the essence or substance ("*specific subject matter*") of a trade mark had to be defined by reference to the Treaty and not just the relevant directive. In paragraphs [5] – [14] she first explained what was meant by the specific subject matter of a trade mark (paragraph [5] – [10]) as set out in case law under the treaty provisions on movement of goods and she then explained that attempts within the TMD (in particular in Articles 5 and 7) to describe the extent and limits of trade mark rights had to be read subject to the treaty (paragraphs [11] – [14]):

> "5. The historical roots of this case-law are of course Articles 28 and 30 EC. Article 30 looms large in the pleadings in this case. Article 28 in contrast gets little mention. It must not however be forgotten that Article 30 is the exception to the fundamental rule enshrined in Article 28 that goods should be able to move freely between Member States. As a derogation from that basic rule, Article 30 is to be strictly construed.
>
> 6. In so construing Article 30 in the context of intellectual and industrial property rights, the Court at an early stage developed the concept of the specific subject-matter of the right, ruling that Article 30 "only admits derogations from [the free movement of goods] to the extent to which they are justified for the purpose of safeguarding rights which constitute the specific

subject-matter of such property". That principle makes it possible to determine, in relation to each type of intellectual property, the circumstances in which the exercise of the right will be permissible under Community law, even though in a cross-border context such exercise by definition impedes free movement.

7. Also at an early stage the Court defined the specific subject-matter of a trade mark right as "the guarantee that the owner of the trade mark has the exclusive right to use that trade mark, for the purpose of putting products protected by the trade mark into circulation for the first time". From that definition the doctrine of exhaustion of trade mark rights followed naturally. The Court thus concluded that "the exercise, by the owner of a trade mark, of the right which he enjoys under the legislation of a Member State to prohibit the sale, in that State, of a product which has been marketed under the trade mark in another Member State by the trade mark owner or with his consent is incompatible with the rules of the EEC Treaty concerning the free movement of goods within the Common Market".

8. The Court further developed the concept of the specific subject-matter of a trade mark right in *Hoffmann-La Roche*, explaining that "the essential function of the trade mark ... is to guarantee the identity of the origin of the trade-marked product to the consumer or ultimate user, by enabling him without any possibility of confusion to distinguish that product from products which have another origin [and to] be certain that a trade-marked product ... has not been subject at a previous stage of marketing to interference ... such as to affect the original condition of the product". Safeguarding the specific subject-matter of a trade mark therefore includes the right to prevent "any use of the trade mark which is liable to impair the guarantee of origin".

9. The specific subject-matter of a trade mark thus has two components. First, there is the right to use the mark for the purpose of putting products protected by it into circulation for the first time in the EC, after which that right is exhausted. Second, there is the right to oppose any use of the trade mark which is liable to impair the guarantee of origin, which comprises both a guarantee of identity of origin and a guarantee of integrity of the trade-marked product.

10. Those core rights are reflected in the Trade marks Directive. Article 5(1) provides that a trade mark confers on its proprietor "exclusive rights therein", and in particular the right to prevent the use in the course of trade of (a) an identical sign in relation to identical goods or services and (b) an identical or confusingly similar sign with regard to identical or similar goods or services.

11. Without qualification, Article 5(1)(a) would give the proprietor of a mark the right to prevent all such use in relation to the goods which it covers. Proprietors could thus prevent imports into one Member State of such goods from another Member State and negate the free movement of goods guaranteed by Article 28 EC. That would however be contrary both to the Treaty and to the stated objective of the Directive, which is intended "to eliminate disparities between the trade mark laws of the Member States which may impede the free movement of goods and the freedom to provide services and distort competition within the common market" and hence to safeguard the functioning of the internal market. Article 7(1) therefore provides that the trade mark owner's right to prevent use of the mark "shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent", thus encapsulating the doctrine of Community exhaustion of trade mark rights.

12. Although Article 7(1) has been described as an exception to the rule in Article 5(1), I do not consider that that is a strictly accurate analysis of the relationship between the two provisions. It seems to me that it is more helpful to describe them as counterbalancing each other. If the language of rule and exception is invoked, then it would be more in the spirit of the interrelationship of Articles 28 and 30 EC for Article 5(1), which potentially restricts imports, to be construed as an exception to Article 7(1), which reflects the basic principle of the free movement of goods.

13. In contrast, Article 7(2) states that Article 7(1) "shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialisation of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market". Article 7(2) therefore clearly is an exception to the basic principle of the free movement of goods. Accordingly, it should not be generously construed. It follows that an overbroad interpretation should not be given either, in general, to the term "legitimate reasons" or, in particular, to the notion of the "condition" of the goods being "changed or impaired".

14. Articles 5 to 7 of the Directive effect a complete harmonisation of the rules relating to the rights conferred by a trade mark and accordingly define the rights of proprietors of trade marks in the Community. The Court has nevertheless already stated that its previous case-law under Article 30 EC must be taken as the basis for determining whether a trade mark owner may under Article 7(2) oppose the marketing of repackaged products to which the trade mark has been

> reaffixed. The same canons of interpretation must apply to other variants of repackaging to which trade mark owners take objection. The Directive must be construed in accordance with the Treaty framework and the core rights developed by the Court and defined above".

192. *Boehringer* (ibid) thus made clear that the very notion of a trade mark in the TMD had to be understood in its wider legal context. In an earlier, seminal, authority in this area (Case C-427/93 *Bristol Myers Squibb v Paranova* [1996] ECR I-3457) the Court of Justice had made all of these points clear. It explained that the issue had to be understood in the context of the hierarchy of legislative norms. As with any other piece of secondary legislation the TMD had to be construed in the light of the Treaty rules on free movement of goods (ibid paragraph [27]) and further that the provision had been framed to correspond with the language and terminology used by the Court in earlier judgments in interpreting the superior Treaty rules on the free movement of goods (ibid paragraph [31]). In the face of an argument that the TMD permitted a proprietor to use a trade mark in a manner which would be inconsistent with the Treaty the Court stated:

> "35 To accept the argument that the principle of exhaustion under Article 7(1) cannot apply if the importer has repackaged the product and reaffixed the trade mark would therefore imply a major alteration to the principles flowing from Articles 30 and 36 of the Treaty.
>
> 36 There is nothing to suggest that Article 7 of the directive is intended to restrict the scope of that case-law. Nor would such an effect be permissible, since a directive cannot justify obstacles to intra-Community trade save within the bounds set by the Treaty rules. The Court's case-law shows that the prohibition on quantitative restrictions and measures having equivalent effect applies not only to national measures but also to those emanating from Community institutions (see, most recently, Case C-51/93 *Meyhui v Schott Zwiesel Glaswerke* [1994] ECR I-3879, paragraph 11)".

193. The reference by the Court to its judgment in *Meyhui* is to the fundamental constitutional principle that even the Community institutions cannot depart from the Treaty; and this, of course, is a reason why subordinate legislation cannot be inconsistent with the Treaty since if it could it would imply (wrongly) that the legislative institutions were constitutionally competent to depart from the Treaties themselves, which they are not.

194. The cases cited above concern the relationship between the rights conferred by the TMD and the Treaty rules on the free movement of goods. To take another obvious illustration a right conferred by a directive (such as the TMD) could not permit the right holder to facilitate a price fixing cartel or abuse a dominant position contrary to Articles 101 and 102 TFEU which prohibit such conduct. Such directly effective and fundamental prohibitions cannot be undermined by secondary legislation. The TMD is silent as to the relationship between trade mark usage and competition but no one has suggested in this litigation that because of this silence the TMD must be construed

as permitting and countenancing the use of trade marks in violation of the supervening Treaty rules on competition.

(iii) The 2015 amendments to the TMD – the "recast"

195. The Claimants submitted that 2015 recast amendments to the TMD must be taken into account, not least because of the (uncontroversial) principle that once an EU measure is adopted but prior to expiry of the implementation period Member States are, due to the general principle of cooperation and solidarity, required to refrain from acting in a way that would undermine the new legislation. In the text below I explain how the revisions to the TMD also make clear that the statutory delineation of trade mark rights remains subject to a series of overarching legal and policy limitations.

196. The TMD was "recast" in December 2015 by Directive (EU) 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the laws of the Member States relating to trade marks (Recast) (the "*recast TMD*"). This measure (like the TPD) was adopted under Article 114(1) TFEU. The relevant substantive provisions of the recast TMD do not become effective before January 2019 (under Article 54).

197. For present purposes it suffices to point out that the recast TMD provides: (i) for derogations to usage rights based upon general national law; (ii) that it is to be read consistently with international law including TRIPS; and (iii), that the exclusive rights conferred upon proprietors are expressed in negative terms relating to the prevention of unauthorised use by third parties. These are evident from Recitals 40 and 41 and Article 4(3) and Article 10.

198. As to both the right of Member States to create public interest exceptions to trade mark use rights and as to the relationship between the TMD and national and international law Recitals 40 and 41 provide:

> "(40) This Directive should not exclude the application to trade marks of provisions of law of the Member States other than trade mark law, such as provisions relating to unfair competition, civil liability or consumer protection.
>
> (41) Member States are bound by the Paris Convention for the Protection of Industrial Property ('the Paris Convention') and the TRIPS Agreement. It is necessary that this Directive be entirely consistent with that Convention and that Agreement. The obligations of the Member States resulting from that Convention and that Agreement should not be affected by this Directive. Where appropriate, the second paragraph of Article 351 of the Treaty on the Functioning of the European Union should apply".

199. Recital 40 casts the right of Member States to create exceptions in general terms and refers to unfair competition, civil liability and consumer protection only as examples ("*such as*"). Recital 41 is important since the TMD does not seek to define what those provisions of national law "*other than*" trade mark law are which curtail use, but it is clear from the recital that this would be strongly influenced and possibly

determined by international law such as TRIPS. Of some significance is Recital 21 which recognises that the DOHA Declaration on TRIPS and public health (set out and considered at paragraphs [180] – [181] above) is valid and relevant to the operation of EU law.

200. The substantive reflection of this is found in Article 4(3) entitled "Absolute grounds for refusal or invalidity" which confers a power ("*may*") on Member States to refuse registration or to permit revocation where the "use" is contrary to national law. As such the TMD recognises the right of Member States to introduce derogations to trade mark rights based upon public policy and empowers them to reflect this by refusing registration or in revocation. But it does not compel Member States to do this; they "*may*" refuse registration or revoke a trade mark upon that broader public interest ground. Article 4(3) reads:

> "3. Any Member State may provide that a trade mark is not to be registered or, if registered, is liable to be declared invalid where and to the extent that: (a) the use of that trade mark may be prohibited pursuant to provisions of law other than trade mark law of the Member State concerned or of the Union...".

201. As to the identification of the exclusive rights conferred upon trade mark holders this is covered by Article 10 entitled "Rights conferred by a trade mark". Article 10(1) and (2) states:

> "1.The registration of a trade mark shall confer on the proprietor exclusive rights therein.
>
> 2.Without prejudice to the rights of proprietors acquired before the filing date or the priority date of the registered trade mark, the proprietor of that registered trade mark shall be entitled to prevent all third parties not having his consent from using in the course of trade, in relation to goods or services, any sign where...".

202. Article 10(2) then proceeds to identify the conditions which must exist to justify a proprietor being able to prevent third party use (e.g. that the third party mark must be identical and used in relation to goods or services which are identical etc). Article 10(3) lists a series of usages which "*may be prohibited*" i.e. it is up to the discretion of individual Member States to decide whether they wish to introduce such rights into national law. By way of example Article 10(3)(e) permits Member States to confer upon proprietors the right to prevent third party usage " *... using the sign on business papers and in advertising*".

203. Recital 16 describes in policy terms the rationale behind the need to grant rights of preclusion; it is to ensure that the trade mark performs its function which is as an indication of origin:

> "16. The protection afforded by the registered trade mark, *the function of which is in particular to guarantee the trade mark as an indication of origin*, should be absolute in the event of

> there being identity between the mark and the corresponding sign and the goods or services".

204. The recast TMD also explains that the essential function of a trade mark is connected to *actual* usage. However, it does so by way of a limitation on the proprietor's right to use, namely if the trade mark is not used it may be lost. Recitals 31 and 32 accordingly explain:

> "(31) Trade marks fulfil their purpose of distinguishing goods or services and allowing consumers to make informed choices only when they are actually used on the market. A requirement of use is also necessary in order to reduce the total number of trade marks registered and protected in the Union and, consequently, the number of conflicts which arise between them. It is therefore essential to require that registered trade marks actually be used in connection with the goods or services for which they are registered, or, if not used in that connection within five years of the date of the completion of the registration procedure, be liable to be revoked.
>
> (32) Consequently, a registered trade mark should only be protected in so far as it is actually used and a registered earlier trade mark should not enable its proprietor to oppose or invalidate a later trade mark if that proprietor has not put his trade mark to genuine use. Furthermore, Member States should provide that a trade mark may not be successfully invoked in infringement proceedings if it is established, as a result of a plea, that the trade mark could be revoked or, when the action is brought against a later right, could have been revoked at the time when the later right was acquired".

205. So far as the relationship between the recast TMD and the superior rules of the Treaty are concerned Recital 28 states that the specific provisions in the directive on free movement of goods are designed to follow from the relevant Treaty principles:

> "(28) It follows from the principle of free movement of goods that the proprietor of a trade mark should not be entitled to prohibit its use by a third party in relation to goods which have been put into circulation in the Union, under the trade mark, by him or with his consent, unless the proprietor has legitimate reasons to oppose further commercialisation of the goods".

206. The recast TMD is based upon the conclusion that it is a proportionate measure and one which, is in accordance with the principle of subsidiarity in Article 5 TFEU: cf. Recital 42. Since the directive is expressly stated to be a recasting there is no duty on Member States to implement it by altering national law save in respect of *"...those provisions which represent a substantive amendment as compared with the earlier Directive.*" (Recital 45).

207. The recast TMD does not address at all the relationship between trade marks and competition policy. But the recast TMD was brought into effect following the report

prepared by the Commission "*Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A Single Market for Intellectual Property Rights Boosting creativity and innovation to provide economic growth, high quality jobs and first class products and services in Europe*" (Brussels, 24.5.2011 COM(2011) 287 final). This Communication was one of the policy documents which led to the recasting of the TMD: See Recital 6. The Communication emphasises that the use of *all* intellectual property rights must be subject to competition law:

> "Promoting creation and innovation and driving economic growth are common goals of intellectual property and competition law. Strong protection and enforcement of IPR should be accompanied by rigorous application of competition rules in order to prevent the abuse of IPR which can hamper innovation or exclude new entrants, and especially SMEs, from markets".
>
> (Emphasis added)

208. The relevant point is that the recast TMD (like its predecessor) does not address the relationship between trade marks and superior Treaty rules; this is because it is simply assumed, and hence implicit, that the rights in the measure are of necessity subject to *all* overarching relevant Treaty rules.

(5) Council Regulation (EC) No 207/2009 of 26 February 2009 on the Community trade mark ("the CTMR")

(i) The CTMR

209. I turn now to the CTMR which is the specific subject matter of Ground 10. The regulation sets out a system for the creation of EU wide, Community trade marks ("CTMs"). The CTMR does not replace the laws of the Member States on trade marks: see Recital 6.

(ii) Trade marks are property rights: Recital 11

210. Recital 11 makes clear that trade marks are property rights:

> "A Community trade mark is to be regarded as an object of property which exists separately from the undertakings whose goods or services are designated by it. Accordingly, it should be capable of being transferred, subject to the overriding need to prevent the public being misled as a result of the transfer. It should also be capable of being charged as security in favour of a third party and of being the subject matter of licences".

(iii) The unitary character of CTMs

211. Article 1 is at the heart of one of the Claimants' grounds. It introduces the concept of the "*unitary character*" of a CTM. It is to have "*equal effect*" across the Community.

Article 1(2) stipulates that "*its use [not] be prohibited, save in respect of the whole Community*":

> "Article 1
>
> Community trade mark
>
> 1. A trade mark for goods or services which is registered in accordance with the conditions contained in this Regulation and in the manner herein provided is hereinafter referred to as a 'Community trade mark'.
>
> 2. A Community trade mark shall have a unitary character. It shall have equal effect throughout the Community: it shall not be registered, transferred or surrendered or be the subject of a decision revoking the rights of the proprietor or declaring it invalid, nor shall its use be prohibited, save in respect of the whole Community. This principle shall apply unless otherwise provided in this Regulation".

212. The Claimants point out that the *raison d'etre* of the concept of unitariness is as a stimulant to Europe wide competition and the integration of the market which are ideals entrenched elsewhere in the Treaties. The object and purpose of the "*unitary character*" is explained at Recitals (2), (3) and (4):

> "(2) It is desirable to promote throughout the Community a harmonious development of economic activities and a continuous and balanced expansion by completing an internal market which functions properly and offers conditions which are similar to those obtaining in a national market. In order to create a market of this kind and make it increasingly a single market, not only must barriers to free movement of goods and services be removed and arrangements be instituted which ensure that competition is not distorted, but, in addition, legal conditions must be created which enable undertakings to adapt their activities to the scale of the Community, whether in manufacturing and distributing goods or in providing services. For those purposes, trade marks enabling the products and services of undertakings to be distinguished by identical means throughout the entire Community, regardless of frontiers, should feature amongst the legal instruments which undertakings have at their disposal.
>
> (3) For the purpose of pursuing the Community's said objectives it would appear necessary to provide for Community arrangements for trade marks whereby undertakings can by means of one procedural system obtain Community trade marks to which uniform protection is given and which produce their effects throughout the entire area of the Community. The principle of the unitary character of the Community trade mark

> thus stated should apply unless otherwise provided for in this Regulation.
>
> (4) The barrier of territoriality of the rights conferred on proprietors of trade marks by the laws of the Member States cannot be removed by approximation of laws. In order to open up unrestricted economic activity in the whole of the internal market for the benefit of undertakings, trade marks should be created which are governed by a uniform Community law directly applicable in all Member States".

213. The object of Article 1(2) has been further explained in case-law. In Case C- 149/11 *Leno Merken BV v Hagelkruis Beheer BV* (19th December 2012) ("*Leno Merken*") the Court of Justice described the objectives pursued by the CTMR as follows (at paragraph [40]-[42]):

> "…it is apparent that the Regulation seeks to remove the barrier of territoriality of the rights conferred on proprietors of trade marks by the laws of the member states by enabling undertakings to adapt their activities to the scale of the Community and carry them out without restriction. The Community trade mark thus enables its proprietor to distinguish his goods and services by identical means throughout the Community, regardless of frontiers. On the other hand, undertakings which do not wish to protect their trade marks at Community level may choose to use national trade marks and are not obliged to apply for registration of their marks as Community marks".

The Court continued (at paragraph [41]):

> "In order to achieve those objectives, the European Union legislature provided, in article 1(2) of Regulation No 207/2009 read together with recital (3) thereto, for the Community trade mark to have a unitary character, which results in it enjoying uniform protection and having equal effect throughout the entire area of the Community. It may not, in principle, be registered, transferred or surrendered or be the subject of a decision revoking the rights of its proprietor or declaring it invalid, nor may its use be prohibited, save in respect of the whole Community".

(iv) Public policy limitations on CTM rights

214. Community trade marks are not absolute. Article 4 defines a CTM. Under Article 6 it is to be obtained by registration. Articles 7 and 8 govern the grounds on which registration may be refused. CTMs which are contrary to public policy may not be registered. Article 7(1)(f) provides:

> "1. The following shall not be registered:

…

> (f) trade marks which are contrary to public policy or to accepted principles of morality…".

215. Article 9 provides that a CTM "*shall confer on the proprietor exclusive rights therein*", which are then defined in negative terms as a right to prevent:

> "A Community trade mark shall confer on the proprietor exclusive rights therein. The proprietor shall be entitled to prevent all third parties not having his consent from using in the course of trade …".

216. Once the requirements of the CTMR are satisfied, a CTM is guaranteed uniform protection throughout the EU. The principle of the "*unitary character*" means that a CTM must ("*shall*") be given "*equal effect throughout the Community*". Article 1(2) also identifies a non-exhaustive range of acts which are unlawful unless done in respect of the whole Community, including the registration, transfer or surrender of a CTM, the revocation of the rights of a proprietor, and the prohibition on the use of a CTM.

(v) Preservation of the right of Member States to apply national (public policy) rules to CTMs

217. Article 110 is an important provision which confirms that Member States may introduce measures to restrict the use of a CTM to the extent that national law prohibits the use of a national trade mark. The article is relevant in the present case because the Claimants argue that it cannot be relied upon by Parliament to derogate from the "unitary" scope of the CTMs that they own and which are, otherwise, curtailed by the Regulations. Article 110 clarifies that where Member States for legitimate reasons prohibit use under domestic law then they have a concomitant power to do the same in relation to the use of a CTM. The measure does not compel Member States to take the same measures against CTMs that they take against the use of domestic trade marks; the provision is permissive ("*may*"). The context to the provision is apparent from the titles to the sections of the Regulation in which it sits. First, it is positioned under Title XI to the Regulation which concerns "*Effect on the Laws of the Member States*". Secondly, it is also in Section 2 of Title XI entitled: "*Application of national laws for the purpose of prohibiting the use of Community trade mark"*. Specifically the particular title to Article 110 itself is "*Prohibition of use of Community trade marks*". Article 110(2) provides:

> "2. This Regulation shall, unless otherwise provided for, not affect the right to bring proceedings under the civil, administrative or criminal law of a Member State or under provisions of Community law for the purpose of prohibiting the use of a Community trade mark to the extent that the use of a national trade mark may be prohibited under the law of that Member State or under Community law".

218. I address this in detail at Section N(4) below in relation to Ground 10.

(vi) The 2015 Amendments to the CTMR

219. The CTMR was amended by Regulation (EU) 2015/2424 of the European Parliament and of the Council of 16 December 2015 amending Council Regulation (EC) No 207/2009 on the Community trade mark and Commission Regulation (EC) No 2868/95 implementing Council Regulation (EC) No 40/94 on the Community trade mark, and repealing Commission Regulation (EC) No 2869/95 on the fees payable to the Office for Harmonization in the Internal Market (Trade marks and Designs) ("*the amended CTMR*"). The purpose of the amended CTMR was to bring Regulation 207/2009 - the CTMR - up to date in the light of experience.

220. The terminology of Regulation (EC) No 207/2009 is updated and the 'Community trade mark' becomes the 'European Union trade mark' ('EU trade mark'). The Office for Harmonization in the Internal Market (trade marks and designs) becomes the 'European Union Intellectual Property Office'. The amended CTMR makes a large number of amendments to the procedures relating to the EU trade marks.

221. The unitary character of trade marks, set out in Article 1 CTMR, and the rights of Member States confirmed by Article 110, are unaffected by the amendments.

222. The exclusive rights conferred remain a right to prevent third party use. Article 9 thus commences with the following:

> "Rights conferred by an EU trade mark
>
> 1. The registration of an EU trade mark shall confer on the proprietor exclusive rights therein. 2.Without prejudice to the rights of proprietors acquired before the filing date or the priority date of the EU trade mark, the proprietor of that EU trade mark *shall be entitled to prevent all third parties not having his consent from using* in the course of trade, in relation to goods or services, any sign where ...".
>
> (emphasis added)

223. This Regulation became effective on 23 March 2016. However the substantive provisions must be applied only as from 1 October 2017 or, in relation to a small minority of provisions, from 1st October 2018 (cf. Article 4).

(6) Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights ("the Enforcement Directive")

224. I refer briefly to the directive which harmonises trade mark enforcement rules. The Enforcement Directive lays down basic principles which are to be respected across the whole of the EU. The recitals make it clear that it is not exhaustive of the rules which apply and that it is to be read as subject to international law and in particular TRIPS. Recitals (4) – (6) provide:

> "(4) At international level, all Member States, as well as the Community itself as regards matters within its competence, are

> bound by the Agreement on Trade-Related Aspects of Intellectual Property (the "TRIPS Agreement"), approved, as part of the multilateral negotiations of the Uruguay Round, by Council Decision 94/800/EC and concluded in the framework of the World Trade Organisation.
>
> (5) The TRIPS Agreement contains, in particular, provisions on the means of enforcing intellectual property rights, which are common standards applicable at international level and implemented in all Member States. This Directive should not affect Member States international obligations, including those under the TRIPS Agreement.
>
> (6) There are also international conventions to which all Member States are parties and which also contain provisions on the means of enforcing intellectual property rights. These include, in particular, the Paris Convention for the Protection of Industrial Property, the Berne Convention for the Protection of Literary and Artistic Works, and the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations".

(7) Directive 2014/40/EU of the European Parliament and of the Council of 3rd April 2014 (the "TPD")

(i) Legislative competence

225. I turn now from international law and general EU trade mark measures to measures specific to tobacco. The TPD is the second EU measure focusing upon control of the manufacture, presentation and sale of tobacco. The first was Directive 2001/37/EC of the European Parliament and of the Council. The TPD was adopted to reflect changes in "*scientific, market and international developments*" (cf. Recital 1). It was promulgated under Articles 53(1), 62 and 114 TFEU.

226. Article 114 empowers the EU to adopt measures for the approximation of laws, regulation and administrative action in the Member States which have as their object the establishment and functioning of the internal market. Article 114(3) states:

> "The Commission in its proposals … concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective".

(ii) Points deriving from the Recitals

227. A number of relevant points arise from the recitals to the Directive.

228. First there are substantial differences existing between the practices of the Member States in relation to the imposition of restrictions on the manufacture, sale and

promotion of tobacco products: Recital 4 – "*there are still substantial differences between the Member States' laws, regulations and administrative provisions on the manufacture, presentation and sale of tobacco and related products which present obstacles to the smooth functioning of the internal market."* These disparities should be eliminated (Recital 5).

229. Second, the TPD is a direct response to the FCTC and the WHO Guidelines which represent a "*consensus*" between, *inter alia*, the Member States. Further, this is consistent with the principle in Article 114(3) TFEU that EU law shall accord health matters a "high level of protection":

> "(7) Legislative action at Union level is also necessary in order to implement the WHO Framework Convention on Tobacco Control ('FCTC') of May 2003, the provisions of which are binding on the Union and its Member States. The FCTC provisions on the regulation of the contents of tobacco products, the regulation of tobacco product disclosures, the packaging and labelling of tobacco products, advertising and illicit trade in tobacco products are particularly relevant. The Parties to the FCTC, including the Union and its Member States, adopted a set of guidelines for the implementation of FCTC provisions by consensus during various Conferences.
>
> (8) In accordance with Article 114(3) of the Treaty of the Functioning of the European Union (TFEU), a high level of health protection should be taken as a base for legislative proposals and, in particular, any new developments based on scientific facts should be taken into account. Tobacco products are not ordinary commodities and in view of the particularly harmful effects of tobacco on human health, health protection should be given high importance, in particular, to reduce smoking prevalence among young people".

230. Third, EU policy (consistent with the objectives of the FCTC) has a particular focus on deterring young people from taking up smoking:

> "(21) In line with the purposes of this Directive, namely to facilitate the smooth functioning of the internal market for tobacco and related products, taking as a base a high level of health protection, especially for young people, and in line with Council Recommendation 2003/54/EC, Member States should be encouraged to prevent sales of such products to children and adolescents, by adopting appropriate measures that lay down and enforce age limits".

231. Fourth, the packaging and labelling requirements are intended to ensure conformity with the FCTC:

> "(24) Adaptation of the provisions on labelling is also necessary to align the rules that apply at Union level to international developments. For example, the FCTC guidelines

> on the packaging and labelling of tobacco products call for large picture warnings on both principal display areas, mandatory cessation information and strict rules on misleading information. The provisions on misleading information will complement the general ban on misleading business to consumer commercial practices laid down in Directive 2005/29/EC of the European Parliament and of the Council".

232. Fifth, the TPD addresses the implications of different types of labelling and packaging in the context of the conveyance to consumers of different (pro-smoking) messages:

> "(25) The labelling provisions should also be adapted to new scientific evidence. For example, the indication of the emission levels for tar, nicotine and carbon monoxide on unit packets of cigarettes has proven to be misleading as it leads consumers to believe that certain cigarettes are less harmful than others. Evidence also suggests that large combined health warnings comprised of a text warning and a corresponding colour photograph are more effective than warnings consisting only of text. As a consequence, combined health warnings should become mandatory throughout the Union and cover significant and visible parts of the surface of unit packets. Minimum dimensions should be set for all health warnings to ensure their visibility and effectiveness.
>
> (26) For tobacco products for smoking, other than cigarettes and roll-your-own tobacco products, which are mainly consumed by older consumers and small groups of the population, it should be possible to continue to grant an exemption from certain labelling requirements as long as there is no substantial change of circumstances in terms of sales volumes or consumption patterns of young people. The labelling of these other tobacco products should follow rules that are specific to them. The visibility of health warnings on smokeless tobacco products should be ensured. Health warnings should, therefore, be placed on the two main surfaces of the packaging of smokeless tobacco products. As regards waterpipe tobacco, which is often perceived as less harmful than traditional tobacco products for smoking, the full labelling regime should apply in order to avoid consumers being misled.
>
> (27) Tobacco products or their packaging could mislead consumers, in particular young people, where they suggest that these products are less harmful. This is, for example, the case if certain words or features are used, such as the words 'low-tar', 'light', 'ultra-light', 'mild', 'natural', 'organic', 'without additives', 'without flavours' or 'slim', or certain names, pictures, and figurative or other signs. Other misleading elements might include, but are not limited to, inserts or other additional material such as adhesive labels, stickers, inserts, scratch-offs and sleeves or relate to the shape of the tobacco

> product itself. Certain packaging and tobacco products could also mislead consumers by suggesting benefits in terms of weight loss, sex appeal, social status, social life or qualities such as femininity, masculinity or elegance. Likewise, the size and appearance of individual cigarettes could mislead consumers by creating the impression that they are less harmful. Neither the unit packets of tobacco products nor their outside packaging should include printed vouchers, discount offers, reference to free distribution, two-for- one or other similar offers that could suggest economic advantages to consumers thereby inciting them to buy those tobacco products.
>
> (28) In order to ensure the integrity and the visibility of health warnings and maximise their efficacy, provisions should be made regarding the dimensions of the health warnings as well as regarding certain aspects of the appearance of the unit packets of tobacco products, including the shape and opening mechanism. When prescribing a cuboid shape for a unit packet, rounded or bevelled edges should be considered acceptable, provided the health warning covers a surface area that is equivalent to that on a unit packet without such edges. Member States apply different rules on the minimum number of cigarettes per unit packet. Those rules should be aligned in order to ensure free circulation of the products concerned".

233. Sixth, the TPD balances the need to protect health with other fundamental rights, proportionality and international law:

> "(59) The obligation to respect the fundamental rights and legal principles enshrined in the Charter of Fundamental Rights of the European Union is not changed by this Directive. Several fundamental rights are affected by this Directive. It is therefore necessary to ensure that the obligations imposed on manufacturers, importers and distributors of tobacco and related products not only guarantee a high level of health and consumer protection, but also protect all other fundamental rights and are proportionate with respect to the smooth functioning of the internal market. The application of this Directive should respect Union law and relevant international obligations".

(iii) The TPD is a "first" and "basic" measure of harmonisation: Recital 53

234. Recital 53 (set out below) refers to the directive as constituting "*a first set of basic common rules*". The TPD is a measure of partial harmonisation. It reflects a form of lowest common denominator but leaves it to individual Member States to go further if they wish.

(iv) Relationship with international law/TRIPS, FCTC

235. A second issue concerns the relationship between the TPD and international law but Recitals (53) – (55) address this matter:

> "(53) Tobacco and related products which comply with this Directive should benefit from the free movement of goods. However, in light of the different degrees of harmonisation achieved by this Directive, the Member States should, under certain conditions, retain the power to impose further requirements in certain respects in order to protect public health. This is the case in relation to the presentation and the packaging, including colours, of tobacco products other than health warnings, for which this Directive provides a first set of basic common rules. Accordingly, Member States could, for example, introduce provisions providing for further standardisation of the packaging of tobacco products, provided that those provisions are compatible with the TFEU, with WTO obligations and do not affect the full application of this Directive.
>
> (54) Moreover, in order to take into account possible future market developments, Member States should also be allowed to prohibit a certain category of tobacco or related products, on grounds relating to the specific situation in the Member State concerned and provided the provisions are justified by the need to protect public health, taking into account the high level of protection achieved through this Directive. Member States should notify such stricter national provisions to the Commission.
>
> (55) A Member State should remain free to maintain or introduce national laws applying to all products placed on its national market for aspects not regulated by this Directive, provided they are compatible with the TFEU and do not jeopardise the full application of this Directive. Accordingly and under those conditions, a Member State could, inter alia, regulate or ban paraphernalia used for tobacco products (including waterpipes) and for herbal products for smoking as well as regulate or ban products resembling in appearance a type of tobacco or related product. Prior notification is required for national technical regulations pursuant to Directive 98/34/EC".

Article 1 makes clear that the *principal* measure of international law that the TPD is intended to give effect to is the FCTC.

(v) Prohibition on, inter alia, use of trade marks in relation to advertising of tobacco products

236. Article 8 governs health warnings. It provides as follows:

"CHAPTER II

Labelling and packaging

Article 8

General provisions

1. Each unit packet of a tobacco product and any outside packaging shall carry the health warnings provided for in this Chapter in the official language or languages of the Member State where the product is placed on the market.

2. Health warnings shall cover the entire surface of the unit packet or outside packaging that is reserved for them and they shall not be commented on, paraphrased or referred to in any form.

3. Member States shall ensure that the health warnings on a unit packet and any outside packaging are irremovably printed, indelible and fully visible, including not being partially or totally hidden or interrupted by tax stamps, price marks, security features, wrappers, jackets, boxes, or other items, when tobacco products are placed on the market. On unit packets of tobacco products other than cigarettes and roll-your-own tobacco in pouches, the health warnings may be affixed by means of stickers, provided that such stickers are irremovable. The health warnings shall remain intact when opening the unit packet other than packets with a flip-top lid, where the health warnings may be split when opening the packet, but only in a manner that ensures the graphical integrity and visibility of the text, photographs and cessation information.

4. The health warnings shall in no way hide or interrupt the tax stamps, price marks, tracking and tracing marks, or security features on unit packets.

5. The dimensions of the health warnings provided for in Articles 9, 10, 11 and 12 shall be calculated in relation to the surface concerned when the packet is closed.

6. Health warnings shall be surrounded by a black border of a width of 1 mm inside the surface area that is reserved for these warnings, except for health warnings pursuant to Article 11.

7. When adapting a health warning pursuant to Articles 9(5), 10(3) and 12(3), the Commission shall ensure that it is factual or that Member States shall have a choice of two warnings, one of which is factual.

> 8. Images of unit packets and any outside packaging targeting consumers in the Union shall comply with the provisions of this chapter".

237. Articles 13 and 14 regulate what may be placed on tobacco products and upon packets and outside packaging. Article 13(3) puts it beyond doubt that the activities that may be prohibited include the use of trade marks:

> "Article 13
>
> Product presentation
>
> 1. The labelling of unit packets and any outside packaging and the tobacco product itself shall not include any element or feature that:
>
> (a) promotes a tobacco product or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions; labels shall not include any information about the nicotine, tar or carbon monoxide content of the tobacco product;
>
> (b) suggests that a particular tobacco product is less harmful than others or aims to reduce the effect of some harmful components of smoke or has vitalising, energetic, healing, rejuvenating, natural, organic properties or has other health or lifestyle benefits;
>
> (c) refers to taste, smell, any flavourings or other additives or the absence thereof;
>
> (d) resembles a food or a cosmetic product;
>
> (e) suggests that a certain tobacco product has improved biodegradability or other environmental advantages.
>
> 2. The unit packets and any outside packaging shall not suggest economic advantages by including printed vouchers, offering discounts, free distribution, two-for-one or other similar offers.
>
> 3. The elements and features that are prohibited pursuant to paragraphs 1 and 2 may include but are not limited to texts, symbols, names, trade marks, figurative or other signs.
>
> Article 14
>
> Appearance and content of unit packets
>
> 1. Unit packets of cigarettes shall have a cuboid shape. Unit packets of roll-your-own tobacco shall have a cuboid or cylindrical shape, or the form of a pouch. A unit packet of cigarettes shall include at least 20 cigarettes. A unit packet of

> roll-your-own tobacco shall contain tobacco weighing not less than 30g
>
> 2. A unit packet of cigarettes may consist of carton or soft material and shall not have an opening that can be re- closed or re-sealed after it is first opened, other than the flip-top lid and shoulder box with a hinged lid. For packets with a flip-top lid and hinged lid, the lid shall be hinged only at the back of the unit packet".

(vi) The right of the Member States to introduce additional restrictions on advertising: Standardisation of the packaging of tobacco products

238. Article 24 entitled "Free movement" is an important provision which makes clear that Member States may adopt prohibitive measures justified on grounds of public health. It has been subject to much debate in Court and is the subject of a specific ground of challenge: Ground 11. It provides as follows:

> "Article 24
>
> Free movement
>
> 1. Member States may not, for considerations relating to aspects regulated by this Directive, and subject to paragraphs 2 and 3 of this Article, prohibit or restrict the placing on the market of tobacco or related products which comply with this Directive.
>
> 2. This Directive shall not affect the right of a Member State to maintain or introduce further requirements, applicable to all products placed on its market, in relation to the standardisation of the packaging of tobacco products, where it is justified on grounds of public health, taking into account the high level of protection of human health achieved through this Directive. Such measures shall be proportionate and may not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. Those measures shall be notified to the Commission together with the grounds for maintaining or introducing them.
>
> 3. A Member State may also prohibit a certain category of tobacco or related products, on grounds relating to the specific situation in that Member State and provided the provisions are justified by the need to protect public health, taking into account the high level of protection of human health achieved through this Directive. Such national provisions shall be notified to the Commission together with the grounds for introducing them. The Commission shall, within six months of the date of receiving the notification provided for in this paragraph, approve or reject the national provisions after having verified, taking into account the high level of protection

> of human health achieved through this Directive, whether or not they are justified, necessary and proportionate to their aim and whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between the Member States. In the absence of a decision by the Commission within the period of six months, the national provisions shall be deemed to be approved".

(vii) The five year mandatory review: Article 28

239. Under Article 28 the Commission is under a duty, after five years, to submit to the Parliament, the Council and the European Economic and Social Committee and to the Committee of the Regions a report on the application of the Directive. This shall include "*... in particular, the elements of the Directive which should be reviewed or adapted in the light of scientific and technical developments, including the development of internationally agreed rules and standards on tobacco and related products…*" (Article 28(2)). Amongst the matters that the Commission must report upon are "*experience*" gained taking into account national and international legal, economic and scientific developments; and changes in market circumstances constituting "*…a substantial change in circumstances*". The terms of the review are broad enough to capture the experience, worldwide, of those States that had introduced standardised packaging such as Australia and the United Kingdom.

240. The provision reads:

> "Article 28
>
> Report
>
> 1. No later than five years from 20 May 2016, and whenever necessary thereafter, the Commission shall submit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a report on the application of this Directive. When drafting the report, the Commission shall be assisted by scientific and technical experts in order to have all the necessary information at its disposal.
>
> 2. In the report, the Commission shall indicate, in particular, the elements of the Directive which should be reviewed or adapted in the light of scientific and technical developments, including the development of internationally agreed rules and standards on tobacco and related products. The Commission shall pay special attention to:
>
> (a) the experience gained with respect to the design of package surfaces not governed by this Directive taking into account national, international, legal, economic and scientific developments;

(b) market developments concerning novel tobacco products considering, inter alia, notifications received under Article 19;

(c) market developments which constitute a substantial change of circumstances;

(d) the feasibility, benefits and possible impact of a European system for the regulation of the ingredients used in tobacco products, including the establishment, at Union level, of a list of ingredients that may be used or present in, or added to tobacco products, taking into account, inter alia, the information collected in accordance with Articles 5 and 6;

(e) market developments concerning cigarettes with a diameter of less than 7,5 mm, and consumer perception of their harmfulness as well as the misleading character of such cigarettes;

(f) the feasibility, benefits and possible impact of a Union database containing information on ingredients and emissions from tobacco products collected in accordance with Articles 5 and 6;

(g) market developments concerning electronic cigarettes and refill containers considering, amongst others, information collected in accordance with Article 20, including on the initiation of consumption such products by young people and non-smokers and the impact of such products on cessation efforts as well as measures taken by Member States regarding flavours;

(h) market developments and consumer preferences as regards waterpipe tobacco, with a particular focus on its flavours.

The Member States shall assist the Commission and provide all available information for carrying out the assessment and preparing the report.

3. The report shall be followed-up by proposals for amending this Directive, which the Commission deem necessary to adapt it - to the extent necessary for the smooth functioning of the internal market - to developments in the field of tobacco and related products, and to take into account new developments based on scientific facts and developments concerning internationally agreed standards for tobacco and related products".

(8) Section 94 Children and Families Act 2014

241. I turn now to the position in the United Kingdom. Section 94(1) and (2) of the Children and Families Act 2014 confer upon the Secretary of State the power to make

regulations to achieve two specified purposes relating to the health of persons both under but also above aged 18. The policy objectives are defined as "*reducing the risk of harm to, or promoting, the health or welfare of people*":

> "Regulation of retail packaging etc of tobacco products
>
> (1) The Secretary of State may make regulations under subsection (6) or (8) if the Secretary of State considers that the regulations may contribute at any time to reducing the risk of harm to, or promoting, the health or welfare of people under the age of 18.
>
> (2) Subsection (1) does not prevent the Secretary of State, in making regulations under subsection (6) or (8), from considering whether the regulations may contribute at any time to reducing the risk of harm to, or promoting, the health or welfare of people aged 18 or over".

242. Section 94(3) sets out certain conditions that the Secretary of State must in effect be satisfied of:

> "(3) The Secretary of State may treat regulations under subsection (6) or (8) as capable of contributing to reducing the risk of harm to, or promoting, the health or welfare of people under the age of 18 if the Secretary of State considers that—
>
> (a) at least some of the provisions of the regulations are capable of having that effect, or
>
> (b) the regulations are capable of having that effect when taken together with other regulations that were previously made under subsection (6) or (8) and are in force".

243. Section 94(4) contains an important deeming provision:

> "(4) Regulations under subsection (6) or (8) are to be treated for the purposes of subsection (1) or (2) as capable of contributing to reducing the risk of harm to, or promoting, people's health or welfare if (for example) they may contribute to any of the following—
>
> (a) discouraging people from starting to use tobacco products;
>
> (b) encouraging people to give up using tobacco products;
>
> (c) helping people who have given up, or are trying to give up, using tobacco products not to start using them again;
>
> (d) reducing the appeal or attractiveness of tobacco products;

> (e) reducing the potential for elements of the packaging of tobacco products other than health warnings to detract from the effectiveness of those warnings;
>
> (f) reducing opportunities for the packaging of tobacco products to mislead consumers about the effects of using them;
>
> (g) reducing opportunities for the packaging of tobacco products to create false perceptions about the nature of such products;
>
> (h) having an effect on attitudes, beliefs, intentions and behaviours relating to the reduction in use of tobacco products.
>
> (5) Regulations under subsection (6) or (8) are to be treated for the purposes of subsection (1) as capable of contributing to reducing the risk of harm to, or promoting, the health or welfare of people under the age of 18 if—
>
> (a) they may contribute to reducing activities by such people which risk harming their health or welfare after they reach the age of 18, or
>
> (b) they may benefit such people by reducing the use of tobacco products among people aged 18 or over".

244. Section 94(6) empowers the Defendant to make provision about the retail packaging of tobacco products:

> "(6) The Secretary of State may by regulations make provision about the retail packaging of tobacco products".

245. And these may include very specific provisions relating to a variety of types of advertising related activity:

> "(7) Regulations under subsection (6) may in particular impose prohibitions, requirements or limitations relating to—
>
> (a) the markings on the retail packaging of tobacco products (including the use of branding, trade marks or logos);
>
> (b) the appearance of such packaging;
>
> (c) the materials used for such packaging;
>
> (d) the texture of such packaging;
>
> (e) the size of such packaging;
>
> (f) the shape of such packaging;
>
> (g) the means by which such packaging is opened;

(h) any other features of the retail packaging of tobacco products which could be used to distinguish between different brands of tobacco product;

(i) the number of individual tobacco products contained in an individual packet;

(j) the quantity of a tobacco product contained in an individual packet.

(8) The Secretary of State may by regulations make provision imposing prohibitions, requirements or limitations relating to—

(a) the markings on tobacco products (including the use of branding, trade marks or logos);

(b) the appearance of such products;

(c) the size of such products;

(d) the shape of such products;

(e) the flavour of such products;

(f) any other features of tobacco products which could be used to distinguish between different brands of tobacco product.

(9) The Secretary of State may by regulations—

(a) create offences which may be committed by persons who produce or supply tobacco products the retail packaging of which breaches prohibitions, requirements or limitations imposed by regulations under subsection (6);

(b) create offences which may be committed by persons who produce or supply tobacco products which breach prohibitions, requirements or limitations imposed by regulations under subsection (8);

(c) provide for exceptions and defences to such offences;

(d) make provision about the liability of others to be convicted of such offences if committed by a body corporate or a Scottish partnership.

(10) The Secretary of State may by regulations—

(a) provide that regulations under subsection (6) or (8) are to be treated for the purposes specified in regulations under this subsection as safety regulations within the meaning of the Consumer Protection Act 1987;

> (b) make provision for the appropriate minister to direct, in relation to cases of a particular description or a particular case, that any duty imposed on a local weights and measures authority in Great Britain or a district council in Northern Ireland by virtue of provision under paragraph (a) is to be discharged instead by the appropriate minister.
>
> (11) The Secretary of State may by regulations make provision amending, repealing, revoking or otherwise modifying any provision made by or under an enactment (whenever passed or made) in connection with provision made by regulations under any of subsections (6), (8), (9) or (10)".

246. Finally for present purposes Parliament required the consent of the devolved administrations to be obtained before regulations could be made:

> "(12) The Secretary of State must—
>
> (a) obtain the consent of the Scottish Ministers before making regulations under any of subsections (6), (8), (9) or (10) containing provision which would (if contained in an Act of the Scottish Parliament) be within the legislative competence of that Parliament;
>
> (b) obtain the consent of the Welsh Ministers before making regulations under any of those subsections containing provision which would (if contained in an Act of the National Assembly for Wales) be within the legislative competence of that Assembly;
>
> (c) obtain the consent of the Office of the First Minister and deputy First Minister in Northern Ireland before making regulations under any of those subsections containing provision which would (if contained in an Act of the Northern Ireland Assembly) be within the legislative competence of that Assembly".

247. The Regulations come into force in 20 May 2016, the deadline for the implementation of TPD.

(9) The Regulations

(i) Restrictions imposed on the external packaging and on the products themselves: Regulations 3-6

248. The Regulations implement aspects of the TPD. However, the principal object is to introduce standardised packaging. It is undeniably correct, as the Claimants contend, that the Regulations will exert substantial limitations upon the tobacco companies' use of their intellectual property rights. But the curtailment is not absolute. Standardised packaging entails a limited right to use trade marks on packaging and products and has no material impact on the use of trade marks outside the consumer

context, for instance in relation to wholesale trade packaging or on corporate letterheads or in trade magazines. In addition, the Regulations do not prohibit the dissemination of information about the identity of the producer (Schedule 1(3)) so that, although this information is not communicated in the form of a trade mark, it can, nonetheless, operate in conjunction with permitted trade marks to facilitate the use of the mark as an indicator or identifier of origin. I set out below Regulations 3-6 which set out the rules now applicable to the packaging of cigarettes and to the appearance of the tobacco products themselves. There are equivalent restrictions imposed on hand rolled tobacco (in Regulations 7 and 8):

> "Permitted colour or shade of packaging of cigarettes
>
> 3.—(1) No person may produce or supply any cigarettes in breach of any of the provisions of this regulation or Schedule 1 (exceptions to paragraphs (2) and (3)).
>
> (2) The only colour or shade permitted on or for the external packaging of a unit packet or container packet of cigarettes is Pantone 448 C with a matt finish, but this is subject to paragraph (4) and Schedule 1.
>
> (3) The only colour or shade permitted on or for the internal packaging of a unit packet or container packet of cigarettes, is either—
>
> (a) white, or
>
> (b) Pantone 448 C with a matt finish,
>
> but this is subject to paragraph (4), Schedule 1 and paragraph 3(1) of Schedule 2.
>
> (4) Nothing in paragraph (2) or (3) prohibits any warning, statement, text, picture, image, symbol or marking which is required by any enactment (whenever passed or made) other than these Regulations; but see paragraph 3 of Schedule 1 which imposes conditions in relation to any text required in accordance with regulation 7(4)(a)(i) of the General Product Safety Regulations 2005 (name and address of producer)(7).
>
> Material, shape, opening and contents of unit packet of cigarettes
>
> 4.—(1) No person may produce or supply any cigarettes in breach of any of the provisions of this regulation.
>
> (2) A unit packet of cigarettes must be made of carton or soft material.
>
> (3) A unit packet of cigarettes must be cuboid in shape, although any such cuboid may have bevelled or rounded edges.

(4) A unit packet of cigarettes may contain an opening that can be re-closed or re-sealed after it is first opened but only if that opening is a flip top lid or a shoulder box hinged lid.

(5) A flip-top lid may be hinged only at the back of the packet.

(6) A shoulder box hinged lid may be hinged only along one of the two smallest sides of the packet.

(7) The sides of a unit packet of cigarettes which is a shoulder box with a hinged lid must have a height (measured between the front and back surfaces of the packet) of at least 16 millimetres.

(8) A unit packet of cigarettes must contain a minimum of 20 cigarettes.

Appearance of cigarettes

5.—(1) No person may produce or supply any cigarettes in breach of any of the provisions of this regulation.

(2) The only colour or shade permitted on or for the paper, casing, filter or other material forming part of a cigarette (apart from the tobacco contained in it) is plain white with a matt finish, but this is subject to the following provisions.

(3) Any paper or casing that surrounds the end of a cigarette that is not designed to be lit may be coloured in such a way as to imitate cork.

(4) A cigarette may have text printed on it to identify the brand name and variant name of the cigarette but only if each of the following conditions is met.

(5) Those conditions are—

(a) that the text appears parallel to, and not more than 38 millimetres from, the end of the cigarette that is not designed to be lit,

(b) that the text does not contain any character which is not alphabetic, numeric or an ampersand,

(c) that the first letter of any word is in upper-case type or lower-case type,

(d) that the rest of any word is in lower-case type,

(e) that the text is printed in Helvetica type,

(f) that the colour of the text is black,

> (g) that the text is in a normal, weighted, regular typeface, and
>
> (h) that the size of the text is no larger than 8 point.
>
> Further provisions about the packaging of cigarettes
>
> 6. No person may produce or supply any cigarettes in breach of any of the provisions of Schedule 2 (further provisions about the packaging of cigarettes)".

(ii) Preservation of registration rights: Regulation 13

249. Regulation 13 is part of the basis of Ground 10. The Claimants submit that it highlights the illegality of the Regulations in the light of Article 110(2) CTMR (see Section N in relation to Ground 10 below). It reads:

> "Regulations not to affect registration of trade marks etc
>
> 13.—(1) For the avoidance of doubt, nothing in, or done in accordance with, these Regulations—
>
> (a) forms an obstacle to the registration of a trade mark under the Trade marks Act 1994, or
>
> (b) gives rise to a ground for the declaration of invalidity of a registered trade mark under section 47(1) of that Act (grounds for invalidity of registration).
>
> (2) Without limiting paragraph (1), nothing in, or done in accordance with, these Regulations—
>
> (a) causes any trade mark to be contrary to public policy or to accepted principles of morality for the purposes of section 3(3)(a) of that Act (absolute grounds for refusal of registration),
>
> (b) amounts to an enactment or rule of law which prohibits the use of a trade mark for the purposes of section 3(4) of that Act,
>
> (c) amounts to a rule of law by which the use in the United Kingdom of any trade mark is liable to be prevented for the purposes of section 5(4) of that Act (relative grounds for refusal of registration),
>
> (d) causes an application for the registration of a trade mark under that Act to be one which is made in bad faith, or
>
> (e) prevents an applicant for the registration of a trade mark under that Act from having such a *bona*

fide intention as is mentioned in section 32(3) of that Act (application for registration of trade mark).

(3) Paragraph (4) applies for the purposes of section 6(3) of the Trade marks Act 1994 (meaning of "earlier trade mark") if the trade mark there mentioned is a registered trade mark and its use is affected by these Regulations.

(4) A *bona fide* use of the trade mark is to be regarded as having taken place during the two years there mentioned if there would have been such use of the trade mark during that period were these Regulations not in force.

(5) Paragraph (6) applies for the purposes of—

(a) section 6A(3) of the Trade marks Act 1994 (raising of relative grounds in opposition proceedings in case of non-use), or

(b) section 47(2B) of that Act (grounds for invalidity of registration), if the earlier trade mark there mentioned is a registered trade mark and its use is affected by these Regulations.

(6) If any provision of these Regulations causes any non-use of the trade mark within the period of five years there mentioned, such provision is to be regarded as a proper reason for that non-use, provided that the trade mark would have been put to such genuine use as is there mentioned were these Regulations not in force.

(7) Paragraph (8) applies for the purposes of section 46(1)(a) or (b) of the Trade marks Act 1994 (revocation of registration) if the use of the registered trade mark there mentioned is affected by these Regulations.

(8) If any provision of these Regulations causes any non-use of the registered trade mark within the period of five years there mentioned, such provision is to be regarded as a proper reason for that non-use, provided that the registered trade mark would have been put to such genuine use as is there mentioned were these Regulations not in force.

(9) To the extent that any provision of the Trade marks Act 1994 mentioned in this regulation (a "relevant provision") applies to international trade marks (UK) (whether by virtue of that Act, the Trade marks (International Registration) Order 2008 or otherwise, and whether with or without modifications), then provision made by this regulation in relation to that relevant provision shall also apply (with any necessary modifications) to international trade marks (UK).

(iii) The duty to conduct periodic reviews: Regulation 21

250. Regulation 21 requires the Secretary of State in consultation with the devolved authorities to conduct periodic reviews with the first report being published before no later than five years from the coming into force of the Regulations:

> "*Review*
>
> 21.—(1) The Secretary of State must from time to time—
>
> (a) carry out a review of these Regulations, in consultation with the appropriate ministers in Wales, Scotland and Northern Ireland,
>
> (b) set out the conclusions of the review in a report, and
>
> (c) publish the report.
>
> (2) In carrying out the review, the Secretary of State must, so far as is reasonable, have regard to how Articles 13 and 14 of Directive 2014/40/EU of the European Parliament and of the Council of 3rd April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC(22) (which are implemented by means of regulations 4, 8 and 10 of these Regulations) is implemented in other member States.
>
> (3) The report must in particular—
>
> (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations,
>
> (b) assess the extent to which those objectives are achieved, and
>
> (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.
>
> (4) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.
>
> (5) Reports under this regulation are afterwards to be published at intervals not exceeding five years".

E. GROUND 1: THE REGULATIONS ARE UNLAWFUL AS CONSTITUTING THE IMPLEMENTATION OF AN UNLAWFUL POWER UNDER ARTICLE 24(2) TPD:

(1) The issue

251. The Claimants submit that the Regulations are unlawful because they purport to be predicated upon Article 24(2) TPD, which is itself unlawful. This latter issue had formed the basis of an earlier judicial review and since this ground raised an issue concerning the validity of EU legislation it was referred to the Court of Justice by the High Court in 2015. Advocate General Kokott gave her opinion on 23rd December 2015 and the Court of Justice handed down judgment on 4th May 2016. In line with the opinion of the Advocate General, the Court rejected the submissions of the Claimants and upheld the legality of the TPD, including Article 24(2): see Case C-547/14 *Philip Morris Brands SARL and Others* (4th May 2016) ("*Philip Morris*").

252. It follows from the judgment of the Court of Justice that since the TPD and Article 24(2) are lawful, the parasitic or contingent challenge under national law predicated upon the invalidity of the TPD and article 24(2) necessarily fails.

253. The judgment, and the opinion of the Advocate General, provide important guidance on a range of issues which are relevant to other grounds which have arisen in this case. In particular they address: whether the regulation of tobacco control is a matter of exclusive or shared competence as between the Member States and the EU; the scope of the power / right of Member States to adopt tobacco control measures which are outwith the scope of the TPD; how public health interests and rights are to be reconciled with other fundamental rights; and the nature of the proportionality test. The judgment and opinion also address important matters relevant to the interpretation of the TPD, such as the importance of public health as both a legitimate objective to be pursued by the EU and Member States and public health as a fundamental right belonging to individuals; and the relevance of the FCTC and the WHO Guidance. The actual conclusions of the Court of Justice are accordingly relevant to (*inter alia*): Ground 7 (section K) on the scope and effect of Articles 17 and 52 of the Fundamental Charter in the context of the Claimants' submissions about respect for property rights; Ground 9 (Section M) on Article 16 of the Fundamental Charter on the right to conduct business; Ground 11 (section O) on the application of the test under Article 24(2) TPD; Ground 12 (Section P) on the competence of the Secretary of State to adopt the Regulations at all; Ground 14 (section R) on the application of the rules on the free movement of goods; and Ground 16 (section T) on the argument of the Tipping Claimants that Regulation 5 is *ultra vires* the TPD. It is therefore relevant to set out the conclusions in some detail.

(2) The questions referred to the Court of Justice

254. The following questions were referred to the Court. In its judgment, for various technical reasons, which it is not necessary to delve into, the Court did not address each of the questions posed[7]. The full suite of Questions posed were as follows:

> "*Legal basis*

[7] In particular the Court declined to answer Question 1 point (c)(iv), and Questions 4-6. In relation to Question 7 the Court also only answered that part which concerned Article 7 TPD

1. Is the Directive invalid in whole or in part because Article 114 TFEU does not provide an adequate legal basis? In particular:

(a) In relation to Article 24(2) of the Directive:

(i) on its proper interpretation, to what extent does it permit Member States to adopt more stringent rules in relation to matters relating to the "standardisation" of the packaging of tobacco products; and,

(ii) in light of that interpretation, is Article 24(2) invalid because Article 114 TFEU does not provide an adequate legal basis?

(b) Is Article 24(3) [of the Directive], which allows Member States to prohibit a category of tobacco or related products in specified circumstances, invalid because Article 114 TFEU does not provide an adequate legal basis?

(c) Are the following provisions invalid because Article 114 TFEU does not provide an adequate legal basis:

(i) the provisions of Chapter II of Title II [of the Directive], which relate to packaging and labelling;

(ii) Article 7 [of the Directive], insofar as it prohibits menthol cigarettes and tobacco products with a characterising flavour;

(iii) Article 18 [of the Directive], which allows Member States to prohibit cross-border distance sales of tobacco products; and,

(iv) Articles 3(4) and 4(5) [of the Directive], which delegate powers to the Commission in relation to emission levels?

Proportionality and fundamental rights

2. In relation to Article 13 [of the Directive]:

(a) on its true interpretation, does it prohibit true and non-misleading statements about tobacco products on the product packaging; and,

(b) if so, is it invalid because it violates the principle of proportionality and/or Article 11 of the Charter of Fundamental Rights?

3. Are any or all of the following provisions of [the Directive] invalid because they infringe the principle of proportionality:

(a) Articles 7(1) and 7(7), insofar as they prohibit the placing on the market of tobacco products with menthol as a characterising flavour and the placing on the market of tobacco products containing flavourings in any of their components;

(b) Articles 8(3), 9(3), 10(1)(g) and 14, insofar as they impose various pack standardisation requirements; and,

(c) Articles 10(1)(a) and (c), insofar as they require health warnings to cover 65% of the external front and back surface of the unit packaging and any outside packaging?

Delegation/implementation

4. Are any or all of the following provisions of [the Directive] invalid because they infringe Article 290 TFEU:

(a) Articles 3(2) and (4) concerning maximum emission levels;

(b) Article 4(5) relating to measurement methods for emissions;

(c) Articles 7(5), (11) and (12) concerning the regulation of ingredients;

(d) Articles 9(5), 10(1)(f), 10(3), 11(6), 12(3) and 20(12) concerning health warnings;

(e) Article 20(11) concerning the prohibition of electronic cigarettes and/or refill containers; and/or,

(f) Article 15(12) concerning data storage contracts?

5. Are Articles 3(4) and 4(5) [of the Directive] invalid because they breach the principle of legal certainty and/or impermissibly delegate powers to external bodies that are not subject to the procedural safeguards required by EU law?

6. Are any or all of the following provisions of [the Directive] invalid because they infringe Article 291 TFEU:

(a) Article 6(1) concerning reporting obligations;

(b) Article 7(2)-7(4) and 7(10) concerning implementing acts relating to the prohibition of tobacco products in certain circumstances; and/or,

(c) Articles 9(6) and 10(4) concerning health warnings?

Subsidiarity

7. Is [the Directive] and in particular Articles 7, 8(3), 9(3), 10(l)(g), 13 and 14 invalid for failure to comply with the principle of subsidiarity?

(3) The issues decided in the case

255. Before analysing discrete issues it is of some relevance to make some introductory observations which place the judgment into context. First, the challenge was to EU legislation, not to measures adopted by Member States. As such the test of proportionality described by the Court was in relation to challenges to EU legislation adopted following agreement by the Council of Ministers and the Parliament; and not the legislation of an individual Member State which does not have that level of international consensus attached to it. The Supreme Court in *Lumsdon* (ibid) observed that the test for proportionality at the EU level of EU legislation was less strict than that applied at the national level. Accordingly statements made by the Court about the nature of the proportionality test are of passing but not decisive relevance in this case. Second, in relation to the application of the proportionality test by the Court reference was made on a number of occasions to the paucity of information provided by the referring Courts. It will be evident to any reader of the judgment that the evaluation of the components of the proportionality test is very cursory and in many instances conclusionary. In my view this is a reflection of the fact that the parties did not place before the Court detailed evidence. Again I have therefore gained little assistance as to how I should approach the complex evidential issues arising in the present cases from the approach adopted by the Court of Justice to the assessment of the evidence before it; greater assistance is provided by the judgment of the Court of Justice in *Scotch Whisky* (ibid), which did (like the present case) concern a measure of a Member State.

(i) Factors relevant to interpretation: Health protection, the FCTC and WHO Guidance

256. I turn now to consider some of the principal factors treated by the Court of Justice as relevant to interpretation. In paragraph [57] of her opinion the Advocate General, in rejecting the submission that the adoption of the TPD pursuant to Article 114 TFEU was *ultra vires,* emphasised the importance of public health protection and the fact that the TPD in addition to fulfilling a function of improving the internal market also pursued "*... a high level of health protection. That objective is precisely consistent with the task conferred on the Union legislature in primary law, as can be expressly seen from Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights*."

257. The Court held likewise emphasising throughout the judgment that the pursuit of health was a fundamental objective of the EU and, indeed, an interest and right which was superior to other conflicting rights: see for example paragraphs [61], [144], [156], [170], [176] and [197]. In particular the Court emphasised as considerations warranting the elevation of public health as a guiding principle, the "*addictive effects*"

of tobacco and its impact upon children who, because of addiction, were to be treated a "*particularly vulnerable class of consumers*".

258. Both the FCTC and the WHO guidelines are important considerations capable of affecting EU law and policy. In the context of an argument that the TPD created obstacles to internal trade within the EU and was therefore unlawful in the light of Article 114 the Advocate General said:

> "73. … Be that as it may, it is settled case-law that recourse to Article 114 TFEU as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from multifarious development of national laws, provided the emergence of such obstacles is likely and the harmonisation measure adopted is designed to prevent them.
>
> 74. That is precisely the case here, in particular if account is taken of the work of the World Health Organisation (WHO) as an international context.
>
> 75. The EU institutions taking part in the preliminary ruling proceedings and some of the participating Member States have argued convincingly that under the WHO Framework Convention on Tobacco Control the Union and its Member States were called upon to limit or prohibit the use in tobacco products of ingredients which may improve their taste, including the use of menthol. Although this is not apparent from the wording of the Framework Convention itself, it is clear from the Guidelines for Implementation of Articles 9 and 10 which were adopted by the Conference of Parties a few years ago.
>
> 76. Whilst those guidelines are not as such legally binding, they do constitute internationally applicable recommendations for implementation of the WHO Framework Convention by its Parties. They therefore also serve as a guide for the EU Member States which concluded that Framework Convention.
>
> 77. In these circumstances, the Union legislature could legitimately assume that rules on the use of menthol and other characterising flavours in tobacco products would soon be adopted at national level if uniform provisions were not introduced at Union level.
>
> 78. The reason for the fact, highlighted by some of the parties, that in reality hardly any national rules in this regard had been enacted in the EU Member States for a considerable period of time appears to be that the Commission had prepared for and initiated the legislative procedure for the adoption of the contested directive within the EU at more or less the same time as the WHO Guidelines appeared.

> 79. Furthermore, the Union legislature could reasonably assume that any national rules to implement the WHO Framework Convention would differ from one Member State to the next and thus lead to the creation of new obstacles to trade in the internal market unless a harmonisation measure was adopted at Union level. Those Guidelines do not stipulate any specific measures for the Parties to the Convention, but accord them extremely broad latitude; in particular, the Guidelines allow them to choose between prohibitions and mere restrictions on the use of flavouring ingredients in tobacco products and only contain examples of such ingredients.
>
> 80. Accordingly, the doubts expressed by a number of participating undertakings and by Poland as to the existence of present or future differences between Member States' laws, regulations and administrative provisions are all unfounded".

259. She considered it "*self–evident*" that Article 114 could be used to take account of developments at the level of international law or recommendations made by international bodies. She cited in support Article 3(5) TFEU which states:

> "In its relations with the wider world, the Union shall uphold and promote its values and interests and contribute to the protection of its citizens. It shall contribute to peace, security, the sustainable development of the Earth, solidarity and mutual respect among peoples, free and fair trade, eradication of poverty and the protection of human rights, in particular the rights of the child, as well as to the strict observance and the development of international law, including respect for the principles of the United Nations Charter".

260. The Court also attached very great probative weight to the FCTC and to the WHO Guidelines which were intended to assist the contracting parties (which includes all of the Member States and the EU) *"…in implementing the binding provisions of that convention"* (ibid paragraph [111]). These were drawn up on the basis of the very best scientific evidence and reflected an international consensus (ibid paragraph [112]). They were, whilst being non-binding, capable of exerting "*decisive influence*" (ibid paragraph [113]). Elsewhere the Court stated that for all of these reasons the Guidelines must "…*be recognised as being of particularly high evidential value*" (paragraph [175]). It is right to observe that the Court of Justice made these comments in the context of provisions of the TPD which are expressed as mandatory or "binding" under the FCTC whereas the standardised packaging provisions of the FCTC are measures which contracting states are urged and recommended to adopt but which are not stated to be mandatory. This fact does <u>not</u> (as the Claimants have submitted) mean however that the FCTC and WHO Guidelines are now wholly irrelevant. The TPD implements the whole of the FCTC including its mandatory and non-mandatory parts. Indeed Article 24 TPD and all of the myriad references to the TPD being a measure of partial harmonisation are a reflection of the fact that, in accordance with their own international law obligations under the FCTC, Member States of the EU acting in their dual capacities as contracting states of the FCTC might choose to adopt standardised packaging rules which go beyond the TPD and

when they do so they will take into account the FCTC and the WHO Guidelines. To suggest that the FCTC is irrelevant is wrong both under EU law and international law. In my view it might be going too far to say, in relation to non-mandatory parts of the FCTC, that both the FCTC and the WHO Guidelines are "*decisive*", but they nonetheless remain important and relevant as guides to interpretation of the TPD and as to the powers and rights of the Member States to adopt tobacco control measures, including but not limited to standardised packaging measures.

(iii) The threat of an increase in illicit trade

261. I turn now to address a point which arose in the course of submissions which was also raised, albeit lightly, in the written submissions to the High Court, namely the argument that the legislation is unlawful because it will increase illicit trade. With regard to the submission that a ban on menthol cigarettes would increase illicit trade the Advocate General was deeply unimpressed:

> "84. A number of undertakings taking part in the preliminary ruling proceedings object that smuggling will increase and the black market in menthol cigarettes will flourish. However, this is no more than a mere assertion, with little by way of substantiation.
>
> 85. Furthermore, it is also irrelevant whether smuggling and black market trade can be effectively prevented by the measures laid down in the Directive. Instead, the crucial factor is that it will become more difficult for consumers to continue to obtain supplies of menthol cigarettes and other flavoured cigarettes after a prohibition on the placing on the market of tobacco products with characterising flavours has taken effect. This alone justifies the view that such a prohibition cannot fail to help to ensure a high level of health protection. The fact that prohibitions may possibly be circumvented in isolated cases does not in general militate against their appropriateness for attaining the objective pursued".

262. She was equally unimpressed (cf. ibid paragraph [99]) when the same argument was made about the TPD rules on packaging: "*As regards the increase in smuggling and the flourishing of the black market predicted by some parties, I consider that argument to be just as unconvincing in the present context as previously in connection with the prohibition on characterising flavours*". See also her rejection of related arguments about threats to illicit trade at paragraph [182].

263. It can be presumed that the Court adopted the same view because it did not address the Claimants' arguments in this regard.

(iii) The legality of Article 24(2) TPD / the right of Member States to adopt further measures relating to tobacco control, including standardised packaging

264. I turn next to the issue of the scope of the right of Member States to adopt measures relating to the branding and promotional material. As explained above at paragraph [253] the issue of the power or competence of the Member States to adopt legislation such as the Regulations is directly relevant to a number of Grounds of challenge in this case. Question 1(a) posed by the High Court asked whether Article 24(2) was invalid because Article 114 TFEU did not provide a proper legal basis for it. The analysis of the question posed raised questions about the scope of the measure and the relative powers of the EU and the Member States. The Advocate General rejected the submissions of the Claimants that Article 24(2) TPD was unlawful. Her reasons on validity were essentially adopted by the Court. She also set out fully the issue surrounding the proper construction of the right or power conferred upon the Member States under Article 24(2). It is helpful to set out her analysis in full since it reflects the range of relevant arguments:

> "The Member States' right to establish further requirements in relation to the standardisation of the packaging of tobacco products (question 1(a))
>
> 105. First of all, question 1(a) casts doubt on the legal basis for Article 24(2) of the Directive. Under that provision, the Directive does not 'affect the right of a Member State to maintain or introduce further requirements, applicable to all products placed on its market, in relation to the standardisation of the packaging of tobacco products, where it is justified on grounds of public health, taking into account the high level of protection of human health achieved through this Directive. …'
>
> 106. The applicants in the main proceedings and their interveners take the view that that provision cannot be based on Article 114 TFEU because it does not lead to the removal of obstacles to trade, but to the creation of such obstacles. In support of their view, the participating undertakings essentially claim that Article 24(2) of the Directive enables the Member States to undermine the free movement of goods in respect of tobacco products by introducing more stringent rules on packaging than those laid down at Union level.
>
> 107. In this regard, the participating undertakings, like the United Kingdom, Ireland and Norway, adopt a particularly *broad interpretation* of Article 24(2) of the Directive. They presume that under that provision the Member States are to be permitted to impose more stringent requirements on the packaging of tobacco products *in any respect*, regardless of whether or not that aspect of the packaging has been the subject of harmonisation by EU law.
>
> 108. In fact, on such a broad interpretation, Article 24(2) of the Directive could be contrary to the objective of Article 114

TFEU, which is based on improving the functioning of the internal market. On such an interpretation, the Directive would harmonise the requirements for the packaging of tobacco products, but at the same time give Member States the right to continue to derogate from that harmonisation without respecting the conditions and procedures specifically laid down for that purpose under Article 114(4) to (10) TFEU. As BAT aptly puts it, the harmonisation given with one hand would therefore be taken away by the other.

109. However, it would be premature to conclude out of hand, without more in-depth consideration of the subject, that Article 24 of the Directive is incompatible with Article 114 TFEU and could not therefore be adopted on that legal basis. The broad interpretation of Article 24(2) of the Directive adopted by the participating undertakings, the United Kingdom, Ireland and Norway is not the only conceivable approach. In addition, according to established case-law, if secondary EU legislation permits more than one interpretation, its wording must be understood in such a way that it is consistent with primary law and its validity cannot be called into question.

110. It seems to be perfectly possible to interpret Article 24(2) of the Directive in conformity with primary law, in particular ensuring that it is compatible with the legal basis of Article 114 TFEU. It is possible — in accordance with the view taken by the EU institutions taking part in the preliminary ruling proceedings, as well as France and Portugal — to adopt a *narrow interpretation* of Article 24(2) of the Directive and to interpret that provision of the Directive as permitting the Member States to adopt 'further rules' only in so far as the Union legislature itself has not carried out any harmonisation.

111. Such a narrow interpretation of Article 24(2) is also most consistent with the purpose and scheme of Directive 2014/40. Contrary to the view apparently taken by the applicants in the main proceedings and some of their interveners, the Directive does not give rise to full harmonisation, but only partial harmonisation or — in the words of Article 1(b) — it seeks 'to approximate the laws, regulations and administrative provisions of the Member States concerning certain aspects of the labelling and packaging of tobacco products'. This is also suggested by recital 53 in the preamble to the Directive, which states that 'in light of the different degrees of harmonisation achieved', the directive merely 'provides a first set of basic common rules' 'in relation to presentation and the packaging'.

112. It is true that the Directive includes an entire chapter with provisions on the labelling and packaging of tobacco products, ranging from the shape and the minimum content of unit packets to the requirement of (combined) health warnings and

the prohibition of certain misleading statements on product packaging. Contrary to the view taken by a number of the undertakings taking part in the proceedings, there is nevertheless still scope for a wide variety of additional national rules on the labelling and packaging of tobacco products. In particular, it can be inferred from Article 28(2)(a) of the Directive that certain package surfaces are not governed by the Directive and the Commission monitors, among other things, developments at national level.

113. Thus, the Member States remain free, in particular, to lay down their own requirements as to colours of all parts of the packaging which are not reserved for warnings, extending as far as the standardisation of packaging. Colouring is regulated — indirectly — in the Directive at most in so far as Article 13 prohibits tobacco products being given a misleading or deceptively positive presentation.

114. Against this background, the objection raised by some of the undertakings taking part in the preliminary ruling proceedings that a provision based on Article 114 TFEU, like Article 24 of the Directive, could not permit the Member States to adopt *any* more stringent national rules on the labelling and packaging of tobacco products because such matters in their entirety 'fall within the scope of the Directive' is unconvincing. That objection, which is probably fuelled by the fear of some of the undertakings concerned that national rules will be adopted to introduce plain packaging, ignores the fact that even today many aspects of the labelling and packaging of tobacco products are still to be regulated in EU law, not least colouring.

115. If one were to follow the participating undertakings' argument, the partial harmonisation of the Member States' laws, regulations and administrative provisions pursued by Directive 2014/40 would be reinterpreted as full harmonisation. This would be contrary to the broad discretion which the Union legislature enjoys under Article 114 TFEU in selecting the most appropriate method of approximation. The Union legislature is not required, when having recourse to Article 114 TFEU, to decide 'all or nothing' between full harmonisation and no harmonisation at all but may also — as in this case — opt for partial harmonisation.

116. The same conclusion follows, moreover, from the judgments relied on by the applicants in the main proceedings. It is true that in its first judgment on tobacco advertising the Court held a directive based on internal market competences, including on Article 100a of the EC Treaty (now Article 114 TFEU), to be unlawful because it did not contain any provisions on the free movement of products complying with the directive. However, if that passage of the judgment is

read in context, it becomes apparent that the Court certainly did not intend to slam the door on the adoption of directives for the *partial harmonisation* of certain matters. Instead, it expressly recognised that internal market harmonisation measures could contain clauses allowing Member States to adopt stricter measures for the protection of the general interest.

117. Only if the Union legislature were not seeking any free movement for products covered by and complying with a directive is it prevented from having recourse to Article 114 TFEU. In addition, the Union legislature may not permit the Member States to prevent, *on grounds relating to the matters harmonised by the Directive,* the import, sale or consumption of tobacco products which comply with the Directive.

118. That is not the case here, however. First of all, Article 24(1) of the Directive expressly recognises the principle of the free movement of tobacco products which comply with the Directive. Second, Article 24(2) of the Directive, interpreted in the light of recital 53, permits the Member States to introduce 'further requirements … in relation to the standardisation of the packaging' only in so far as there is *no* harmonisation by EU law.

119. Certainly, this kind of partial harmonisation means that products cannot automatically be exported from one Member State to another, even if their labelling and packaging complies with the requirements of the Directive in every respect, as each Member State may impose further requirements for non-harmonised aspects of product packaging. Nevertheless, such partial harmonisation also undeniably offers advantages for the functioning of the internal market, since whilst it does not eliminate all obstacles to trade, it does eliminate some. In the present case, this means, for example, that manufacturers of tobacco products throughout the internal market are able to use cigarette packets which have a uniform basic design and are required to adapt that design to the specificities of their respective national laws, regulations and administrative provisions only in certain details (colours, for example), but no longer in every respect.

120. It is true that those provisions of Article 24(1) and (2) of the Directive and the relevant explanations in recital 53 therefore have primarily a clarificatory function. They explain the operation of the partial harmonisation pursued by the Directive. As is impressively illustrated by the fierce dispute between the parties over the lawfulness of possible national rules on the standardisation of packaging, such clarification can make good sense".

265. The Court rejected the argument that Article 24(2) was invalid. It made clear that under the TPD and Article 24(2) Member States did not have the power to adopt *any* tobacco control measure without limitation since this would risk national laws being inconsistent and colliding with the mandatory provisions of the TPD (paragraph [71]). However, the Court made clear (at paragraph [88]) that the TPD was *"... not intended to interfere with the policies of the Member States concerning the lawfulness of tobacco products as such*". The Member States were fettered only in relation to those "*aspects*" of control of tobacco products which were harmonised by the TPD. Member States could hence: "*... maintain or introduce further requirements only in relation to aspects of the standardisation of the packaging of tobacco products which have not been harmonised by the directive"* (paragraph [73]). In the present case, in the light of this judgment, the Claimants have argued that there is no free-standing right on the part of the Member States to adopt legislation in the field of tobacco control but that it is a right conferred only, in effect, by the good grace of the EU and is a strictly limited and circumscribed right. This argument mischaracterises the judgment of the Court of Justice for the following reasons which flow from general considerations of EU and international law, and from the judgment of the Court:

i) Article 24(2) TPD starts by making clear that the TPD "… *shall not affect the right of a Member State to maintain or introduce further requirements"* in the field. It is drafted in this way because it recognises that the Member States possess *pre-existing rights* to regulate health which emanate from international law (such as the FCTC and TRIPS) but also EU law (See Section D(2) and (3) above and Section G(4)(vi) below).

ii) The TPD implements the FCTC which (in itself and through the WHO Guidelines) actively urges and recommends to contracting states that they adopt measures on presentational standardisation. The TPD reflects the fact that under international law the Member States are urged to go beyond the TPD and introduce other restrictive measures (which would include but not be limited to standardised rules relating to promotion, branding, colour and design of tobacco products). Indeed the Court of Justice expressly recognised this in *Philip Morris* (at paragraph [178]) when it recorded that under Section 1.1 of the WHO Guidelines contracting states were *"...encouraged to implement measures beyond those recommended in the guidelines*".

iii) Paragraph [77] of the judgment expressly confirms that it followed from the general scheme of the TPD that it did not bring about full harmonisation of the rules in "*relation to the manufacture, presentation and sale of tobacco products and related products*". This description of the areas of health concern that were not harmonised makes it clear that it would include rules for standardised presentation of all sorts of packaging and (of relevance to the arguments of the tipping paper manufacturers – See Ground 16, Section T below) related tobacco products. It is quite plain that the aspects of tobacco control referred to in this paragraph fall *within* the legitimate sphere of legislative discretion of the Member States.

iv) Recital 53 to the TPD also makes clear that Member States "*retain the power*" to introduce additional restrictions, e.g. the colour of tobacco products or packaging. The reference to *retaining power* only makes sense as an acknowledgment by the EU legislature that Member States possess pre-

existing powers to regulate health in this area, i.e. that the jurisdiction is not contingent upon a conferral of power by the TPD.

v) Recital 55 of the TPD is also consistent with this conclusion and is very clear in that it states that Member States "…*should remain free to introduce national laws applying to all products placed on its national market for aspects not regulated*" by the TPD. Once again this is an acknowledgement of the pre-existing right of the Member States to regulate all products, which includes the packaging thereof and the products themselves (a conclusion which is also relevant to the arguments of the tipping manufacturers at Ground 16 below).

vi) In paragraph [74] of the Judgment the Court of Justice explained that the purpose of the TPD was only to harmonise "*certain aspects of labelling and packaging*". It followed that the TPD was not intended to: "*harmonise all aspects of the labelling and packaging of those products*". All other "aspects" lay within the pre-existing prerogative of the Member States to legislate upon.

vii) In paragraph [134] of the judgment the Court of Justice described the legislative process which the TPD reflected as one, in substance, of rolling or staged harmonisation. The clear implication behind this statement is that Member States are free to legislate but that the EU will "*in stages*" adopt its own legislation which, upon adoption, will require "…*only the gradual abolition of unilateral measures adopted by the Member States*". This description of the legislative process only makes sense if the Member States enjoy an *a priori* right to legislate.

viii) In paragraph [219] the Court explained that the case concerned an "*area*" (internal market with health implications) which was not the exclusive competence of the EU to legislate in. It was an area of shared competence between the Member States and the EU which was therefore governed by the principle of subsidiarity. The adoption of tobacco control measures (of whatever type) by the Member States was thus entirely lawful under the Treaties.

ix) Finally, whilst the Member States enjoy an independent legislative power, it is not untrammelled. First, it cannot be exercised in a way which is inconsistent with the TPD (cf Judgment paragraph [73]). Second, it would, in accordance with normal principles, not be capable of being exercised in a manner which was otherwise inconsistent with the EU treaties or other superior rights and obligations for example stemming from international law – such as the ECHR.

266. In the light of the above, the argument that the provisions of the Regulations are unlawful because the TPD is unlawful necessarily fails. First, it fails because the TPD is not invalid; but secondly, it fails because even if (*ex hypothesi*) the TPD had been invalid and quashed it would still leave Member States with their pre-existing power and competence to adopt tobacco control rules which were otherwise consistent with ordinary principles of EU and international law.

(iv) The proportionality challenge: Margin of appreciation / precautionary principle / impairment of the essence of fundamental rights

267. So far as proportionality is concerned there are three points of particular significance: First, the general test applied; second, the relevance of the precautionary principle; and third, the way in which the Court approached the issue of the impairment of fundamental rights and whether this was a free standing test or part of the wider proportionality test.

268. **Test of proportionality**: I have already set out above (cf paragraph [255]) that because the challenge was to EU legislation the test applied is not necessarily to be equated with the test that a national Court applies to national law measures. In relation to the various proportionality challenges the Advocate General concluded that the TPD was proportionate. She applied a test of manifest (in)appropriateness upon the basis that it was undeniable that in adopting Directive 2014/40 the Union legislature was faced with "*complex economic, social and political questions*". Consequently, "*the Union legislature had to be allowed a broad discretion in respect of the assessments underlying the Directive, not least with regard to the measures which are best able to achieve the high level of health protection prescribed in the European internal market (Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights), especially since forecasts of future market activity may be reviewed as to their plausibility at most*". The Advocate General identified the ingredients of this test in the following way: "*... that is to say, where it is manifestly inappropriate for attaining the legitimate objectives pursued, goes manifestly beyond what is necessary to achieve those objectives or entails disadvantages which are manifestly disproportionate to its objectives. It is irrelevant, on the other hand, whether the measure adopted in the legislative act is the only conceivable measure or even only the most appropriate*". She addressed the sort of evidence base that was needed for the EU to justify restrictive measures. She observed that the Claimants had adduced scientific material but held that it was "*... immaterial whether the health considerations relating to menthol cigarettes cited by the Union legislature — considerations which seem very plausible to me personally — can be proven with sufficient accuracy in the current state of scientific research.*"(ibid paragraph [156]). The Court held likewise. It rejected in fairly cursory terms all of the various proportionality challenges applying a test of manifest disproportionality. It rejected the submission that the prohibition in Article 18 on distant cross border sales to consumers was disproportionate in broad and sweeping terms (cf paragraphs [131] – [135]); and it did likewise in relation to the proportionality challenge to the mandatory requirement in Article 13(1) that health warnings be standardised on the labelling and outer packaging of tobacco products (cf paragraph [153] – [162]). The argument that the prohibition in Article 7 of the placement on the market of products with flavourings was disproportionate received a little more attention (cf paragraphs [170] – [190]). In all of these instances the Court referred to the breadth of the discretion of the EU legislature, the guidance of the FCTC, and the Guidelines and the signal importance of protecting public health as central themes.

269. **Precautionary principle**: So far as the precautionary principle was concerned the Advocate General was clear that this was an area where the EU was entitled and indeed bound to adopt the precautionary principle (ibid paragraph [157]):

> "...where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists if the risk materialises, the precautionary principle justifies the adoption of restrictive measures, provided those measures are non-discriminatory and objective".

She relied in this regard upon the "*call*" made by the FCTC: "*... the call made within the framework of the WHO to limit or prohibit internationally the use in tobacco products of ingredients which may improve their taste, including the use of menthol is also nothing other than an expression of the precautionary principle*". This was consistent with EU law which demanded a high level of health protection citing Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU and the second sentence of Article 35 of the Fundamental Charter. In these circumstances she emphatically (cf. paragraph [160]) rejected the submission that the TPD ban on menthol cigarettes was manifestly inappropriate for attaining the abovementioned objective and thus for contributing to a high level of health protection in the European internal market. The Court did not explicitly refer to the precautionary principle in terms, but it did refer to the discretion of the EU in terms which are redolent of the precautionary principle. For instance the Court, in rejecting an argument about the lack of evidence of the necessity of the Article 7 TPD prohibition, referred to the FCTC and the Guidelines which recommended that in order to safeguard health the Contracting States should go beyond that specifically recommended in the Guidelines (ibid paragraph [178]) and prohibit ingredients which "*may be used to increase palatability*". In paragraph [158] the Court again spoke in prophylactic terms of the prohibition in Article 13 being justified by the need to "*protect consumers against the risks associated with tobacco use*".

270. **Affecting or impairing the essence of a fundamental right**: An issue addressed by the Court of wider significance to the present case (in particular under Ground 7, Section K below) is the way in which the Court couched the proportionality test where there was a need to balance competing rights protected under the Fundamental Charter. The Claimants argue that the Regulations impair or affect the "*essence*" of their property rights and that as such the proportionality test is irrelevant and the Regulations are illegal because of Article 52 of the Fundamental Charter which (they argue) goes (well) beyond the level of protection provided for in A1P1 ECHR and renders illegal <u>any</u> interference with the essence of a fundamental right. I address this fully at Section K below. The Claimants have in this regard referred not only to the judgment in *Philip Morris* but also to the related case brought by a manufacturer of e-cigarettes who complained about the restrictions on advertising and promotion contained in Article 20 TPD: Case C-477/14 *Pillbox 38(UK) Ltd v Secretary of State for Health* (4th May 2016) (*Pillbox*). It is therefore relevant to consider both *Philip Morris* and *Pillbox*. In *Philip Morris* the Court rejected the submission that the TPD exerted <u>any</u> affect upon the essence of the right to property in Article 17, even though the Court accepted that the right <u>had</u> in fact been interfered with: see paragraphs [151] and [148]. The Court has thus made very clear that an effect or impairment of the "*essence*" of a right is not to be equated with a mere interference of the right. The Court did not, however, explain or even address how that analysis was to be conducted and whether it was separate from or part of the overall proportionality

analysis. On one view it appears that the Court treated the two evaluations as discrete. However, in *Pillbox* the Court did conduct a more detailed analysis. In that case the Claimants argued that the restrictions in Article 20 TPD violated Articles 16 and 17 of the Fundamental Charter (on the right to conduct business and the right to property). The Court rejected emphatically both contentions. The approach of the Court is significant because it stated that the implications of Article 52 of the Fundamental Charter, which includes the requirement that the essence of a fundamental right be respected, were matters that had to be implemented or applied within the test of proportionality: See *Pillbox* (ibid) paragraph [159]. Furthermore, the Court was dismissive of the suggestion that the essence of either the right to conduct a business or the right to property had even been affected by the TPD: see paragraphs [156] – [165]. In coming to this conclusion the Court took account of the limitation inherent in the asserted rights themselves. For instance in relation to the Article 16 right to conduct a business the Court observed (cf paragraphs [157] and [158]) that it had to be "*examined in the light of its function in society*", and was *"… subject to a broad range of interventions on the part of public authorities which may limit the exercise of economic activity in the public interest*".

(v) The fourth limb of the proportionality test: proportionality stricto sensu / fair balance

271. The Advocate General addressed "*proportionality in the strict sense*" (cf. paragraphs [176ff]) and the specific complaint that the TPD (in prohibiting menthol cigarettes) imposed severe hardship on the tobacco companies and even tobacco farmers. In an important part of her opinion she proceeded to balance the private interests at stake with the public interests. As to this she was of a firm view that the public health interest far outweighed the private, commercial, interests of the tobacco companies:

> "178. From a substantive point of view, the disappearance of menthol cigarettes from the market as a result of the prohibition under EU law on the marketing of tobacco products with characterising flavours may temporarily have negative effects on the economic situation of some farmers engaged in tobacco cultivation, some suppliers to the tobacco industry and some undertakings engaged in the manufacture and marketing of tobacco products, even including some job losses.
>
> 179. It should be borne in mind, however, that the protection of human health has considerably greater importance in the value system under EU law than such essentially economic interests (see Articles 9 TFEU, 114(3) TFEU and 168(1) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights), with the result that health protection may justify even substantial negative economic consequences for certain economic operators.
>
> 180. Moreover, the fact that the prohibition on menthol cigarettes will possibly hit some undertakings, or even whole industry sectors in certain Member States, harder than other undertakings or other Member States' economies does not make the prohibition of characterising flavours under the

> Directive disproportionate. In view of the differences in the Member States' economic structures, it is almost impossible to think of a case in which an EU legislative act affects all undertakings and all Member States in exactly the same way. As the EU institutions taking part in the proceedings before the Court rightly state, the approximation of laws in the European internal market would be rendered largely meaningless if it could occur only where largely similar conditions already exist in any case in all the Member States and between all undertakings concerned.
>
> 181. Aside from this, any economic and social hardships that may be associated with the prohibition on menthol cigarettes are attenuated by the generous transitional period up to 20 May 2020, a period of four years in addition to the period for transposition of the Directive. With regard specifically to the farmers concerned, they may also possibly receive income support under the common agricultural policy".

272. The Court did not refer explicitly to this test in so many words, but did so implicitly in paragraph [154] when addressing the need to balance the interference with the tobacco companies' Article 11 Fundamental Charter rights to freedom of expression and information with the competing right to public health. The Court of Justice concluded that the prohibitions in Article 13 TPD (on disseminating accurate and truthful information) were justified by overriding public health interests and thus a "*fair balance*" had been struck. The Court cited in this regard Case C-157/14 *Neptune Distribution* (17th December 2015) at paragraph [75] where the Court stated (in the context of a dispute about a Regulation requiring controls on the information that could be placed on bottled mineral water) that where public health interests collided with other fundamental rights (such as those under Articles 11 or 16) then a "*fair balance*" had to be struck. The Court then went on to state in that case that in striking this balance the precautionary principle was important (see ibid paragraph [82]).

(vi) Subsidiarity

273. The scope and effect of subsidiarity in relation to Article 114 was considered. The EU is governed by two fundamental principles one of which is subsidiarity, under Article 5(3) TFEU. Article 5 governs competence, conferral, proportionality and subsidiarity:

> "Article 5
>
> 1. The limits of Union competences are governed by the principle of conferral. The use of Union competences is governed by the principles of subsidiarity and proportionality.
>
> 2. Under the principle of conferral, the Union shall act only within the limits of the competences conferred upon it by the Member States in the Treaties to attain the objectives set out therein. Competences not conferred upon the Union in the Treaties remain with the Member States.

> 3. Under the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level. The institutions of the Union shall apply the principle of subsidiarity as laid down in the Protocol on the application of the principles of subsidiarity and proportionality. National Parliaments ensure compliance with the principle of subsidiarity in accordance with the procedure set out in that Protocol.
>
> 4. Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties. The institutions of the Union shall apply the principle of proportionality as laid down in the Protocol on the application of the principles of subsidiarity and proportionality".

274. The Claimants argued that the TPD as a whole and in particular Articles 7, 8(3), 9(3) and 10(1)(g) and Articles 13 and 14, were invalid for failure to comply with the principle of subsidiarity. The Advocate General observed that the EU did not have the exclusive competence to regulate the internal market which fell within the area of shared competences between the Union and its Member States (under Article 4(2)(a) TFEU). The principle of subsidiarity therefore applied to harmonisation measures pursuant to Article 114 TFEU, which included the TPD. Compliance with the principle of subsidiarity was subject to legal review by the Courts of the European Union. That review covered two aspects in particular: first, the substantive compatibility of EU measures with the principle of subsidiarity and, second, their statement of reasons in the light of the principle of subsidiarity. As to substantive compatibility there were two aspects of the test to consider. First, the EU institutions had to satisfy themselves that they were acting only if and in so far as the objectives of the proposed action could not be sufficiently achieved by the Member States (*the negative component* of the test). Secondly, action by the Union was permissible only if and in so far as the objectives of the proposed action could, by reason of the scale or effects of the proposed action, be better achieved at Union level (*the positive component* of the test). These two components of the subsidiarity test ultimately addressed a single question from two different angles, namely whether action should be taken at Union level or at national level in order to achieve the envisaged objectives. The Advocate General was critical of the Claimants' substantive arguments concluding that they were so vague that they did not in principle warrant any review by the Court: "*... their statements are largely so general that even on a favourable reading they lack the necessary substantiation for a review by the Court*." (ibid paragraph [276]). Nonetheless, the Advocate General conducted the subsidiarity review but in relation to the TPD as a whole. She rejected the submission that the Court should examine each provision of the TPD separately (for instance in relation to the prohibition on menthol cigarettes). She was of the opinion that each individual measure was part of a wider, composite, whole which was justified by an overarching policy objective, namely the protection and improvement of public health. In relation to the Claimants' specific argument that the protection of health could be better protected at the national level she concluded that neither the TPD in general nor the specific prohibition on menthol cigarettes was introduced purely on public health grounds. Rather, the aim was to remove obstacles to trade for tobacco products whilst

at the same time ensuring a high level of health protection. The prohibition on all characterising flavours was the price that had to be paid for the circulation of tobacco products in the internal market whilst at the same time ensuring a high level of health protection. Both objectives were closely connected and interrelated. Where a directive simultaneously pursued two interdependent objectives those objectives had to be construed together in the subsidiarity test. The Court agreed with the Advocate General and, on the facts, held that the TPD complied fully with the principle. The analysis was quite brief. The Court relied upon the overall desirability of the establishment of a uniform set of rules for establishing an internal market (see paragraphs [219]-[224]) and a conclusionary statement that the proposal for the directive and the impact assessment contained sufficient information and evidence to justify the measures being taken at the EU level.

(4) Conclusions

275. The following summarises the main points emerging from the judgment in *Philip Morris* which are relevant to the issues arising in this judgment:

i) The TPD and Article 24(2) thereof are valid. The area of tobacco control is an issue relating to the internal market and public health and forms an area of shared competence between the EU and the Member States.

ii) The FCTC and the recommendations in the WHO Guidelines are evidence based and reflect a wide international consensus. The TPD is intended to implement the FCTC and in this regard the WHO Guidelines are, whilst not binding, nonetheless of very great probative value in interpreting the TPD.

iii) Member States have a pre-existing right and competence to adopt legislation in the field of tobacco control. They may exercise this jurisdiction subject to (i) general principles of EU law and (ii) ensuring that such national measures do not conflict with the harmonised measures in the area adopted by the EU.

iv) It follows that the Claimants' challenge to the Regulations based upon the alleged invalidity of the TPD fails.

F. GROUND 2: THE "LIMITED" WEIGHT ATTACHED TO THE CLAIMANTS' EVIDENCE

(1) The issue

276. The Claimants contend that the Regulations are unlawful because generally only "*limited*" weight was accorded to the Claimants' evidence submitted during the consultation exercise. This was an argument advanced primarily by BAT in relation to its own evidence but the general thrust of the submission was adopted by all the Claimants. There is a closely related but subsidiary aspect to the ground raised only by BAT which is that *its* own evidence (i.e. irrespective of whether the Court rejected the submission in relation to the generality of the tobacco company evidence), and especially its expert evidence, was not accorded proper or fair weight. In respect of both the primary general argument and the secondary specific argument the Claimants contend that their evidence was of the very highest quality and integrity and demanded to be accorded great weight. The issue arises because the Defendant's

Chief economist, Mr Derbyshire, stated in evidence that "*limited weight*" was attached to the expert evidence of the Claimants during the consultation exercise because it, in effect, fell short of methodological best practice.

277. This stance is thus a discrete ground of challenge in these proceedings relating to the legality of the consultation process. But the point *also* resonates in the context of the other freestanding grounds which involve a consideration of the Claimants' evidence such as proportionality and in the context of alleged violations of property rights. Professor Hammond, an expert instructed on behalf of the Secretary of State, conducted a comprehensive analysis of the expert evidence tendered by the Claimants both during the consultation and for the purposes of the litigation from the perspective of adherence to methodological best practice. His conclusions are that in myriad and material ways the evidence falls short and as such was not and is not entitled to be accorded significant weight. He attacks the Claimants' experts for, *inter alia*: lacking independence; failing to peer review their work or rely upon the peer reviewed and/or independent research work of others; ignoring the weight of pre-existing research on the topic; failing to benchmark or verify their conclusions against the internal documents generated by the tobacco companies; and, setting up impossibly high and unrealistic standards against which to measure the justifications for the Regulations.

278. The Claimants have retaliated. They have launched an attack upon the independence of the experts relied upon by the Secretary of State complaining that they are biased because they adhere to the "*tobacco control*" lobby and, for instance in relation to Professor Hammond, accept substantial research grant money from tobacco control interests. In their written submissions on proportionality in relation to the Pechey Elicitation review (see paragraphs [139] – [142] above) they refer to: "*The Pechey Study, which consisted of asking 33 anonymous (but far from impartial) "experts" in anti-tobacco research for their "best guess estimates" of the likely impact of standardised packaging over a two year period from which an average prediction was calculated (the "Pechey Estimate")*". The Claimants have also adduced expert opinion evidence which attacks the methodological "best practice" rules for research that are held up as the appropriate benchmark by the Secretary of State. For instance, they put forward expert opinion evidence from a Professor Klick which, if correct, suggests that, more or less, the total evidence base generated over the past few decades by scientists and researchers (worldwide) on the issue of the effect of advertising and promotion on the behavioural patterns of actual and potential tobacco consumers is wrongheaded, irrelevant and based upon flawed thinking and techniques.

279. The issue is thus live and hotly contested. I address it below (a) in order to analyse the specific (BAT led) complaint about the consultation process but also (b) because it is important in analysing the Claimants' evidence on other grounds.

280. The question of the intrinsic quality of the evidence is a fundamental one, not least because of Article 5(3) FCTC and the WHO guidelines (see paragraphs [168] – [175] above) to the effect that the tobacco industry should be treated as having adopted a deliberate policy of subverting public health policy through, *inter alia*, the deployment of its substantial capital and organisational resources to generate evidence designed to contradict the established policy consensus. The premise behind Article 5(3) FCTC is that, to put the point in an unvarnished form, this evidence is unreliable, i.e. false.

281. The present litigation has thrown into sharp relief all of these controversies and the issue for this Court is how they translate into practical rules of evidence which can be applied to the facts of this case. The legal framework for this ground takes as one point of reference Article 5(3) FCTC and the WHO guidance. But it also engages (i) with ordinary common law principles of evidence and how a Court, in the context of a judicial review, should evaluate expert and other evidence; and (ii) with the effect of CPR 35 on expert evidence.

(2) The basic methodological principles

282. I start by setting out the basic methodological principles which the Secretary of State put forward as, in effect, internationally recognised best practice and which he submits should be used in the evaluation of the evidence in this case. He cites numerous literature sources for these principles and, moreover, characterise them as common sense quality controls to be applied during a consultation but also during Court proceedings.

(i) Independence & bias / conflict of interest

283. The importance of independence is obvious: a researcher who has no affiliation which could give rise to a conflict of interest is less likely to be subject to bias. Independence can be compromised by any sort of financial relationship with a person or party who seeks a particular result. This can extend from the provision of research funding to fees for the preparation of expert reports. But bias can arise from less overt and far more subtle sources. So for instance academics have long recognised the concept of "confirmation bias" which is said to arise when a decision maker seeks only to collect or give credit to evidence which leads to (the confirmation of) a particular preferred result. Such confirmation bias can be subconscious; it need not indicate a deliberate intent to distort an evidence collection or decision making process. It is sometimes said to arise as a risk when an administrative decision is quashed by a Court and remitted to a decision maker to be retaken; in such circumstances there is a risk that the decision maker will set out with determination to take the same decision again but this time curing the defect that led to the adverse judicial decision. In an appropriate case good administration can mean that a new team of officials is instructed to take the remitted decision with a clear instruction to apply a fresh mind to the issue.

284. Independence is not an absolute requirement; in normal litigation where expert evidence is required experts are instructed by parties and they may be very well paid to present an opinion to the Court. The quality of that evidence cannot be automatically discounted simply because it is advanced on behalf of those who are *parti pris*. The same will apply to evidence submitted in the course of a consultative process. Consultees advance their point of view and frequently support that with expert evidence. Expert opinion evidence is thus submitted in a multiplicity of different circumstances ranging from consultations through regulatory proceedings to litigation. A common question therefore is how such opinion evidence is to be evaluated especially given that in the context of scientific and technical research (much of which is conducted by academics with no compromising affiliations) a premium is placed upon independence.

285. The problems associated with a lack of independence can be overcome. Where there is full disclosure of the facts giving rise to the actual or perceived lack of independence those who subsequently come to read or rely upon the research output can evaluate the research through the optic of possible bias and predisposition. The more acute the possible bias the more extensive might need to be the extent of the disclosure. A researcher who receives a research grant from an interested party which served only to defray research costs may be in a different position to an individual who stands personally to gain through the receipt of a substantial fee. Disclosure of the nature and extent of the interest may therefore be important but it is not a complete answer. Sometimes the expert evidence might concern a subject matter which is of great complexity and which is, thereby, exceedingly difficult for a Court or decision maker to unravel so that the mere fact that the author has declared an interest does not equip a reader with the tools needed to determine whether *in actual fact* the research output is affected or distorted by that declared interest. This is certainly true of the research which is before this Court, whether it derives from pre-existing literature sources or from the new research conducted by experts instructed by the parties, such as the regression analyses. In the present case both sides accuse the other of bias or predisposition. Chantler rejected the suggestion that tobacco control experts were biased as "*absurd*" (Chantler Report paragraph [6.9]; see paragraph [113] above). In my view I would not wholly dismiss the proposition that tobacco control experts might, albeit subconsciously, feel so strongly about the correctness of their cause that their opinion might be influenced by that view. It is for this reason that whilst independence is a relevant factor it is not necessarily the determinative factor and adherence *to other* quality control practices such as peer review and/or benchmarking against internal documents can play an important and possibly crucial role in providing the guarantee that the research output is of the highest quality.

286. The conclusion that I have arrived at about bias is not dissimilar to the observations of Judge Kessler in the *US Judgment* (ibid at pages [7] – [9]). She concluded:

> "Much of the Defendants' criticisms of Government witnesses focused on the fact that these witnesses had been long-time, devoted members of "the public health community." To suggest that they were presenting inaccurate, untruthful, or unreliable testimony because they had spent their professional lives trying to improve the public health of this country is patently absurd. It is equivalent to arguing that all the Defendants' witnesses were biased, inaccurate, untruthful, and unreliable because the great majority of them had earned enormous amounts of money working and/or consulting for Defendants and other large corporations, and therefore were so devoted to the cause of corporate America that nothing they testified to, even though presented under oath in a court of law, should be believed. Such simplistic attacks on the credibility of the sophisticated and knowledgeable witnesses who testified in this case are foolish.
>
> All of this is not to deny that there were significant differences in the overall qualifications of the Government's witnesses and

> the Defendants' witnesses. There were. The Government's witnesses, viewed as a whole, were far more experienced, credentialed, and active in the area of smoking and health, whatever their particular area of specialty, than were the Defendants'. Many of the Government experts had participated extensively, over many years, in the long and drawn-out process of ascertaining the consensus of scientific opinions embodied in each Surgeon General's Report. Virtually every one had taught at a well-regarded academic institution and written numerous peer-reviewed articles in their particular area of specialty. Many of the Government witnesses continued "hands on," clinical work in their fields despite heavy commitments for research, writing, teaching, and lecturing to their peers.
>
> The Defendants' witnesses were obviously well educated in their areas of specialty. Indeed, as was mentioned on many occasions, Defendants even presented the testimony of an impressive Nobel Prize winner. However, rarely did these witnesses have the depth and breadth of experience of the Government witnesses. Many had worked only in large corporations, and many for only one or two such employers. Many -- although not all -- had written relatively few peer-reviewed articles. Many of the highest paid experts of Defendants, while well credentialed in their particular fields, such as economics, presented relatively narrow testimony tailored to the particular problem or issue they were retained to opine on for purposes of this litigation. A few of Defendants' experts had done virtually no individual research and written virtually no peer-reviewed articles, and a few were unfamiliar with the relevant facts and/or the major scientific literature on the issue about which they testified.
>
> While the testimony of each person -- expert or fact witness -- was evaluated on its own merits, there can be no denying that, as a group, the Government's witnesses were far more knowledgeable, experienced, and active in their respective fields".

(ii) Peer review

287. Peer review is the process by which an authored work is submitted to the scrutiny of others for constructive criticism. It is a process of intellectual democratisation whereby anyone can access the research and evaluate it. Not infrequently a previously unknown researcher or Ph.D student emerges from a non-mainstream academic institution who manages to puncture the previous orthodoxy and thereby contribute to the debate. The underlying premise is that "*sunlight bleaches*" - by exposing research results to scrutiny their strengths and deficiencies are highlighted and this not only enables the original researchers to go back and improve the work but it also enables other researchers to build on the peer reviewed platform. The process of peer review is routine in the editorial practices of the better scientific and technical

publications. Material that is not peer reviewed will not by definition be of inferior quality but since the practice of peer review is so widespread an absence of peer review may be a legitimate reason for querying the integrity of that research; and even more so if it is deliberately not peer reviewed. The advantages of peer review are obvious: it imposes upon researchers an incentive to ensure that their material is intellectually and evidentially robust; it enables proposals for publication to be criticised and thereby improved; and it ensures that as thinking on an issue evolves it does so with the weight of academic and scientific opinion in support. It is a process which enables concerns relating to an absence of independence to be mitigated. The advantages can be seen by considering how research results would evolve without the process. It would mean that errors or weaknesses or bias in original research risk not being identified and there is correspondingly diminished incentive for researchers to get it right first time around. If research that has not been peer reviewed is then used as a platform for subsequent researchers to build upon it can lead to errors being self-perpetuated. Mr Derbyshire, for the Secretary of State, put the point in the following way:

> "...the degree to which the data used and the analyses of it has been independently or widely scrutinised should be considered. Such consideration helps counteract the conflict of interest issues referred to above. The analyst or decision-maker is able to place greater weight on data and analysis that describes transparently what work has been done and any issues arising (such as conflicts), has been peer reviewed and has been published for critique by a wider audience. Wider scrutiny can help ensure all analysis is being considered and there is not selective reporting of favourable findings and non-reporting of unfavourable results. Such scrutinised analysis is more informative than a non-peer-reviewed, opaque analysis seen only by a few people".

288. The Claimants reject this analysis. They submit that the fact that their evidence is exposed in litigation and subject to judicial review is a superior process to peer review. I fundamentally disagree. I have, in this litigation, had the opportunity to test the proposition thoroughly. I set out my conclusions in relation to Ground 3 and as to the sort of process that would have to occur to enable a Court adequately to resolve disputes of this type at paragraphs [630] – [648] below. Courts do not have the time or resources to take research away and then spend months unpicking and reverse engineering it so that it can be re-performed using different and improved assumptions, even assuming that the Court has the technical ability to do so. In judicial review the argument might not even focus upon the actual nuts and bolts merits as opposed to issues such as margin of appreciation. In the present case nearly 30 expert reports have been tendered and relied upon, predominantly from the Claimants. For the most part the evidence was simply used in written submissions and as cross references in footnotes to the written submissions and only a modest proportion was in actual fact highlighted during the course of oral argument. These reports however cover an enormous array of different issues and many seek to build upon prior research a significant portion (but not all) of which is not peer reviewed or from independent researchers. It is an almost impossible task for a Court in such circumstances to assess the accuracy of the entirety of a vast body of evidence such as

this. In fact this case serves to highlight the importance of the Court having available to it methodological tools, such as research best practice guidelines and principles, with which to assess the evidence.

289. I give below one illustration of how the process of peer review can result in an iterative and incremental perfection of results. This is found in the exchange between the parties as to the relative reliability of different data sources. In his first report Professor Mulligan (for the Claimants) was critical of the 2014 Impact Assessment for failing to consider data sources that measured smoking prevalence frequently enough to permit a valid comparison of rates of prevalence immediately prior to, and following, the introduction of standardised packaging in Australia. Professor Mulligan relied, in particular, upon two pieces of research by Messrs. Kaul & Wolf[8] ("Kaul & Wolf"). There is evidence that this research was funded by the tobacco industry. In this research the authors sought evidence of an effect brought about by standardised packaging upon smoking prevalence in Australia and found none. Professor Mulligan points out that the researchers modelled the trend of smoking prevalence in Australia prior to introduction of standardised packaging and considered the degree to which prevalence fell faster than that trend following standardised packaging. Professor Mulligan attributed substantial weight to the Kaul & Wolf Reports. He rejected the criticisms made of that work in the 2014 Impact Assessment for an alleged lack of statistical "power". Professor Mulligan pointed out that Kaul & Wolf did not control for changes in cigarette prices and accordingly even if standardised packaging had exerted no impact upon prevalence one would then have expected Kaul & Wolf to observe a decrease in prevalence beyond trend but since they observed no decrease beyond trend at all this suggested that standardised packaging had an, unanticipated, upward effect upon smoking prevalence.

290. In his second report Professor Mulligan returned to this theme. He, once again, relied upon Kaul & Wolf to undermine the data sources relied upon in the 2014 Impact Assessment. Other experts instructed by the Claimants also relied upon this same research.

291. Kaul & Wolf have, however, subsequently been peer reviewed by Diethelm & Farley. These researchers were critical of the conclusions arrived at by Kaul & Wolf. They sought to re-work the data relied upon and concluded that, properly understood, it demonstrated the opposite conclusion to that arrived at by Kaul & Wolf. The episode demonstrates the importance of peer review. It is especially important if a vested interest seeks to rely, and build upon, research that it has funded because rigorous peer review minimises the risk that non-independent research results are perpetrated by other non-peer reviewed researchers with the consequence that a growing body of un-reviewed research gains traction. I have subjected this particular episode to more detailed substantive analysis at paragraphs [619] – [624] below. Ms Demetriou QC, in her closing submissions, then subjected Diethelm & Farley to her own forensic criticism. No doubt, other (independent) researchers may take the work of Diethelm & Farley and subject it to additional review and over time the process of peer review might result in a perfected analysis. If, at the end of the day, it is established that the

[8] Kaul A and Wolf M "The (Possible) Effect of Plain Packaging on the Smoking Prevalence of Minors in Australia: a Trend Analysis", University of Zurich, May 2014; and, Kaul A and Wolf M "The (Possible) Effect of Plain Packaging of Smoking Prevalence in Australia: a Trend Analysis", University of Zurich, 1st June 2014.

data relied upon initially by Kaul & Wolf disproves the proposition the Claimants seek to assert then it will do no more than demonstrate the critical importance of a proper peer review process being applied to *precisely* the sorts of evidence which are in issue in this case. I am not (remotely) in a position to decide who is right and who is wrong. I can, however, conclude from this that the process of peer review is an important one with serious implications for the issues arising in the present litigation.

(iii) Internal documents: The need for corroboration and benchmarking of expert evidence

292. I turn next to the importance of being able to benchmark the Claimants' expert opinions against internal documents generated by the Claimants themselves. It has been a striking feature of the evidence adduced by the tobacco companies during the consultation process (and replicated in the Court proceedings) that it is virtually devoid of any reference to the internal documents of the tobacco companies themselves. This has been the subject of litigation in the US. It was one of the prime reasons why in the FCTC the WHO expressed such profound scepticism at the motives of the tobacco companies and as to the reliability of their evidence. Chantler, in his Report, commented adversely upon the fact that the tobacco companies criticised the evidence base relied upon by the tobacco control lobby (which evidence Chantler accepted) but declined to produce the internal focus reports and other analysis which he considered undoubtedly existed. One of the reasons given by the Defendant for attributing limited weight to the Claimants' expert reports was precisely because of an inability to have confidence in the data and facts which underlay the assumptions and conclusions in the Claimants' expert evidence and the concern that the outward (expert-led) views of the Claimants would be contradicted or qualified by their internal documents. Mr Derbyshire, the Department of Health Chief Economist and Analyst, explained in evidence to the Court that whilst some of the primary data used by the Claimants' experts was available to the Department much was not. As such some of the expert analysis submitted was simply not verifiable.

293. BAT however complained specifically that the Department did not have access to every data source that it should have had access to when the Minister decided to lay draft Regulations before Parliament. In a sector and market where there is a systemic concern about the reliability of data and research submitted by the tobacco industry if those companies and parties do not *ensure*, when *they* place research before a decision maker, that *their* research is *fully* verifiable including, where necessary, disclosure of underlying internal documents (for and against), then this is a factor that the decision maker is entitled to take account of when weighing and evaluating that evidence. If that minimum standard is not adhered to then it cannot subsequently be complained that the decision maker failed to obtain access to all the underlying data and information sources. There is an onus on consultees as well as upon the decision maker. If a consultee provides fully and comprehensively its research and everything underpinning it which would enable it to be checked and verified then the objection that the decision maker has failed to perform a verification (since if it had it would then have attributed greater weight to the evidence) might carry greater conviction; but if a consultee chooses not to do this then a complaint made later that the decision maker erred in not obtaining more data may ring hollow.

(iv) Internal documents: Tobacco companies' statements to the High Court

294. In response to my repeated questions to the tobacco companies during the hearing (and in view of the Secretary of State's sustained criticism of the Claimants' evidence) as to the nature and extent of their internal assessment of the issues arising, JTI and PMI (only) produced carefully crafted written statements.

295. JTI stated that it had not conducted research on whether the introduction of standardised packaging in the UK would or would likely discourage children in the UK from taking up smoking. It stated also that this was in conformity with its "global position". I set out verbatim JTI's position to the Court:

> "(a) JTI does not market its products to minors;
>
> (b) JTI does not market its products in order to encourage anyone to take up smoking or to discourage anyone from quitting;
>
> (c) JTI does not conduct market research involving or in relation to minors;
>
> (d) JTI has no interest in information about minor's consumption of tobacco products; and
>
> (e) JTI does not seek, collect or accept marketing data about minors, or analyse general data to learn about minors".

296. I find this statement remarkable. The evidence from the Secretary of State (which is not disputed by the Claimants and indeed was reflected in the evidence of JTI's own experts[9]) is that the vast majority of smokers take up smoking before they are in their early 20s and most before they are 18 years of age. Youth smoking is critical to the future of the tobacco companies. 600 children per day between the ages of 11 and 15 start smoking in the United Kingdom (see paragraph [63] above). Children can quickly become addicted. These children become the long term customers of the future and then replenish the customer base depleted by adult quitters. Yet, JTI states as a component part of its global strategy and as a specific reason for not having internal documents: *"JTI has no interest in information about minor's consumption of tobacco products"*. How, rhetorically one asks, can JTI have "*no interest*" in information about consumption of tobacco by children? Growth in sales depends upon the advent of youth smoking which is an enormous social and future health problem. And what sort of Nelsonian knowledge is reflected in the global strategy of a company that is not only disinterested but also refuses to even "*accept*" (see paragraph (e) of the JTI position (*supra*)) marketing data about children and which has no interest in even *learning* about children?

297. In relation to this formal statement the Secretary of State expresses profound scepticism. He submitted: (i) that these statements were not supported by statements

[9] Professor Steinberg considered whether the take up of smoking by adolescents would be impacted upon by standardised packaging. He stated that it was "*widely acknowledged*" that most smokers begin smoking before the age of 18 and he accepted that it made sense for the Government to focus its policy on deterring the advent of youth smoking.

of truth and witness statements from senior management (though a short statement was provided during the hearing); (ii) that no other tobacco company claimed to lack internal documents of this type; (iii) and that the statements were in any event inconsistent with statements made elsewhere in JTI's submissions that it "*continuously conducts analysis in respect of brand equity and downtrading ... based on the current package of its brands in the UK*". From this the Secretary of State submitted that even if this statement in JTI's submissions reflected the full extent of the internal research conducted by JTI it inevitably follows that JTI did in fact hold relevant internal documentation about the impact of its current packaging on smoking habits, which is a very relevant issue; and also, by applying the same logic, it must have carried out analysis in respect of the impact of its current packaging (which is plain packaging) in Australia. The statement is also inconsistent with the findings of fact made by Judge Kessler about the parties in that case in the *US Judgment*.

298. PMI was the other Claimant company to submit a statement of its position. It accepted that it was a matter of record that although prevalence and consumption had been declining for years its profits had been increasing. It submitted: "*What matters for PMI is its market share and profit margin; not aggregate consumption or prevalence*". PMI set out the following written statement during the hearing:

> "As far as those instructing us and our solicitors are aware, neither the PMI Claimants nor the Australian business of the Philip Morris international, Inc group has conducted any detailed assessment of the impact of SP in Australia on prevalence or consumption. Nor did PMI produce any business plan or other documents which carried out a detailed assessment of the predicted impact of SP on prevalence and consumptions in the UK. Indeed PMI does not generally conduct analysis of the impact of regulatory measures on prevalence or consumption. Its analyses are directed towards the performance of its own brands".

299. I confess to also finding this statement perplexing. It amounts to a statement that in relation to fundamental aspects of PMI's business, which is one of the most highly regulated in the world, it does not conduct any "*detailed"* (whatever that term means) research or analysis *at all*. If PMI did not perform this sort of work in-house in relation to Australia and the UK, the first two states worldwide to introduce legislation, then there has to be a reason why not. PMI objects elsewhere to the Regulations because they amount to an "… *unprecedented and radical curtailment of [PMI's] intellectual property rights (and the billions of pounds of damage that will ensue*)" – yet they say that they do not "*generally*" (again – whatever that term means) conduct any internal assessment of this unprecedented and radical threat to the business? It is hard to conceive of any international company turning quite so deliberately away from analysing this sort of fundamental threat, unless there was a compelling strategic justification, namely the fear that such internal analysis and evaluation might, in due course, in regulatory or judicial proceedings, be exposed to critical scrutiny. This brings me to the position of the WHO to the internal documents of the tobacco companies.

(v) Internal documents: The WHO conclusions on the state of the internal documentation of the tobacco companies

300. World Health Organisation Assembly Resolution 54.18 (2001) called on WHO to continue to inform Member States of the activities of the tobacco industry that had a negative impact upon tobacco control efforts. In furtherance of this Resolution WHO produced a document entitled: "*The Documents: What they are; what they tell us: and how to search them – A practical Manual*" (the "*WHO Manual*") which explained how to search the vast number of tobacco company documents which had been made public following litigation in the US. The documents are held in various online accessible archives in the US and the UK and now amount to about 50 million pages, though of course the percentage of relevant documents is only a tiny fraction of this total. The archiving process started in 1998 when about six million documents from seven manufacturers doing business in the US became available to the public as a result of legal action. There were documents from 7 cigarette manufacturers and two affiliated organisations: Philip Morris Incorporated, R.J. Reynolds Tobacco Company, Brown & Williamson Tobacco Corporation, British American Tobacco Industries, Lorillard Tobacco Company, the American Tobacco Company, the Liggett Group, and the Tobacco Institute and the Council for Tobacco Research. The documents include letters, fax, memos and other notes written by company scientists, consultants, lawyers, top executives, other employees and outside organizations and amounted to over 35 million pages. In 2002 the WHO Regional Office for the Eastern Mediterranean published the first edition of the WHO Manual with the aim of helping journalists, public health professionals and advocates, government officials and the public to search the documents and thereby expand their use outside academia. The WHO Tobacco Free Initiative subsequently published a second edition of the manual. The Manual provides lists of research literature into the documents as of July 2004.

301. The WHO sets out its conclusions on a range of issues. A number are relevant to this litigation. Of particular significance are those on the following topics: (a) the advertising policies of tobacco companies; (b) the extent to which tobacco companies conduct research into the psychology of smokers in order to enable them better to target their advertising; (c) the strategies adopted by tobacco companies toward the creation of sensitive documents and document retention; and (d), the tactics deployed by tobacco companies to circumvent regulatory or judicial processes.

302. In relation to advertising, and in particular advertising towards children, WHO addressed the claim made generally by the tobacco companies, and repeated in the present litigation, that the tobacco companies do not advertise to children. WHO rejected the claim:

> "5. Advertising, promotion and other ways of marketing cigarettes
>
> Tobacco companies and their public relations firms have always insisted that advertising does not cause non-smokers to take up the habit, but is intended to get those already smoking to switch brands. And the companies deny vigorously that they ever marketed to children. The documents reveal the complete opposite to be true. The marketing experts in the tobacco companies knew the essential arithmetic: current smokers quit

> or die; therefore new smokers are always needed. Since the majority of adult smokers begin in their teenage years, this is the group that had to be targeted by advertising and promotions. The tobacco companies have created "children shouldn't smoke until they are adults" campaigns around the world, without ever mentioning the health reasons for not smoking. Internal company documents show these campaigns to be a public relations effort to deflect the severe criticism against the industry for such successful promotions as those using the Joe Camel character, which may have hooked millions of teenagers into smoking. Also, the companies believe that such campaigns will lessen the number of laws restricting sales and marketing to young people.
>
> The documents confirm that women are especially targeted for cigarette marketing around the world because at the moment they tend to smoke less than men. The documents show how tobacco marketing uses images of liberation, equality ("You've come a long way baby" was one slogan used), slimness, health, vigour and good times to appeal to women, especially with cigarettes identified as "women's" brands. The manufacturers of "thin" or "slim" women's cigarettes marketed to women understood that per unit of tobacco such cigarettes delivered a higher concentration of nicotine.
>
> Evidence from the documents indicates that tobacco companies now more often target working class men and women and less educated people. In the United States, ethnic groups such as African-Americans, Hispanics and Pacific Islanders are considered separate "market segments" by the industry, as are homosexuals.
>
> As the prevalence of smoking decreases in the developed world, the planning and strategy documents of the multinational tobacco companies show their eagerness to expand profits by vigorous marketing in other parts of the world, especially where restrictions are fewer and the population less aware of the risks".

303. An issue in the present case is the impact of psychological factors, including addiction, upon consuming patterns and the general economics of supply. Experts instructed by the Secretary of State criticise the Claimants' experts for, they argue, ignoring this important influence on the economics of tobacco supply. In relation to research conducted internally about the psychology of smokers the WHO concluded:

> "6. The sociology and psychology of smokers
>
> The tobacco industry knows its customers better than any business in the world. Each year thousands of researchers with advanced degrees in marketing, psychology, sociology and interviewing do research on which people are more likely to

> smoke, why they continue to smoke, which ones are likely to quit smoking and how to induce them not to, and how people respond to advertising. The documents show the close attention the industry pays to social and economic class, racial character, age and sex, level of education, patterns of smoking, and many other subcategories. For example, research by a Canadian company tried to predict which schoolchildren would become future smokers".

304. The tobacco companies state that they are not interested in and do not collect information on a range of key issues, including marketing directed towards children and young adults. I have expressed my concerns about this above and the inference that might be drawn that, if correct, it reflects a deliberate attempt to avoid generating inculpatory documents. WHO stated:

> "7. Destruction, disposal or alteration of secret Documents
>
> Some of the industry documents, released by the court in Minnesota, reveal the extent to which the tobacco industry suppressed their own research that showed the ill-effects of smoking, both from direct smoking and exposure to smoke of non-smokers. The main reason for suppression was to avoid discovery of the research or other incriminating documents in any possible lawsuit".

305. The overall conclusion of WHO was the following:

> "8. The web of deceit and deceitful practice
>
> None of the categories of "discovery" is explicitly labelled deceit, bribery, smuggling or dirty tricks. Yet even though some incriminating documents were destroyed and others may have been concealed from the courts, what were turned over amply reveal the incredible range of corporate malfeasance. This includes: evidence of political "dirty tricks"; use of carefully staged scientific conferences to "keep the controversy alive"; use of secretly paid consultants and journalists to cast doubt on the ill-effects of tobacco; trying to rewrite the rules of standard epidemiological science; casting doubt on national and international scientific agencies; conspiracy and collusion by the multinational companies to retard measures for tobacco control; undermining of and spying on international organizations such as WHO and anti-tobacco nongovernmental organizations; setting up or subsidizing pro-tobacco organizations that appear to be acting independently (such as smokers' associations, scientific groups, restaurant and hotel associations, agricultural and tobacco grower associations, among others); destruction of documents; and even possible involvement in smuggling".

(vi) Internal documents: The findings in the US Judgment about internal documents

306. I turn now to the judgment of Judge Kessler in the *US Judgment*. In September 1999 the United States Government alleged in proceedings (described by the Judge as "massive") that the tobacco companies violated, and continued to violate, the Racketeer Influenced and Corrupt Organizations Act 18 U.S.C. §§ 1961-1968 ("*RICO*"), by engaging in a prolonged, unlawful conspiracy to deceive the American public about the health effects of smoking and environmental tobacco smoke, the addictiveness of nicotine, the health benefits from low tar, "light" cigarettes, and by their alleged manipulation of the design and composition of cigarettes in order to sustain nicotine addiction. It was alleged that for about fifty years the companies had falsely and fraudulently denied contrary to RICO: (1) that smoking caused lung cancer and emphysema and other types of cancer; (2) that environmental tobacco smoke caused lung cancer or endangered the respiratory and auditory systems of children; (3) that nicotine was a highly addictive drug which they had manipulated in order to sustain addiction; (4) that they had marketed and promoted low tar/light cigarettes as less harmful when in fact they were not; (5) that they had intentionally marketed tobacco products to young people under the age of 21years and denied doing so; and (6), that they had concealed evidence, destroyed documents, and abused (attorney-client) privilege to prevent the public from knowing about the dangers of smoking and to protect the industry from adverse litigation.

307. The Court addressed, as a recurring theme running throughout its findings and conclusions, the mismatch between the exculpatory *external public* statements of the tobacco companies and especially the opinions expressed by experts on their behalf, and, the inculpatory *internal private* documents of the companies.

308. After a 9 month trial the Court upheld the vast majority of the allegations levelled against the tobacco company defendants. The judgment was introduced (in Section A "overview") in the following way which was damning about the internal document policy of the tobacco companies:

> "The seven-year history of this extraordinarily complex case involved the exchange of millions of documents, the entry of more than 1,000 Orders, and a trial which lasted approximately nine months with 84 witnesses testifying in open court.
>
> Those statistics, and the mountains of paper and millions of dollars of billable lawyer hours they reflect, should not, however, obscure what this case is really about. It is about an industry, and in particular these Defendants, that survives, and profits, from selling a highly addictive product which causes diseases that lead to a staggering number of deaths per year, an immeasurable amount of human suffering and economic loss, and a profound burden on our national health care system.
>
> Defendants have known many of these facts for at least 50 years or more. Despite that knowledge, they have consistently, repeatedly, and with enormous skill and sophistication, denied

> these facts to the public, to the Government, and to the public health community.
>
> Moreover, in order to sustain the economic viability of their companies, Defendants have denied that they marketed and advertised their products to children under the age of eighteen and to young people between the ages of eighteen and twenty-one in order to ensure an adequate supply of "replacement smokers," as older ones fall by the wayside through death, illness, or cessation of smoking.
>
> In short, Defendants have marketed and sold their lethal product with zeal, with deception, with a single-minded focus on their financial success, and without regard for the human tragedy or social costs that success exacted.
>
> Finally, a word must be said about the role of lawyers in this fifty-year history of deceiving smokers, potential smokers, and the American public about the hazards of smoking and second hand smoke, and the addictiveness of nicotine. At every stage, lawyers played an absolutely central role in the creation and perpetuation of the Enterprise and the implementation of its fraudulent schemes. They devised and coordinated both national and international strategy; they directed scientists as to what research they should and should not undertake; they vetted scientific research papers and reports as well as public relations materials to ensure that the interests of the Enterprise would be protected; they identified "friendly" scientific witnesses, subsidized them with grants from the Center for Tobacco Research and the Center for Indoor Air Research, paid them enormous fees, and often hid the relationship between those witnesses and the industry; and they devised and carried out document destruction policies and took shelter behind baseless assertions of the attorney client privilege".

309. The Court found as fact that from the 1950s through to the present day (2006), different tobacco companies, at different times and using different methods, had intentionally targeted marketing at young people under the age of 21 in order to recruit "*replacement smokers*" to ensure the economic future of the tobacco industry. The Court was scathing in its rejection of the claims made by the tobacco companies that they did not market to young people. It accepted the independent research which concluded that marketing was a substantial contributing factor to youth smoking and the Court also accepted the evidence of tobacco control experts, who were described as "*credible*", who found that marketing was a significant causative factor in encouraging youth smoking initiation and continuation. The Court also focused upon the key psychological factors that resulted in young people taking up smoking, such as the inability of young people to grasp the full implications of smoking. The Court described in the judgment how marketing was directed at the "*normalisation*" and legitimisation of smoking. The conclusion was that the advertising adopted by the tobacco companies was effective in reaching young people. The Judge rejected the

Claimants' submission that marketing was designed simply to retain market share. There was a "*mountain*" of evidence to the contrary.

310. After the evidence on this issue was summarised the Court came to the following conclusions according to a "beyond any reasonable doubt" standard of proof (cf. pages 1149ff, paragraphs [3296ff]):

> "Conclusions
>
> 3296. The evidence is clear and convincing -- and beyond any reasonable doubt – that Defendants have marketed to young people twenty-one and under while consistently, publicly, and falsely, denying they do so. Dolan WD, 24:3-16; Krugman WD, 17:2-19:1; Chaloupka WD, 30:8- 32:20; Biglan WD, 100-379.
>
> 3297. In response to the mountain of evidence to the contrary, Defendants claim that all the billions of dollars they have spent on cigarette marketing serves the primary purpose of retaining loyal customers ("brand loyalty"), and the secondary purpose of encouraging smokers to switch brands. They deny that any of their marketing efforts are aimed at encouraging young people to initiate smoking or to continue smoking. Dolan WD, 61:6-16.
>
> 3298. In fact, the overwhelming evidence set forth in this Section -- both Defendants' internal documents, testimony from extraordinarily qualified and experienced experts called by the United States, and the many pictorial and demonstrative exhibits used by the Government – prove that, historically, as well as currently, Defendants do market to young people, including those under twenty-one, as well as those under eighteen. Defendants' marketing activities are intended to bring new, young, and hopefully long-lived smokers into the market in order to replace those who die (largely from tobacco-caused illnesses) or quit. Defendants intensively researched and tracked young people's attitudes, preferences, and habits. As a result of those investigations, Defendants knew that youth were highly susceptible to marketing and advertising appeals, would underestimate the health risks and effects of smoking, would overestimate their ability to stop smoking, and were price sensitive. Defendants used their knowledge of young people to create highly sophisticated and appealing marketing campaigns targeted to lure them into starting smoking and later becoming nicotine addicts. Dolan WD, 24:3-16; Krugman WD, 84:1-99:23; Chaloupka WD, 30:8-32:20; Biglan WD, 100-379.
>
> 3299. As a result, 88% of youth smokers buy the three most heavily advertised brands -- Marlboro, Camel, and Newport. Fewer than half of smokers over the age of twenty-five purchase these three brands. For example, in 2003, Marlboro,

the most heavily marketed brand, held 49.2% of the twelve to seventeen year old market but only 38% of smokers over age twenty-five. Eriksen WD, 52:17-54:10; (no bates) (US 17684A).

3300. Independent scientific studies published in prestigious peer-reviewed scientific journals and in official government reports have confirmed Defendants' knowledge, as demonstrated in their internal documents, that their marketing contributes substantially to the initial demand for and continuing use of cigarettes by young people. Over the past ten years, there have been a number of comprehensive reviews of the scientific evidence concerning the effects of cigarette marketing, including advertising and promotion, on smoking decisions by young people. The weight of all available evidence, including survey data, scientific studies and experiments, reports of public health and governmental bodies, and the testimony of experts in this case, supports the conclusion that cigarette marketing is a substantial contributing factor to youth smoking initiation and continuation. Eriksen WD, 55:4-20.

3301. Defendants spent billions of dollars every year on their marketing activities in order to encourage young people to try and then continue purchasing their cigarette products in order to provide the replacement smokers they need to survive. Defendants' expenditures on cigarette advertising and promotion have increased dramatically over the past decades, and in particular since the signing of the MSA. Krugman WD, 23:10-24:4. Over the decades, Defendants have used the full range of marketing tools available to them at any particular time, including: advertising on television, radio, and billboards, and in magazines and newspapers; sponsoring events, such as sporting events, bar promotions, festivals, concerts, and contests; providing coupons, price reductions, and free packs with purchases; providing gifts with purchases (known as "continuity items") such as t-shirts, mugs, and sporting goods; direct-mail marketing by sending magazines and other materials directly to individuals' homes; distributing free cigarette samples at retail stores, public events, bars, or other locations; and strategically locating "point of sale" advertising and promotions at retail outlets young people are most likely to frequent, such as convenience stores. Krugman WD, 43:14-2; Dolan WD, 48:6-3.

3302. In the face of this evidence, Defendants have denied, over and over, with great selfrighteousness, that they have marketed to youth".

(vii) Internal documents: Domestic civil procedure rules / CPR 35.

311. The domestic civil procedural rules in this jurisdiction require experts to adopt a balanced approach to the evidence and to take account of points both for and against. They may not act as hired guns. From the above citation from the *US Judgment* which refers to a "mountain" of "overwhelming" evidence, the reference to the internal documents of the tobacco companies showing how they conducted extensive internal analysis of the impact on children in paragraph [3298] is significant. The documents relied upon in the US litigation were held to reflect the current position of the tobacco companies as of the date of the judgment, 2006. It has not been suggested by the tobacco companies in this litigation that these documents are inaccurate or no longer reflective of their actual, internal, policies and positions or that they no longer reflect the reality of the tobacco market (though see paragraphs [294] – [297] above). The companies seek to contend that they do not target children through their advertising and promotional policies. The Secretary of State challenges this. He submits that protestations made in Court without the backing of internal disclosure is unacceptable and unconvincing. He points out that, as Judge Kessler found as a fact, disclosed documents from the US show that targeting youth has been a major and enduring plank in the marketing strategies of tobacco companies and that in curtailing branding the Regulations will serve to prevent adverse impacts on children. He cites as illustrative only a 1984 Strategic document from RJ Reynolds which states:

> "Younger adult smokers have been the critical factor in the growth and decline of every major brand and company over the last 50 years. They will continue to be just as important to brands/companies in the future for two simple reasons: The renewal of the market stems almost entirely from 18-year old smokers. No more than 5% of smokers start after age 24. The brand loyalty of 18-year old smokers far outweighs any tendency to switch with age".[10]

312. Professor Hammond cites an extensive list of research analysis which describes a causal connection between tobacco marketing and youth smoking[11]. In the Report he prepared in the context of the consultation in Ireland (the Hammond Ireland Report) he stated:

> "A wide range of industry documents highlight the importance of tobacco marketing targeted at youth. A published review[12] of tobacco company documents concluded:
>
> > "Industry documents show that the cigarette manufacturers carefully monitored the smoking habits of teenagers over the past several decades. Candid quotes

[10] The Hammond Ireland Report (March 2014) refers to other internal tobacco company documents disclosed in US proceedings which are to the same overall effect.

[11] Hammond Ireland pages 7ff and footnotes 30ff.

[12] Cummings K, Morley RJ, Horan JD, Steger C, Leavell NR, "Marketing to America's youth: evidence from corporate documents" (Tob Control 2002; 11 Sppl1:15-17).

> from industry executives refer to youth as a source of sales and as fundamental to the survival of the tobacco industry. The documents reveal that the features of the cigarette brands (that is, use of filter, low tar, bland taste, etc), packaging (that is, size, colour and design), and advertising (that is, media placements and themes and imagery) were developed specifically to appeal to new smoker (that is, teenagers). Evidence also indicates that relevant youth orientated marketing documents may have been destroyed and that the language used in some of the more recent documents may have been sanitised to cover up efforts to market to youth"".

313. Yet the Claimants submitted in these proceedings that internal documents were not relevant to the tasks the experts were instructed to perform. I do not agree. For instance the Claimants' experts addressed and were profoundly damning of the pre-existing literature and research base which indicated that branding and advertising were causative of changes in consumer behaviour and, it could logically be inferred therefore, that restrictions upon such branding and promotion would equally also affect consumer behaviour (i.e. away from smoking). The internal disclosed documents suggest that tobacco companies engage in extensive marketing and research into this very issue and that these documents support the Secretary of State's position. Yet, the Claimants' external experts who addressed this issue ignore this source of evidence. Professor Devinney was instructed to examine the consumer research evidence which was relied on by the Defendant in introducing the Regulations. Professor Steinberg was instructed to examine whether the Regulations were likely to discourage children from taking up smoking. The Secretary of State submitted in relation to these two examples that the best, and possibly the only, way properly to test the Defendant's evidence or to assess the likely impact of standardised packaging on smoking initiation in children: *"... is by reference to evidence concerning the impact of tobacco marketing and branded packaging on smoking behaviour generally. On any view tobacco industry documents which address the impact of packaging and marketing on smoking behaviour must be relevant to the questions being addressed by JTI's experts. Professor Steinberg's assertion that such evidence is "irrelevant" because most forms of tobacco packaging have been prohibited in the UK is patently absurd in light of the fact that tobacco marketing on packaging and cigarettes has (until the coming into force of these Regulations) always been permitted in the UK*".

314. Professor McKeganey conducts a review of some of the main pieces of research literature in a report dated 5th August 2014. It was prepared on behalf of BAT for the purposes of the consultation process. But it was, as with all of BAT's other evidence used in that process, also tendered as relevant to the broader issues arising in the litigation and was therefore relied upon for grounds which went beyond the limited objections relating to the consultation process itself. But (as with so much of the other evidence) it was not updated nor was it subject to the normal and requisite expert declaration under CPR 35. Professor McKeganey adopted the position that at times researchers who generated results in favour of tobacco control were biased and that this was a real obstacle to providing a clear assessment of the evidence results they generated. In this he distinguished between the "*natural and inevitable*

divergences of opinion on the part of different experts", and bias. He set out his view that tobacco research had become as much a "*moral activity as an investigative one, a weapon used by the "researcher-activist" in the "fight against tobacco*"". The upshot of this was that, in substance, a Court should discount the evidence advanced in favour of tobacco control; it was unreliable and biased:

> "What this had meant in practice is that the principles of transparency and openness, for so long foundational tablets of the scientific enterprise, have on occasion been sacrificed in what is seen as an academic and political war to be fought against the tobacco industry".

Professor McKeganey then goes on to review various pieces of research literature and he concludes with an overarching and central proposition that decisions to start smoking during adolescence are related to factors *other than* those related to packaging and design of tobacco products. He argues that the appeal of branded packaging is not empirically supported as a factor that significantly increases the likelihood of smoking initiation during childhood and it does not operate significantly to motivate changes in smoking behaviour in adults. In short evidence that supported tobacco control was unreliable because it was subject to moral crusader bias; and the reliable evidence was that which opposed tobacco control. Yet, and once again I repeat the criticism that I make of so many of the Claimants' experts, his conclusions contradict a very great deal of research by independent peer reviewed researchers, and also the internal research of the tobacco industry, and his conclusions contradict the findings of Judge Kessler who, after a comprehensive nine month trial, found the opposite, and he ignores the adverse conclusions of WHO upon analysis of the tobacco companies' internal documentation. What I find unacceptable is the preparation of a report which by its total refusal to engage with any of this contra-material simply conveys the impression that it does not exist and that the best way to refute it is to ignore it. Yet, at the same time and inconsistently, Professor McKeganey accepts that the principles of transparency and openness are "*foundational tablets of the scientific enterprise*". Had Professor McKeganey confronted head-on the contrary evidence, including that from the tobacco companies, then it is hard to see how he could have advanced the opinions that he did; at the very least he would have been compelled to provide a proper rationale for why his opinion could be sustained in the light of this inconsistent evidence. Further analysis of this evidence is set out at paragraphs [381] – [383] below.

315. This point is important in the overall context of this case because to succeed on evidential grounds the Claimants must not only establish that their own, new, post-Australian implementation quantitative evidence is powerfully probative, but also refute or oust or at the very least massively discount the probative value of pre-Australian qualitative evidence which is against them. And that substantial task will not be achieved by reports from experts, howsoever distinguished, which simply fail to address the contrary evidence base (which must include internal assessments) and the adverse conclusions on that evidence base by researchers, Courts and international organisations such as the WHO. One is left in the case of Professor McKeganey with an expert report that is *prima facie* inadmissible because it fails to adhere to domestic civil procedure rules but that, even when fully considered, appears slanted and partial.

316. Experts owe their primary duty to the Court. Detailed rules governing the conditions under which experts give evidence in this jurisdiction are set out in CPR 35. 35PD2.1 provides that expert evidence should be the independent product of the expert uninfluenced by the pressures of litigation. 35PD 2.3 states: *"Experts should consider all material facts, including those which might detract from their opinions".* How can an expert consider all material facts including those that are inculpatory to their client if they do not ask for and/or receive relevant internal documentation? Moreover, where experts rely upon data or information selected and provided to them by their clients then the obvious concern arises that the client has felicitously chosen to provide only exculpatory information and data that serves its cause. Where this arises, an expert, in conformity with CPR 35 and PD 2.1, should give careful consideration to explaining in a transparent way in the resultant report what steps if any he or she has taken to *ensure* that the data and information provided is accurate and fairly representative. And an expert might, if he or she suspects that the client has been carefully selective or adopted a policy of destroying internal documents or not recording (in disclosable form or otherwise at all) the substance of sensitive issues, say as much in the final report.

317. What is conspicuously missing in the present case is evidence based upon the internal documents of the companies in question or any satisfactory explanation as to why this has not been given or in those strictly limited cases where it has been provided in part any account of the efforts made by the expert to obtain satisfaction that the material provided meets the highest standards of fairness and impartiality.

318. Uniquely in this case there is an international consensus from within the WHO and across the world that tobacco companies are set on subverting national health policies antithetical to their financial interests. This is, in part, due to experiences in the US courts and the sharp conflict between public utterances and private analysis. There is in such circumstances a real premium upon full observance with the principles laid down in the CPR *and* (in so far as there is day light) with best and transparent research and publication practices generally. It is in this way that the tobacco companies can persuade a systemically sceptical world that their research is valid and worthy of the great probative weight they claim for it.

319. My concern lies not just with the position of a single Claimant company but, rather, with what has the appearance of being an industry wide practice not to adduce internal documents or to allow their experts to see and review and then rely upon internal documents. The position in this case is quite different to that which arises in typical civil litigation when the experts will prepare their reports <u>following</u> disclosure and taking the disclosure into full account and where the opposing side to the litigation and the Court can evaluate the expert's report in the light of the disclosure or discovery. Experience tells one that very frequently the best experts of all are the middle and senior management within client companies who live with the issues on a daily basis and understand deeply the dynamics of their own markets. These internal views, in all their unvarnished glory, are routinely the most telling and perspicacious of all. I give an illustration referred to in another context during the hearing which typifies just how sophisticated the tobacco companies are in researching how to maximise the desirability of tobacco products to consumers. Imperial Tobacco Limited filed, in 2010, a patent application for an invention relating to the packaging of tobacco. The Description in the patent states that the invention has as its object:

"*… to provide an attractive and moderate-priced package for tobacco related articles which can be handled in a convenient way by means of one hand*": Patent Application Description paragraph [8]. Paragraphs [14] and [15] of the Description explain how the invention was to facilitate smoking whilst driving or whilst operating a computer or generally when the smoker only has one hand free. The Description says that the "*…package can rest well in the user's hand, and the one-hand use of the package is fast and convenient*". What does this presuppose about the state of internal documentation? It presupposes that a very great deal of thought has been targeted upon the way in which packaging can maximise convenience and speed during various manoeuvres and work operations. The level of sophisticated thought which has gone into the invention and into the filing illustrates the effort that has inevitably gone into being creative about packaging and how the use of tobacco can be maximised even in those circumstances where it would be otherwise difficult to achieve.[13]

(iv) Referencing of the existing literature base

320. I now move away from internal documents to the next aspect of methodological best practice which concerns the efficacy of researchers and experts addressing the existing literature base. I start with the criticism made by the Secretary of State that the tobacco companies and their experts failed to grapple with the pre-existing evidence base which has been generated over a number of decades by scientists and researchers worldwide. The Claimants' experts however attack that evidence as fundamentally unsound as a matter of principle, and, in any event, superseded by their up to date regression analysis. The Defendant makes three points which concern: (i) the intrinsic value of the existing literature base which is based upon successive pieces of peer reviewed material; (ii) the evidential value of consistency between the outcome of peer reviewed research; and (iii) evidential problems related to selectivity of prior research.

321. The first point relates to the importance of best practice to the evolution of research over time. Research is a progressive process; one researcher builds upon the research of another. Over time advances emerge from this iterative and incremental process and the sum is thus far more than the individual parts. This steady process is enhanced because along the way each prior piece of prior research has been generated according to best practice. This is important because when experts, in the context of litigation, refer to prior sources and state that they are peer reviewed and independent this is capable of carrying weight as a probative badge of quality. And conversely if an expert's report ignores prior research or only selects research which has not been peer reviewed or which is not independent this logically is an indicator of lesser quality.

[13] In *Gestmin SGPS S.A. v (1) Credit Suisse (UK) Limited (2) Credit Suisse Securities (Europe) Limited* [2013] EWHC 3560 (Comm) Legatt J, at paragraph [22], in the different though analogous context of a dispute as to whether oral or documentary evidence was best, extolled the virtues of internal documentary evidence, stated: "*… the best approach for a judge to adopt in the trial of a commercial case is, in my view, to place little if any reliance at all on witnesses' recollections of what was said in meetings and conversations, and to base factual findings on inferences drawn from the documentary evidence and known or probable facts. This does not mean that oral testimony serves no useful purpose – though its utility is often disproportionate to its length. But its value lies largely, as I see it, in the opportunity which cross-examination affords to subject the documentary record to critical scrutiny and to gauge the personality, motivations and working practices of a witness, rather than in testimony of what the witness recalls of particular conversations and events. Above all, it is important to avoid the fallacy of supposing that, because a witness has confidence in his or her recollection and is honest, evidence based on that recollection provides any reliable guide to the truth*." (Emphasis added)

322. The second point concerns the probative value of consistent source evidence. The greater the volume of best practice compliant evidence pointing in a single direction the more likely it is that the thrust of that evidence should be taken as indicative of the correct result or answer. This is important because where the accumulated weight of the prior (independent, peer-reviewed) research points in one direction the fact that there may be limitations in individual pieces of research becomes of much less significance. Hence when experts include as part of their analysis a comprehensive review of source material and where that material meets best practice standards then the direction of travel of the evidence is a stand-alone factor which adds probative weight to the particular expert's opinion.

323. The third and related point concerns selectivity: the correctness of an answer cannot be decided simply by weighing the evidence in support of it. In a wide ranging consultation on a controversial topic where views are polarised there may frequently be a significant volume of well crafted and persuasive material that can be pointed to as supporting one side or the other. But it is precisely because of this that the decision maker must exercise judgment having systematically reviewed all of the evidence in the round. If following such a review it can be seen that there is a common thread or widespread consensus then "volume" in that sense may be influential. In *R (on the application of British Academy of Songwriters Composers and Authors et Ors v Secretary of State for Business innovation and skills* [2015] EWHC 1723 (Admin) at paragraph [229] the Court stated:

> "229. ...the ability of any court to conduct an intensive review will depend also upon the evidence put before it by the parties. In this case the manner in which the attack on the economic logic of the decision has been advanced makes it difficult to accept. If a Court is to overturn an economic assumption made by a decision maker then it has to have before it *all* of the evidence that the decision maker considered so that it can be assessed in the round. It cannot be open to a Court to reject the Defendant's assessment if only a small portion of the relevant evidence is relied upon for that challenge. By its nature - and especially in relation to an issue which splits an industry and stimulates partial submissions reflecting defined economic interests - if only that portion of the evidence which reflects but one side of the argument is put before the court then it will, inevitably, appear to be a powerful and coherent body of evidence which is inconsistent with the decision maker's reasons. However, that might be for the very reason that it is only a portion of the evidence that was before the decision maker. To then say that there is a coherent body of evidence that contradicts the decision is true but an inapposite conclusion since it does not necessarily indicate that the impugned decision was outwith the decision maker's proper discretion. In this case submissions inviting rejection of the Defendant's economic pricing-in theory have rested upon only a small portion of the actual evidence before the decision maker. I have now read the contrary evidence. Submissions made have not focused upon why these other experts are wrong nor have they

> sought to weigh the pros and cons of competing economic theories".

324. I agree with all of the three points made by the Secretary of State and summarised above in this regard. They each provide yardsticks which may be applied to evidence.

(ix) Transparency and the ability to verify: Best practice guidance given by economic regulators

325. It follows from the above that the evidential value of research and analysis is enhanced if it can be verified. As such "transparency" is very important. Valuable guidance on how the principle of transparency might be interpreted in practice is found in the "Best Practice" guidance given by economic regulators who regularly receive and rely upon empirical and econometric evidence from affected companies. Competition authorities are prime examples since, increasingly, they rely upon these sorts of statistical analyses as evidence. I set out below the view of the Competition and Markets Authority ("CMA") in the UK and the view of the Competition Directorate of the EU. Both have issued guidance documents setting out "best practice" for the submission of economic evidence. The guidance is relevant to the analysis which arises in the present case since it sets out how such evidence should be prepared and tendered in order to achieve maximum probative value. Importantly, there is nothing in the guidance which is unique or special to competition law. These regulators state that econometric modelling can be useful <u>but</u> it inherently involves simplification and reliance upon multiple assumptions and rarely, if ever, is it conclusive in and of itself. It must therefore be verified against the evidence it relies upon <u>and</u> the real life facts of the markets in which it operates.

326. The CMA has provided guidance on "best practice" for submissions of technical, economic analysis (CC2com3). There the CMA explains that it increasingly receives submissions from parties involving formal economic modelling and sophisticated empirical work. The CMA accepts that such evidence is beneficial to their evidence collecting and assessment tasks. However, to ensure that the evidence submitted is of the highest quality the CMA has laid down various guidelines. Three general principles are identified: (i) clarity and transparency; (ii) completeness; and (iii) replicability of results. Clarity and transparency focus upon the need for clear presentation of results and conclusions including precise and clear statements of the methodology used, the assumptions made, and the justifications of the methodology and the assumptions. Such evidence must be comprehensible. The fact that the recipient is an expert regulator does not mean that all of its officials are capable of interpreting complex econometric or statistical analyses. This is a recognition that complex evidence must be made digestible to non-specialists. It is a point of real practical significance in a case such as the present. The important point is made:

> "Submissions should be understandable to non-economists, and [CMA] economists should be able to determine how the analysis enables the parties' economic experts to reach the submitted conclusions".

Completeness requires, *inter alia*, that all relevant assumptions should be identified and discussed and the CMA should be able to understand both the results and the economic theory and modelling that generate the results without having to seek

further information. Under the heading "Replication of results" the CMA states as follows:

> "In a number of cases, the [CMA] will want to replicate the results of the analysis that has been submitted. This means that parties should be prepared to respond to a … request at very short notice, for all relevant computer code and data files necessary for the [CMA's] economists to reproduce the results presented in the parties' submissions. This will include the raw and the cleaned data and the programs for obtaining the latter from the former".

When it assesses any form of econometric modelling it is critical for the CMA to be able to understand the assumptions which underlie the modelling so that the reasonableness of those assumptions may be tested. The CMA seeks to test assumptions: "... *against all the evidence it has received in the case*". In order to test the robustness of the results the parties are required to provide all relevant program files that have enabled the parties to manipulate and clean the raw data in preparation for the analysis. Data may be "cleaned" for a variety of acceptable reasons. However, the CMA will verify whether the parties have, for instance, discarded results or observations because they are considered as "outliers" or because of reporting error. Parties are required to provide precise descriptions of the data-cleaning process and they are invited to provide an annotated computer code specifying the nature and number of data records eliminated or changed at each and every step in the analysis.

327. The EU Commission has also produced a best practice guide which it uses in the context of merger cases, which is where empirical evidence is frequently submitted ("Competition best practice for the submission of economic evidence and data collection in cases concerning the applications of Article 101 and 102 TFEU in merger cases"). The Commission adopts a position which is very similar to that of the CMA. However there are a number of additional points of detail worth mentioning. First, the Commission requires parties to ensure that their "… *economic analysis meets certain minimum technical standards at the outset*" (paragraph [2]). Second, parties should comply with methodological standards which are "*prevalent*" in the industry (paragraph [3]). Third, all analysis must be capable of being reconciled with the underlying facts and evidence (ibid). Paragraphs [3] and [4] thus state:

> "3. In order to determine the relevance and significance of an economic analysis for a particular case, it is first necessary to assess its intrinsic quality from a technical perspective, i.e. whether it has been generated and presented to adequate standards. This involves, in particular, an evaluation of whether the hypothesis to be tested is formulated without ambiguity and clearly related to facts, whether the assumptions of the economic model are consistent with the institutional features and other relevant facts of the industry, whether economic models are well established in the relevant literature, whether the empirical methods and the data are appropriate, whether the results are properly interpreted and robust and whether counterarguments have been given adequate consideration.

> 4. Second, one must assess the congruence and consistency of the economic analysis with other pieces of quantitative and qualitative evidence (such as customer responses, or documentary evidence)."

328. The Commission adds: "*Economic models or econometric analysis, as is the case with other types of evidence, rarely, if ever, provide conclusive evidence by themselves*". In paragraph [10] the Commission makes the point that: "*Any economic model which explicitly or implicitly supports a theoretical claim must rely on assumptions that are consistent with the facts of the industry under consideration*".

329. The Commission sets out a basic premise: econometric modelling is based upon assumptions and simplifications of reality. In paragraphs [12] – [14] the Commission states:

> "12. By their very nature, economic models and arguments are based on simplifications of reality. It is therefore normally not sufficient to disprove a particular argument or model, to point out that it is "based on seemingly unrealistic assumptions". It is also necessary to explicitly identify which aspects of reality should be better reflected in the model or argumentation, and to indicate why this would alter the conclusions.
>
> 13. In many cases, economic theory is used to develop a testable hypothesis that is later checked against the data. In that case, the economic analysis makes predictions about reality that can be tested by observations and potentially rejected or verified. Thus, whenever feasible, an economic model should be accompanied by an appropriate empirical model - i.e. a model which is capable of testing the relevant hypotheses given the data available.
>
> 14. Very often simple but well focused measurement of economic variables (prices, cost, margins, capacity constraints, R&D intensity) will provide important insights into the significance of particular factors. Occasionally, more advanced statistical and econometric techniques may provide more useful evidence. In any case, otherwise valid economic analysis may not always produce unambiguous results when applied to the facts of a competition case. Contradictions may result from differences in the data, differences in the approach to economic modelling or in the assumptions used to interpret the data or differences in the empirical techniques and methodologies."

(x) The analysis is context sensitive

330. I must add a caveat to all of the analysis above. I do <u>not</u> suggest that in all cases the above principles will inevitably apply either at all or to the same degree. Every case is fact and context sensitive. So, for instance, in a specific piece of civil litigation where experts are instructed to express an opinion upon, for instance, an issue of alleged clinical negligence it cannot be a sensible criticism that their reports are not peer

reviewed. But it may be a valid criticism if the experts fail to study and take into account the contemporaneous clinical notes. Equally, in a consultation where consultees are given (say) 6 weeks only to respond the fact that the material submitted is not peer reviewed may also be a false complaint. On the other hand in both of these instances if the expert fails, for example, to address fairly and comprehensively the underling pre-existing relevant literature/evidence base or the points in the literature against that expert's opinion that may still be a fair criticism.

(3) The relevant legal principle: Transparency

331. Before moving from the general to the particular position of the parties I should add a few observations about the principle of "transparency" endorsed in the FCTC and Guidance. Article 5(3) FCTC and the Guidelines appear to be unique in international law. No one has identified any other Treaty or Convention which adjudges an entire industry to be guilty of subverting the public interest and which sets out an international consensus that the evidential output of that industry should be treated with the greatest circumspection and that contracting states should ensure transparency and accountability in all of their dealings with tobacco companies. The FCTC does not however spell out how this circumspection should translate into a rule of evidence or practice to be applied at the national level. The isolated fact that the industry has a "prior record" does not mean that it is not entitled to a fair hearing. Article 6 ECHR entitles everyone to a fair hearing and this in principle applies, *par excellence,* to those who espouse unpopular views or causes or who have a history of recidivism. And it must be remembered that the manufacture and sale of tobacco is not prohibited; it is a lawful activity. Article 5(3) FCTC does not say that tobacco companies should not have a fair trial. It advocates vigilance and caution.

332. The provision has been considered albeit briefly by two Courts in recent times. The Claimants cite the dictum of the High Court of Delhi in *Institute of Public Health v Union of India and Ors (*decision of 1 May 2015) at paragraph [8] in relation to Article 5(3) and the Guidelines where the Court stated that the provisions "*only require interaction with the tobacco industry on matters related to tobacco control or public health to be accountable and transparent…*" In another recent decision, the Hague District Court ruled in *Dutch Stichting Rookpreventie Jeugd v the State of the Netherlands* that : "*Article 5(3) only talks about protecting tobacco control policies from the interests of the tobacco industry and does not make it clear what concrete result is to be achieved …*" : [4.8]). The references to ensuring that the tobacco companies are "*accountable and transparent"* by the High Court in Delhi provides only the vaguest of hints at the approach that might be adopted. Neither of these two authorities provides anything by way of guidance as to how, in practical terms, a Court is to approach this issue.

(4) The position of the Secretary of State towards the generality of the Claimants' expert evidence

(i) Secretary of State's basic position

333. The Secretary of State endorses the methodological principles set out above. He points out that they are well established principles adhered to by the international research community and were and are entirely appropriate and germane to the complex scientific, and social, issues arising in this case. In relation to the

consultation process the Secretary of State relied upon the conclusions of independent researchers who analysed the methodological integrity of all of the submissions tendered during the 2012 Consultation and found that the evidence submitted by the tobacco companies was inferior to the generality of the evidence submitted. However, the Secretary of State also submits that the conclusion that the evidence should be accorded limited weight did not prevent that evidence being placed fairly and squarely before Ministers and in any event did not affect Parliament's view when it debated the draft Regulations, and, as such, any error would in any event be irrelevant and immaterial.

(ii) The WHO position

334. The Secretary of State cited in support of his position the WHO position paper recommending standardised packaging attached to the letter from Dr Bettscher of WHO to the Department of Health dated 6 December 2012:

> "Tobacco industry interference
>
> …For decades, tobacco companies have operated with the sole purpose of subverting tobacco control policies in order to expand market share. Their own internal documents confirm this and show the lengths to which the industry will go to deter lawmakers from implementing strong, evidence-based tobacco control measures.
>
> WHO continuously witnesses the tobacco industry's interference in health policy development and implementation. WHO considers the tobacco industry to be the greatest threat to the WHO FCTC's implementation and enforcement worldwide. The tobacco industry produces, promotes and profits enormously from a product scientifically proven to be addictive, to cause disease and death and to give rise to a variety of social ills, including increased poverty. To protect its highly profitable business, large tobacco companies systematically use their political and monetary influence to weaken, delay and defeat tobacco control legislation across the globe. Similarly, tobacco companies use sophisticated methods to undermine meaningful health policies, laws and initiatives that are adopted and implemented. This cannot be allowed to happen in this case".

(iii) Hatchard/Ulucanlar

335. The Secretary of State also cited and relied upon two pieces of literature which analyse the evidence adduced by the tobacco companies in the course of the 2012 UK consultation. These are: (i) Hatchard, Fooks, Evans-Reeves, Ulucanlar and Gilmore, "*A critical evaluation of the volume, relevance and quality of evidence submitted by the tobacco industry to oppose standardised packaging of tobacco products* ("*Hatchard*") BMA Open 2014:4; and (ii), Ulucanlar, Fooks, Hatchard and Gilmore (2014), "*Representation and Misrepresentation of Scientific Evidence in*

Contemporary Tobacco Regulation: A Review of Tobacco Industry Submissions to the UK Government Consultation on Standardised Packaging" ("*Ulucanlar*").

336. In *Hatchard* the authors set out a summary of their comparative analysis of the submissions tendered by consultees comparing, by applying the above criteria, those submitted by the tobacco companies with those submitted by others. Under the heading "*Overview of evidence cited by TTCs in their submissions*" the report concluded:

> "143 Unique pieces of formal written research evidence were referred to or included in the four TTCs' submissions (22 referenced by more than one company) (Table 2): 88 cited to support arguments that SP would not have beneficial impacts on public health; 36 cited to argue that SP will have negative unintended consequences, half of which related to the illicit trade in tobacco; 19 cited to argue that the policy process – particularly the IA – was 'flawed'. TTCs did not cite any research showing that the tobacco industry has extensively studied and holds considerable evidence attesting to the impact of packaging on smoking behaviour (27-30). Of the 143 documents, TTCs promoted 131 as supporting their arguments and contested the methods, findings or accessibility of the remaining 12, all of which were included in the SR. 77 pieces of evidence were used to promote the TTC argument that SP 'won't work' and were therefore the subject of further analysis in this paper.
>
> Among these 77 documents, TTCs did not cite any research showing that the tobacco industry has extensively studied and holds considerable evidence attesting to the impact of packaging on smoking behaviour (34-37). Instead, they cited industry-funded research which critiqued the SR papers, the impact assessment and the consultation document. And they cited a body of independent research into the drivers of youth smoking which, while published in peer-reviewed health and psychology journals with no apparent connection to the tobacco industry, did not explicitly address the role of packaging in youth uptake or prevalence".

337. Under the heading "Discussion" the following is recorded:

> "Four main findings are apparent. TTCs cited a large volume of evidence in their submissions to the UK standardised packaging consultation. Seventy-seven pieces of evidence were used to support the claim that standardised packaging 'won't work' yet just 17 of these actually focused on standardised packaging, 14 of which had a connection with the industry. The quality of the TTCs' evidence on standardised packaging is significantly lower, as judged by independence and peer-review, than that included in the systematic review. Overall, the evidence cited by TTCs is shown, with few exceptions, to fit one of two

> typologies—*either* relevant/no quality indicators *or* parallel/quality indicators... . Furthermore, we show that evidence funded by or otherwise linked to industry is significantly less likely to be peer-reviewed than non-industry-connected evidence".

338. The Secretary of State says the following of Hatchard:

> "Hatchard et al, in their published review of the volume, relevance and quality of the evidence filed by the Tobacco Claimants in the 2012 Consultation found that 77 of the 143 pieces of evidence cited was used to promote the claim that standardised packaging "won't work", but only 17 out of 77 addressed standardised packaging, of which 14 were industry connected - and none of these were published in a peer-reviewed journal. The study assessed the Tobacco Claimants' evidence as being markedly less relevant and of lower quality than the Stirling group's systematic review. 37 out of 37 pieces of evidence included in the Stirling Report focused on standardised packaging, none had a connection with the tobacco industry and 21 out of 37 were published in a peer-reviewed journal. The Chantler Report referred to another independent review published by Ulucanlar et al, criticising the tobacco industry's misuse of evidence in its consultation submissions. Mr Derbyshire in his second witness statement makes a similar point about the quality of the evidence filed by the Tobacco Claimants' experts in these proceedings, concerning the evidence which is continually emerging from Australia: "The reports of the Claimants' experts, which have not been published in peer-reviewed journals, by various means and using different data sources and modelling, contend that the policy is not working. However, many experts working in the field, and whose works are published in respected peer-reviewed journals, are considering the emerging data and concluding that the policy is already proving effective in Australia." The upshot of this analysis was that by reference to benchmarks of reliability the intrinsic quality of evidence submitted by the tobacco companies to the Defendant is: (a) inferior to that submitted by third parties; (b) generally lacking in peer review approval and independence".

339. More generally the Secretary of State submits that the Hatchard conclusions apply to all of the evidence submitted by the tobacco companies post-2012:

> "In relation to the evidence served by the Tobacco Claimants in relation to standardised packaging, the Court is invited to consider the independent analysis carried out by Hatchard et al of the evidence submitted by the Tobacco Claimants to the Department of Health in the 2012 consultation on standardised packaging, published in the British Medical Journal. Hatchard et al examined the volume, relevance, and quality of the

> evidence the Tobacco Claimants cited in their consultation responses. The authors compared the evidence submitted by the Tobacco Claimants with the evidence considered in the Stirling Review. They concluded that the quality of the Tobacco Claimants' evidence was significantly lower than that considered in the Stirling Review, both in terms of independence from the tobacco industry and publication in peer-reviewed journals. Further, they concluded that evidence funded by or linked to the tobacco industry was significantly less likely to be peer-reviewed than non-industry connected evidence. Although this article only addresses the evidence served by the Tobacco Claimants in the 2012 Consultation, the evidence served by the Tobacco Claimants in the 2014 Consultation and in these proceedings is of the same nature and type i.e. generally industry-commissioned and non-peer reviewed. This contrasts with the independent peer-reviewed evidence relied on by the Secretary of State in adopting the Regulations".

340. In *Ulucanlar* the authors explain that they "… *purposively selected and analysed two TTC submissions using a verification-oriented cross-documentary method to ascertain how published studies were used and interpretive analysis with a constructivist grounded theory approach to examine the conceptual significance of TTC critiques*". The authors state:

> "The companies' overall argument was that the SP evidence base was seriously flawed and did not warrant the introduction of SP. However, this argument was underpinned by three complementary techniques that misrepresented the evidence base. First, published studies were repeatedly misquoted, distorting the main messages. Second, 'mimicked scientific critique' was used to undermine evidence; this form of critique insisted on methodological perfection, rejected methodological pluralism, adopted a litigation (not scientific) model, and was not rigorous. Third, TTCs engaged in 'evidential landscaping', promoting a parallel evidence base to deflect attention from SP and excluding company-held evidence relevant to SP. The study's sample was limited to sub-sections of two out of four submissions, but leaked industry documents suggest at least one other company used a similar approach".

341. In a section entitled "Adopting the litigation model" the following is stated:

> "The industry reviews appeared to be embedded within a litigation—not scientific—model. Some industry experts referred to parts of their reports that would normally be labelled 'appendix' or 'chapter' as 'exhibits', and their critiques resembled courtroom testimonies aimed at demolishing the adversary's case. In the main TTC submissions, the experts were posited as sources of higher scientific authority, representing 'the best contemporary scientific thinking' and

> were cited extensively. Demonstrating credibility was an important part of this project, with author CVs in the expert reports ranging between 10 and 20 pages and in one instance taking up 61 pages of a 98-page report. Privileging the individual expert is a legal phenomenon and the legitimacy ascribed to individual experts' testimonies in the courts is fundamentally different from collectively established and consensus-based scientific legitimacy developed within specialised 'communities of practice'. The tobacco company commissioned experts, working outside the peer-review system, dismissed the (peer-reviewed) evidence base for SP as flawed and unusable. In doing so, it was clear that they were attempting to establish an alternative system of scientific legitimacy. Another manifestation of the litigation model was the experts' piece-by-piece approach to reviewing. Individual studies were examined in depth to determine whether any—on its own—constituted a warrant for SP and, following systematic deconstruction, none was found to be good enough to justify SP. In court, each piece of evidence (i.e., each study and the Moodie review) is treated as a separate piece of evidence and each needs to be undermined and discredited in turn until no evidence remains that could damage one's client's case. By contrast, in scientific work, it is essential that the extant research is synthesised and greater confidence in the findings established through the cumulative 'weight of the evidence' .To sum up, the two TTC submissions (by BAT and JTI) and the associated expert reports used different combinations of the techniques of mimicked critique we have documented here to dismiss the entire literature supportive of SP".

(iv) The methodological critique of the Claimants' evidence

342. The Secretary of State instructed Professor Hammond to conduct a detailed review of the methodologies adopted by the experts instructed by the Claimants. His detailed expert report was before the Court. The Claimants have not sought, item by item, to rebut the criticisms levelled by Professor Hammond at their own evidence. Their rebuttal is essentially at the level of broad principle namely that the best practice standards applied by Professor Hammond are irrelevant to the evidence in this case. Professor Hammond provides a methodological critique against what he considered were best research practices such as: reference to pre-existing research; peer review; independence; cross referencing against internal client evidence, etc.

343. His overall conclusion is consistent with the findings of *Hatchard* and *Ulucanlar*, namely that the intrinsic quality of the Claimants' evidence is lacking.

344. In assessing this analysis I have, personally, sought to review Professor Hammond's methodological critique by cross checking his critical individual observations against the actual evidence submitted by the Claimants to see whether I agree. This exercise was undertaken against the evidence in the Court file but also, on occasion, by reference to published material available on the internet which was referred to in the

evidence but not specifically exhibited. In my judgment and in the light of my own cross-referencing exercise the analysis of Professor Hammond should be taken as essentially accurate. In neither their written nor oral submissions have the Claimants challenged the factual accuracy of the methodological critique conducted by Professor Hammond. So, for instance, where he complains that a piece of research tendered by the Claimants is not peer reviewed then that conclusion is not challenged and on my review seems to be correct; or where by reference to a person's CV Professor Hammond suggests that the author of the research relied upon by the Claimants is stepping outside of his area of expertise this also would appear to be supported by the CV; or where he says that a proposition is inconsistent with tobacco company internal documents that also is borne out by such internal documentation as is available.

345. This is important because the Claimants, by way of riposte, do criticise Professor Hammond personally upon the basis that he lacks impartiality being, as it was put, a "*tobacco control man*" who has made his living out of acting for governments and those who oppose smoking. From his CV there is some force in the description. It reflects the fact that the tobacco world is highly polarised and, in my view, it underscores the importance of applying a rigorous evaluative approach to all of the evidence submitted, and not just that tendered by the tobacco companies.

346. I am not saying that every barb cast by Professor Hammond inevitably hits home. A number of his criticisms might fairly be said to go more to the substance of the underlying econometric or economic analysis rather than the research methodology and thereby reflect differences between reasonable experts on matters of substantive detail. But where he does hit the mark is his conclusion that, as a generality, the Claimants' evidence does not follow the broad methodological standards and benchmarks that are more or less universally accepted by the international scientific and technical community as being best practice.

347. Professor Hammond's Report is dated 12th September 2015 and is entitled "Expert Report on Standardised Packaging Regulations in the UK – prepared under the instructions of the UK Department of Health on behalf of the Secretary of State for Health". In Chapter 11 of his report he conducts a detailed review of the Claimants' experts by reference to the standards of publication required by leading scientific journals.

348. His conclusion is in the following terms:

> "Overall, the criteria used in the Expert Reports for assessing the evidence on standardised packaging are inconsistent with the standards of leading scientific journals, with standards of their own published research, and with the methodological standards of tobacco industry research, which companies such as Philip Morris rely on to provide multi-million-dollar marketing campaigns and product development".

349. Professor Hammond advances the following specific criticisms of the experts which in many respects reflect the conclusions of Judge Kessler in the *US Judgment*: (i) that they reveal a lack of expertise in smoking behaviour on the part of their authors; (ii) that there was an unjustified rejection of evidence advanced by others; (iii) that they use flawed methodological criteria; (iv) that there was a failure to account for the

Australian data in a consistent and coherent manner; (v) that there was a failure to take account of their clients' own internal research evidence and documents in relation to marketing and packaging; and (vi) that causal inferences were based upon individual studies rather than the evidence base as a whole which was largely ignored. These criticisms are levelled, in various ways and degrees, at all the expert reports submitted by the Claimants.

350. A particular criticism made by Professor Hammond was that the Claimants' experts failed to account for the Claimants' internal research and business documents. He stated:

> "It would appear that none of the report authors were provided with company's own research evidence and documents on tobacco marketing and packaging. These documents represent the richest source of evidence on smoking behaviour, consumer perceptions, branding, product strategy and marketing practices. Failure to account for this evidence base has important implications for the experts' interpretation of the evidence. For example, several of the reports refer to unproven assumptions, speculation and hypotheses on the effects of cigarette packaging and branding. What the reports refer to as "assumptions" have, in fact, been documented in tobacco industry research and marketing practices over many years. For example, with regard to "speculation" on the importance of pack appeal or false health beliefs, actual market data exists documenting the importance of these factors. In other words, it is not simply speculation that cigarette branding can influence perceptions of risk, it is a fact that many millions of consumers switch to "lower tar" products in the mistaken belief that they were less harmful. In addition, tobacco company documents clearly indicate that these brands target health-concerned smokers. This "real world" evidence has been established not only in reports such as the US Surgeon General's Reports, but in US Federal Court records. However, none of the Claimants' reports contain a single reference to their internal research documents or business practices. This constitutes a major omission, particularly in the context of expert demands for "real world" evidence on the effects of cigarette branding and packaging".

351. In relation to the criticism that the experts lacked expertise in smoking behaviour Professor Hammond states that only one author (Professor Viscusi) had more than one peer-reviewed publication related to tobacco use. A review of the CVs of other authors indicates that they have never published in a scientific journal or received research grants in the area of tobacco use. An exception was Professor McKeganey who had published an empirical study in a peer-review publication. Professor Hammond concludes that a lack of expertise has important implications for how the evidence on standardised packaging has been interpreted. In particular he submitted that in many cases the expert reports failed to identify and account for key sources of evidence. His principal criticism is reserved for the failure of the Claimants' experts

to mention the role of nicotine and addiction in cigarette smoking. He cited internal documents generated by tobacco manufacturers that nicotine was the dominant influence on consumer behaviour with respect to smoking. In particular, he refers to an internal document (admittedly of some vintage but borne out by subsequent peer reviewed literature) by a Mr Claude Teague, a Director of Research and Development at RJ Reynolds Tobacco Company who stated as follows:

> "In a sense, the tobacco industry may be thought of as being a specialised, highly ritualised and stylised segment of the pharmaceutical industry. Tobacco products, uniquely, contain and deliver nicotine, a potent drug with a variety of physiological effects…Thus a tobacco product is, in essence, a vehicle for delivery of nicotine, designed to deliver the nicotine in a generally acceptable and attractive form. Our industry is then based upon design, manufacture and sale of attractive dosage forms of nicotine, and our company's position in our industry is determined by our ability to produce dosage forms of nicotine which have more overall value, tangible or intangible, to the consumer than those of our competitors".

352. None of the tobacco companies in the present case have submitted that this statement no longer represents the position of the manufacturers. Professor Hammond set out various statistics relating to nicotine addiction in the United Kingdom which served to highlight the critical importance of addiction in the sale of tobacco products. He then stated:

> "Although all nine of the expert reports offer opinions on consumer behaviour, none account for nicotine addiction. Indeed, seven of the nine reports do not even contain the word "addiction" or "nicotine". Rather the authors rely upon general principles of consumer behaviour and draw inferences from different consumer product domains, such as beverages and food. The uniquely addictive and hazardous nature of smoking renders these parallels and general principles irrelevant in most cases".

353. He also complained that the experts lacked experience in the areas of smoking initiation. For instance Messrs Professor Steinberg and Professor Mitchell, upon whom the Claimants rely in relation to youth smoking, had never published a single peer-reviewed article in this area. It was Professor Hammond's view that many of the Claimants' experts proffered opinions that contradicted the opinions of international experts in smoking initiation all of whom had produced "authoritative" peer-reviewed reports.

354. Another line of attack advanced by Professor Hammond was upon the rejection by the Claimants' experts of "*more than 90 published studies and empirical reports, including post-implementation data from Australia*". He pointed out that in their respective reviews of this literature Messrs McKeganey, Steinberg, Mitchell, Viscusi, Devinney and Klick did not accept a single study as relevant and reliable. Professor Hammond's criticism was that the Claimants established a set of unobtainable standards and then applied these standards in an inconsistent manner. The underlying

point made by Professor Hammond was that in an area of study characterised by best practice methodologies, such as peer-review, the Claimants' experts levelled criticisms at research work conducted by other experts who did comply with international standards but then, themselves, adopted standards which departed from the international norms. He stated:

> "The expert reports on which the Claimants rely have established a set of unattainable standards and have applied these standards in an inconsistent manner. Several of the experts have conducted research in the different areas of consumer behaviour. I have reviewed the publication list included in their curricula vitae and I did not identify any studies that met the standards they propose for reliable behavioural evidence. The same is true of tobacco industry research: many of the measures and methods the Reports seek to discredit – including experimental studies, observational studies, consumer surveys, and even qualitative research – are the same methods that had been used by the industry to guide their product to development and marketing strategies for decades.
>
> More generally, the methodological criteria used to reject evidence on standardised packaging is inconsistent with the established peer-review standards used in scientific journals. Indeed, several of the reports challenge the integrity of the peer-review system and the credibility of some of the most respected health journals in the world. Jacob Jacoby, who has prepared expert reports on behalf of Philip Morris International, highlights the importance of ensuring that standards for an expert report are consistent with the "relevant scientific community". Jacoby states that reports that are at odds with conventional scientific practice and standards raise questions about their quality:
>
> > "…when evaluating what an expert says or does, one needs to answer several critical questions…Is what is being said and done in keeping with generally accepted scientific practice and wisdom? If not, there is a problem. Is what is being said and done consistent with extant empirical research findings"".

355. A further criticism related to what are called "*social desirability and demand effects*". It was pointed out that the Claimants' experts advanced generic criticisms that could be made of most studies involving human participants, including limitations of sampling, survey measures and general demand effects. A particular example given concerned the expert reports of Professor Devinney and Professor Klick in relation to "*social desirability bias*". This is the tendency for research participants (e.g. survey respondents) to respond in a socially desirable way which may not reflect their true beliefs and attitudes. It is pointed out that this needs to be taken into account since it can skew research results. The criticism made is that Professors Devinney and Klick failed to discuss the likely impact of social desirability bias. Professor Hammond was

of the view that the socially desirable response would be to indicate that all cigarettes and brand variants were equally harmful. Smokers were generally well aware that smoking was socially unacceptable and there was social pressure to agree with the negative health effects of smoking. Professor Hammond argued that to the extent that the findings on standardised packaging were influenced by social desirability bias the findings would tend to underestimate the proportion of smokers who perceived health differences among the brand variants and who did not agree with the health effect of smoking. Professor Hammond's view was that the reports' failure to address the potential consequences of inherent limitations such as social desirability bias represented a departure from accepted scientific practice.

356. Finally, Professor Hammond made an important point about causality and in particular how the process of establishing causality could be complex and how conclusions on causality depended upon the volume and breadth of consistent evidence:

> "The report's criteria and review of studies imply that causality can and should be demonstrated by individual studies. Causality for complex phenomena and outcomes such as smoking is never established by a single study. Indeed, causality is not the property of a single study, but evaluated based upon a body of evidence. A much more appropriate framework for understanding causal inference is the field of epidemiology, which is guided by the Bradford Hill criteria. The criteria consist of a broader – and more realistic – range of criteria that should inform causal inferences, including the strength of association, consistency of findings, specificity of associations, temporality, biological gradient or dose response, plausibility, coherence, and experimentation. In writing about experimentation, Bradford Hill wrote: "Occasionally it is possible to appeal to experimental evidence". In other words, experiments are desirable when feasible, this is often not the case in the real world of public health and medicine. Bradford Hill also cautioned against the risks of setting unattainably high standards for assessing causality:
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> > "In asking for very strong evidence I would, however, repeat emphatically that this does not imply crossing every "small t" and source with every critic, before we act. All scientific work is incomplete – whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action that it appears to demand at a given time"".

(5) Claimants' submissions on research methodology

357. The Claimants' position as it evolved over the course of the hearing manifested itself in a variety of submissions from the different Claimants. I set out below a summary of the principal points made.

(i) Summary of Claimants' submissions

358. First, Article 5(3) FCTC and the Guidelines do not mean that the tobacco companies should not be accorded a fair hearing and this means that their evidence is entitled to be accorded full weight.

359. Second, a number of experts signed statements of truth in accordance with CPR 35 and these should be taken at face value (this point was not advanced by those companies who had tendered statements not in compliance with the CPR). It was submitted that in any event there is no need for CPR compliance in relation to reports submitted in the context of administrative consultations.

360. Third, there was no need for experts to have sight of internal documents because the issues did not warrant it. When it was necessary the companies provided to the expert such material as was necessary. For instance in relation to Professor Mulligan, upon whose regression analyses great reliance was placed, the following was stated in relation to the data he relied upon: "*PMI provided Professor Mulligan with internal data that was relevant to his analysis*".

361. Fourth, there was no need for reports to be peer reviewed. In some cases there was insufficient time for this to occur and in other cases it was simply inappropriate for reports produced for the purpose of litigation. More generally this was an industry with highly polarised views and there was no value in peer review by third parties who fell into one or more of the two camps and would therefore be subject to bias.

362. Fifth, the Claimants' experts were independent and of considerable pedigree and status even though they were paid by the tobacco industry. They had, where appropriate, signed statements of truth and there was no basis to suspect their motives.

363. Sixth, the research techniques adopted by scientists and researchers to produce the substantial body of academic and other literature which suggested that there was a causal and adverse nexus or connection between advertising and prevalence and use was methodologically flawed and inherently likely to generate false results and therefore there was no benefit in experts reviewing that literature or in seeking to address it or correct it.

364. Seventh, the Claimants' evidence was either cogent or it was not. The process of judicial review was the best place for the Claimants' reports to be subjected to scrutiny in a transparent way.

365. The Claimants in written submissions were critical of the principles set out in the FCTC and more generally they argue that the totality of their evidence was both open and transparent:

> "7. The FCTC, being an unincorporated Treaty, is not of direct effect in English law. Like other provisions of the FCTC, moreover, Article 5(3) is expressly limited by the requirements of national law. But even as a matter of international law, Article 5(3) simply does not require that any adverse treatment be given to the evidence before the Court in these proceedings. As the defendant has quite rightly already accepted, Article

5(3) does not affect the claimants' right to participate in the consultation process and to submit evidence in these proceedings. Nor does Article 5(3) affect the appraisal by the Court of the adequacy of the defendant's consultation process or the evaluation of the evidence now before the Court relating to proportionality.

8. To the extent that the defendant implies otherwise, it comes close to contending that tobacco companies alone should be denied the judicial protections afforded to all litigants before the Courts of England and Wales. That implication continues a troubling trend within the defendant's submissions suggesting that its own actions are somehow subject to a lesser standard of review than is truly the case. It joins company with the defendant's contentions that it was entitled to dismiss alternatives to plain packaging presented to it during the consultation process on the basis that none of those alternatives was plain packaging itself and/or that plain packaging forms but one element of a "*comprehensive tobacco control programme*" and that no balancing exercise is required as part of the proportionality analysis. None of these contentions is well-founded.

9. More specifically, nothing in Article 5(3) or the Guidelines requires the United Kingdom Government, or this Court, to exclude or give less weight to otherwise cogent evidence put forward by tobacco companies in an open consultation process or judicial review. All that is required by Article 5(3) is that the Government "*protect*" the United Kingdom's public health policies from the "*interests*" of the tobacco industry "*in accordance with national law*". The national law referred to in Article 5(3) includes domestic law principles of judicial review and the principles of procedural fairness and equality of arms safeguarded by the common law, Article 6 ECHR and Article 47 of the Charter. Excluding or giving less weight to evidence on the basis that it was filed by or prepared on behalf of tobacco companies would be inconsistent with those principles. For that reason, Article 5(3) cannot provide a justification for the defendant taking such an approach. Rather than requiring the exclusion of evidence, Article 5(3) requires that dealings with the tobacco industry be conducted on a transparent basis. In the present case, the Tobacco Claimants' expert evidence, both at the consultation stage and in these proceedings, has been presented in an open and transparent manner. The Tobacco Claimants' experts have provided all of their underlying data and calculations to the defendants' experts for review and analysis. That evidence will also be scrutinised by the Court in a public hearing".

(ii) Claimants' criticism of Hatchard and Ulucanlar

366. The Claimants were highly critical of both Hatchard and Ulucanlar (see paragraphs [335] – [341] above) and the best practice principles they espoused and relied upon. Their work was said to be flawed and illogical and they were biased ("*agenda driven*"). They attacked in particular the criteria of independence and peer review:

> "Hatchard *et al* is a flawed, illogical piece of work. Its fundamental flaw is that its measure of "*quality*" does not, in fact, measure the quality of the evidence at all:
>
> (1) The presence or absence of tobacco funding or other connections does not, in itself, determine the quality of a piece of evidence. It is one thing for a tobacco control research unit funded by tobacco control groups (which themselves receive funds from the defendant) to favour with disdain statements made by tobacco companies. But it is quite another to dismiss evidence presented for the purposes of consultation or litigation by independent academics, whose careers and eminence have been built up over many years, on the basis that they have been paid for the time they have taken to compile their evidence.
>
> (2) Professors Viscusi, Mulligan and Steinberg, for example, are on any view preeminent in their respective fields of endeavour. All of them have tendered their opinions in these proceedings having accepted that their duties to the Court as experts override those owed to the parties instructing them. The independence of the views they express in fact contrasts with the evidence tendered by Professor Hammond (for the defendant), who does not provide his evidence *pro bono*, who has been "*an Investigator on more than 50 research grants and contracts totalling more than $60 million CAD* [approximately £30 million]" mainly in the tobacco control field, and who has failed, for example, to disclose his close involvement in the Pechey Study, upon which he opines extensively, despite repeated attempts by the Tobacco Claimants (rebuffed by the defendant) to ascertain the identities of those who participated in it so that their credentials and independence could be verified. The Stirling Review provides a further context within which independence is lacking. Professor Hammond and Dr Crawford Moodie between them authored or co-authored eight of the 54 studies; and six authors co-authored nearly 60% (32 of 52) of all of the studies considered. To make matters worse, the Stirling Review team was led by Dr Crawford Moodie, (a) reviewing his own work and (b) reviewing the work of a network of scholars with whom he interacts.
>
> (3) Evidence is either cogent or not, irrespective of who funds it. Moreover, if receiving funding from a party with an interest in the issue amounted to a reason to doubt the quality of the evidence, then the same logic must surely apply to evidence

> produced or funded by anti-tobacco advocates or by Governments, including that of the UK. To characterise as "independent" the evidence on one side of a dispute but not the other is self-evidently wrong.
>
> (4) Nor is peer review a meaningful measure of research "*quality*" in this context. Hatchard *et al* itself acknowledges that "*peer-review standards can and do vary in practice*". Peer review typically involves anonymous approval by an unpaid academic working in the same field as the authors, based on a consideration of the article in question. In particular, peer review does not involve independent third parties scrutinising the original dataset relied on by the authors with a view to determining whether the opinions expressed are sustainable on the available evidence.
>
> (5) Indeed, compared with peer review, the judicial review process to which the evidence is now subject is a much more transparent and exacting process. All of the views expressed by the Tobacco Claimants' experts in the consultation process and in these proceedings, and all of the underlying data and calculations, have been amply scrutinised and commented on by the defendant and his paid experts, owing duties to the Court. Not only have the experts interrogated and commented upon each other's work, in many cases the experts have produced their own original research, calculations, and data, which have been scrutinised by the experts on the other side in the same way. Moreover, the requirement of peer review obviously cannot apply to reports compiled within a short timeframe for the purpose of submission to a consultation process (or, indeed, for a judicial review)".

367. In relation to *Ulucanlar*, which was referred to with approval in Chantler, and is cited in the Defendant's evidence, the Claimants again are confrontational:

> "It is not more impressive than Hatchard *et al*, however. It is just as selective and apparently agenda-driven. The Tobacco Claimants make the following specific points:
>
> (1) First, the paper begins with what appears to be a lament that decisions taken in the public domain having serious economic consequences for participants in particular industries (the complaint apparently extends beyond the tobacco industry to the food and alcohol industries) may be subject to the requirements of "*Better Regulation*". This is a policy which the authors criticise as being "*underpinned by neoliberal assumptions concerning business competitiveness, and official guidance* [...] *that regulation should not 'impose costs and obligations' on business and other groups 'unless a robust and compelling case has been made'*". The authors' dislike of Better Regulation leads them to criticise PMI, for example, for

> holding the view that "'*evidence based argumentation'* [is] *a strength of its corporate strategy in opposing SP*" and for believing that "*the prospect of 'government ignoring Better Regulation principles'* [was] *a threat to it*" (page 12). The authors also question the value in the Government scrutinising evidence that has received public funding and been through a peer review process.
>
> (2) Second, the paper is so selective as to be of limited use. Having identified that, between them, JTI and BAT had submitted 1264 pages of documentation to the 2012 consultation, the authors analysed only 19 pages of BAT's submissions (4 pages of one of its expert reports and 15 pages of its consultation response) and only 86 pages of JTI's material. This approach is partly justified in the paper on the basis that it had taken "*one experienced full-time researcher 26 working days to analyse 105 pages, an average of 4 pages per day*.
>
> Third, having cherry-picked particular pages of evidence, the authors proceed to subject those pages to an absurd degree of scrutiny, having little to do with the true message conveyed by the documents. BAT, for example, is accused of quoting evidence in a "*misleading*" way because it submitted that the Department of Health had "*concluded*" in the context of the 2008 consultation on the Future of Tobacco Control that: "*the research evidence into* [plain packaging] *is speculative, relying on asking people what they might do in a certain situation.*" This quotation is undeniably accurate, however. It was stated as a fact within the 2008 consultation (which has never been denied by the defendant as having been accurate; and which the authors do not deny). The stated fact led to the statement that: "[t]*he assumption is that changes in the packaging will lead to changes in behaviour*", all of which appeared under the heading "*Potential disadvantages of plain packaging*." The accusation that BAT quoted 'misleadingly' merely because it described the stated fact as a "*conclusion*" is therefore itself misleading, in so far as it suggests that the stated fact was one not accepted to be true by the defendant.
>
> Fourth, other criticisms are no less pedantic ("[s]*ome industry experts referred to parts of their reports that would normally be labelled 'appendix' or 'chapter' as 'exhibits'*)".

(6) Analysis and conclusions

368. I set out below my conclusions on this issue.

369. First, I accept that the best practice principles set out above and advanced by the Secretary of State and applied by him in the Consultation and in this litigation are (i) an accurate reflection of the best practices used and accepted throughout the

international research community and (ii) are relevant and applicable to the assessment of evidence submitted in the course of a consultation leading up to the adoption of an administrative or legislative measure.

370. Second, the application of each of the best practice principles will be context specific. They do not apply in any absolute manner but must be applied flexibly to take account of the circumstances of the particular case. Adherence to best practice is, however, at a premium in a case such as this where the Claimants have already been found wanting at the level of international governmental opinion and in proceedings before the US courts. The FCTC and WHO Guidelines are unique instruments of international law and practice and they are relevant in law as non-binding guidance to the evaluation that I must make of the evidence.

371. Third, Article 6 ECHR and common law rules of fairness do apply. There is nothing in the FCTC which would permit a decision maker or Court ruling inadmissible evidence simply because it emanated from a tobacco company or from an expert instructed by a tobacco company. The principles should apply across the board to all of the evidence adduced in these proceedings, albeit that the operation and application of the rules might differ as between different experts and parties.

372. Fourth, the fact that an expert is instructed and paid for by one side of an argument does not mean that the expert is, *thereby*, necessarily biased or compromised or has a conflict of interest. However, the fact that an expert is instructed by a body with a clear partisan interest highlights the real importance of that expert adhering to recognised and applicable best standards and to rules of procedure and evidence, such as those laid down in CPR 35.

373. Fifth, the best practice rules are relevant and applicable to the specific facts of the present case, namely the assessment of evidence relating to the impact of standardised packaging on consumption and prevalence. There is nothing in the facts of this case which are *sui genesis* or special and which make the normal best practice rules irrelevant. It is in this respect relevant that the WHO guidelines were treated as admissible and relevant by Advocate General Kokott and the Court in *Philip Morris* (see paragraphs [256] – [260] above) and are referred to in recitals [7] and [24] to the TPD (see paragraphs [229] and [231] above) as a source of guidance to the application and interpretation of EU law in this particular field. The Court of Justice equally considered the Guidelines to be of very great and potentially decisive influence.

374. Sixth, on the basis of my own review of the methodologies adopted by the Claimants' experts in the light of the Secretary of State's evidence on this issue I conclude that that body of expert evidence does not accord with internationally recognised best practice. This is most striking in the context of the evidence submitted during the consultation; but it applies also to a considerable portion of the evidence placed before the Court in relation to other grounds of challenge. This is of course a generalisation about the corpus of evidence as a whole and my criticisms do not apply with equal force to every witness (as I make clear throughout this judgment).

375. Seventh, the four most significant ways in which evidence submitted during the consultation generally fell below best practice are (i) the fact that it was not peer reviewed or based upon peer reviewed material; (ii) the fact that it was not

benchmarked against internal documents[14]; (iii) the fact that the underlying worldwide literature base was largely ignored; and (iv) the fact that it was not verifiable.

376. In conclusion, I am of the clear view that if and insofar as only "*limited*" weight was attached to the Claimants' evidence then this was reasonable, justified and proper. In any event, even if the Claimants' evidence was wrongly accorded "limited" weight there is no actual evidence that this conclusion affected the views of Parliament. The criticism is that civil servants wrongly discounted the evidence but for this then to have tainted the affirmative resolution procedure there needs to be some evidence that this adverse conclusion fed through into Parliament's deliberations. There is no such evidence. Had such a tainting occurred it would have been manifest in the 2014 December Submission (see paragraphs [125] – [133] above) but that document fairly reflects the Claimants' submissions. And further that view would also, in turn, have had to infect Parliament's consideration. However, the Claimants did not identify in the course of the hearing how this could have occurred. Finally, there is an additional more fundamental obstacle: the proportionality assessment I have to make is based upon the evidence as it stands as of the date of judgment, not that as of the date of promulgation of the Regulations. Even if civil servants erred in discounting the Claimants' evidence in 2014, what matters is the state of that evidence before the Court in 2016.

(7) The BAT ground of challenge: Particular criticisms of the methodologies used by BAT's experts

(i) The issue

377. I turn now to the particular criticism advanced only by BAT as to the treatment of its own experts during the consultation which applies even if, otherwise, the Secretary of State acted lawfully in relation to the generality of the evidence tendered during the consultation. BAT submits that the sheer quantity and quality of *its* evidence singles it out and that, regardless of how the other evidence of other Claimants was treated, the

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[14] I note that the tobacco companies have themselves in the past adopted an aggressive approach towards the internal documents of Government officials. The following illustrates their approach to one such document that they considered to be relevant and probative. In the witness statement of Ms Laura Oates, Head of Government Relations at Gallaher Limited, the witness explained that in August 2011 as a result of a FOIA request made by another tobacco manufacturer, JTI obtained an email dated 10th May 2011 sent by a civil servant working for the Defendant to the Australian Department of Health and Ageing which stated:

> "As I'm sure you're aware, one of the difficulties regarding [the introduction of plain packaging for tobacco products] is that nobody has done this and therefore, there isn't any hard evidence to show that it works".

Ms Oates then explained how JTI sought to capitalise upon this internal document. On 8th April 2013 it reproduced it, in full, in a press advertisement published in national newspapers and magazines. The advertisement was subject to investigation by the Advertising Standards Authority who, on 18th July 2014, held that the advert misleadingly: "*...implied that no real evidence existed to support the introduction of plain packaging at the time the ad appeared*". JTI then referred that decision to the Independent Reviewer of ASA Adjudications, Sir Hayden Phillips, upon the basis that it was unreasonable, illogical and unsustainable. JTI submitted that there remained no hard evidence at the time the advertisement appeared in 2013 that plain packaging worked. On 30th October 2014 Sir Hayden Phillips notified JTI that he was minded to conclude that the ASA had misinterpreted the natural meaning of the advertisement. However, on 7th January 2015 the ASA decided to stand by its original determination.

Secretary of State acted unlawfully in giving insufficient weight to the BAT submissions.

378. My starting point is that my general conclusions above apply equally to BAT. The fact that the *quantity* of expert evidence tendered by BAT was more substantial does not improve BAT's position. It is quality not quantity that matters.

(ii) Professor Hammond's conclusion on methodology

379. In relation to BAT Professor Hammond reviewed the reports tendered. In this section of the judgment I summarise some (but not all) of the main objections taken as regards the methodology adopted by BAT's experts. The criticisms focus upon: the competence of the particular author to opine on smoking behaviour; the extent to which the experts dismiss the vast majority of existing research and the grounds for so doing; the extent to which the experts rely upon peer-reviewed literature; and the extent to which the experts make assertions without proof and/or fail to corroborate or benchmark their observations against internal tobacco company documents when this could be expected to be relevant.

380. I have also set out my <u>own</u> conclusions about particular pieces of expert evidence specifically relied upon by BAT (and in particular the opinion of Professor Klick).

(iii) McKeganey

381. I have set out my own comments on this evidence at paragraph [314] – [315] above. In relation to the report of Professor McKeganey which reviewed the evidence that standardised packaging would reduce smoking prevalence Professor Hammond started by observing that Professor McKeganey's CV indicated only two peer-reviewed publications in the area of smoking behaviour: as a third author on a cross-sectional survey on drug use and a publication based upon a BAT-commissioned report. Professor McKeganey rejected the "vast majority" of experimental evidence on standardised packaging upon the basis that it did not take account of evidence of "actual" consumption patterns in the light of standardised packaging. He stated:

> "The neglect of the vast majority of plain packaging studies to measure smokers' actual tobacco use following exposure to plain versus branded packaging, let alone whether any change is statistically or clinically meaningful, is undoubtedly the single greatest methodological weakness of plain packaging studies that sought to inform the potential effectiveness of a population-level behaviour change intervention. Instead, plain packaging research to date has been characterised by assessment of smokers' and non-smokers' attitudes, beliefs, and intentions as they relate to plain packaging and starting/stopping smoking".

382. In relation to the non-use of internal documents Professor Hammond states:

> "On the topic of cigarette packaging addressed in McKeganey's report, to my knowledge none of the major tobacco companies has published or made public any of the hundreds and possibly

> thousands of studies they have undertaken on cigarette packaging, brand imagery and related marketing practices. It would also appear that they have not provided McKeganey with this evidence in the preparation of his report, despite the fact that this evidence is directly related to the issues he has been asked to review".

383. Professor Hammond pointed out that the vast majority of researchers conclude that attitudes, beliefs and intentions represent important mediating variables in models of health behaviour change and consumer behaviour. He pointed out also that Professor McKeganey's own work includes qualitative studies in addition to surveys of attitudes and beliefs as the basis for treatment and policy recommendations. He also pointed out that the type of evidence now required by Professor McKeganey was unattainable and that at the time of the adoption of the Regulations by the Defendant standardised packaging was a novel intervention and that it was therefore impossible to collect adequate naturalistic data on the effects of removing tobacco branding from packs on smoking behaviour. It is relevant that Professor McKeganey does not engage with the express findings in the US Judgment, based in part on internal documents, which established that promotional efforts, including branding, did have a causal effect upon consumer behaviour. I have set out at paragraphs [306] – [310] above the conclusions reached in the *US judgment* by Judge Kessler and at paragraphs [301] - [305] the conclusions of the WHO based upon these internal documents.

(iv) Mitchell

384. Professor Hammond also reviewed the expert material of Professor Mitchell prepared on behalf of BAT which sought to address how adolescents make decisions about health-related behaviours. He is critical of his conclusions upon the basis, inter alia, that he does not address the underlying literature and research base:

> "Mitchell's failure to identify the relevant research literature betrays a general lack of familiarity with smoking behaviour. Indeed, I could not identify a single peer-reviewed publication or research grant in the area of tobacco use or smoking behaviour on Mitchell's CV. In the absence of expertise in the area, it is incumbent upon an expert to review the most relevant and direct evidence. Mitchell's failure to consult the evidence base to inform his opinions is characteristic of the report. Mitchell's opinions are primarily based on literature not specific to smoking behaviour, or amount to outright speculation".

(v) Viscusi

385. Professor Viscusi was instructed on behalf of BAT to address the potential effect of standardised packaging upon the efficacy of health warnings and false beliefs about the harmfulness of tobacco products. BAT relied upon this evidence to support the statement that the risks of smoking had been universally known in the UK for decades. Professor Hammond's essential criticism of Professor Viscusi is that the evidence he relies upon is selective. Professor Hammond, in his report, pointed to the relevant parts of various documents relied upon by Professor Viscusi which were not

referred to but which countered the propositions Professor Viscusi advanced. He also relied upon other studies and research, not referred to by Professor Viscusi, which contradicted the Professor's conclusion. He was highly critical of Professor Viscusi for neglecting the role of addiction in perceptions of risk. Professor Hammond cited literature upon this issue. He also cited internal documents from Brown and Williamson from 1978 which contradicted the conclusions of Professor Viscusi. Internal documents from the tobacco companies suggested that very few consumers were aware of the effects of nicotine and in particular its addictive nature and that it was treated as a poison. Professor Hammond accepted that UK consumers (now) had a greater general awareness that smoking is harmful but he said that there were serious deficits in their knowledge and understanding of the attendant risks. He observed that Professor Viscusi's selective approach ignored evidence which undermined the conclusion that consumers do not have any "information deficits". He stated:

> "Viscusi's failure to mention these data from the same report that he cites represents either a lack of rigour or a deliberate omission, particularly his emphasis on measures of "awareness", for which measures of spontaneous recall are far more relevant than the measures of agreement that are cited in Viscusi's Report".

386. Elsewhere, he identified a number of observations, statements and conclusions drawn by Professor Viscusi. But he then said:

> "Viscusi does not provide a single citation or reference in support of these statements. Nor does he account for the dozens of peer-reviewed studies – including experimental studies, cohort studies and quasi-experimental studies – indicating that recent enhancements to health warnings in terms of their size and message content have significantly increased their effectiveness, with respect to informing the public of the risks of smoking and promoting cessation behaviour".

387. Under the heading "Failure to review literature" Professor Hammond stated:

> "The Viscusi Report fails to provide a full or accurate account of the research literature on key issues, such as when discussing the impact of health warning sizes. As the basis for his opinion that the size of health warnings does not matter, Viscusi cites a single report commissioned by Philip Morris. The report has not been published or peer-reviewed, and omits data published during the last four years, including articles directly relevant to health warning size and standardised packaging. Viscusi also refers to a study of pictorial warnings conducted on behalf of the US Food and Drug Administration (FDA). Again, Viscusi fails to reference the peer-reviewed literature, which includes an empirical analysis of the same question addressed by the FDA study using improved data, which clearly demonstrates the effectiveness of larger pictorial health warnings.

> When suggesting that the design of health warnings has no impact on their noticeability, Viscusi provides a single citation to an unspecified reference in a book that he himself authored. The Viscusi Report appears to totally disregard not only the published literature in the area of tobacco health warnings, but the broader field of health warnings.
>
> Viscusi also offers an opinion regarding the impact of cigarette branding with respect to the influence of pack colour on consumer perceptions:
>
> > "There is no evidence demonstrating the link of any colour to undermining the efficacy of the warnings or misleading consumers as to the risks of smoking".
>
> As described…there is extensive evidence demonstrating how the colour of cigarette packages influences consumer perceptions and is associated with false beliefs. However, the Viscusi Report completely disregards this literature".

For the sake of completeness it is right to record that Professor Viscusi responded to Professor Hammond's criticisms, rejecting them.

(vi) Devinney

388. Professor Devinney is a vigorous critic of peer review. He is an expert instructed by JTI, not BAT. His views on peer review are shared by others, such as Professor Klick below. I refer to it here to show that BAT's criticisms of peer review were shared by others. Professor Devinney says this:

> "Finally, it is my view that the Chantler Report places undue weight on the fact that the studies have been peer-reviewed, or that the Systematic Reviews ascribed to standards of the Cochrane Collaboration.
>
> … there are also known biases in the peer-review process that tend to generate more positive outcomes than negative outcomes…and also concerns that hot topics and those for which there is financial, personal and political investment are more likely to be published with erroneous findings".

389. Professor Hammond responded, with an unconcealed air of incredulity:

> "Devinney proceeds to argue that journals in his field are far more stringent than public health and medical journals, and provides a number of outdated and outright incorrect statistics on journal acceptance rates and times to publication. Regardless of Devinney's personal opinion, peer-review remains the basis for scientific standards, along with comprehensive independent reviews of the evidence base, such as those included in the US Surgeon General's Report".

390. He also highlighted the observation by Professor Devinney that:

> "The hotter a scientific field (with more scientists involved), the less likely the research findings are to be true".

391. He describes this as "*...a puzzling and irrelevant factor with which to criticise a research literature*". His overall conclusion about the approach of Professor Devinney is that his analysis represented a "*...highly unusual framework for evaluating the quality of the literature and provide[s] little or no insight as to the merit of the empirical evidence base*". Professor Hammond devoted 75 paragraphs to a methodological critique of Professor Devinney's report.

(vii) Klick

392. I turn now to Professor Klick. He was retained by BAT to offer an opinion upon the literature regarding the effects of plain packaging on smoking rates. Professor Klick is a professor of law at the University of Pennsylvania; he is also the Erasmus Chair of Empirical Legal Studies at Erasmus University Rotterdam. I was invited by Counsel for BAT to pay *especial* attention to this report: I have. Before turning to the observations of Professor Hammond I therefore offer a number of my own conclusions about this evidence which I confess to finding unsatisfactory in multiple respects. First, although Professor Klick was expressly retained to offer his opinion on the literature regarding the effect of plain packaging on smoking rates in the UK the report does no such thing. In fact it cites remarkably few pieces of actual literature relating to the issue in question. The preponderant part of his opinion seeks to rebut the proposition that peer-review literature produced by independent authors provides a reliable basis upon which to found *any* conclusion. Secondly, there is a remarkable symmetry between the ultimate conclusion arrived at by Professor Klick and the methodological approach adopted by the Claimants generally, which is that it is not possible, using qualitative or quantitative research results pre-dating the Australian experience, to evaluate the impact of a standardised packaging policy in practice. The thrust of his attack, therefore, is to undermine the relevance and weight to be attached to *all* prior literature.

393. The following, which refers to the experts reviewed by the Stirling reviewers, characterises Professors Klick's rhetorical approach:

> "Apparently there is a belief that experts have some magical insight into an issue in which there is no real evidence, spinning the straw of flawed and inapt studies into policy gold. Although the world would be a better place if such predictions were possible, the record on the accuracy of expert predictions is not good, even in fields where the underlying research is of substantially higher quality than exists on the issue of plain packaging".

394. In relation to the numbers contained in the 2014 Impact Assessments he says that since these were prepared by individuals who are not impartial the result is that they can fill in "*whatever numbers they want*" i.e. suggesting that the data has been fabricated. In fact he treats those who have worked for Government or who have produced research literature which is consistent with the Defendants' pro-standardised

packaging proposals as at risk of being subject to "*confirmation bias*" i.e. the subconscious desire to prove one's personal predisposition. He says that this is "*egregious*".

395. I would have found this analytical approach more attractive if Professor Klick had any experience in the specific field of smoking or had undertaken his own research or had conducted detailed analysis of the *actual* literature instead of airily dismissing it in its entirety. Professor Klick's criticisms operate at the highest level of abstraction and assertion and he makes no serious or detailed attempt to engage with the actual literature base that he is so profoundly dismissive of. The conclusion of Professor Klick is that existing literature provides neither a reliable nor relevant foundation for legislation. He is particularly critical because, he says, the existing literature is not "*predictive of real world smoking choices*". He also concludes that the existing studies are irrelevant because in a regime where all packs are plain the effect of the Regulations will dissipate as smokers become better acquainted with plain packs. He then says this:

> "Even putting these crucial relevant issues aside, the methods used in the plain packaging literature are flawed. Virtually every study uses self-selected samples, and the lack of double blind designs makes it likely that subjects are influenced by the expectations and preferences of the researcher. Finally, given the policy preferences of the public health community, this is an area where publication bias is likely to be present. Each of these flaws likely overstates the true magnitude of any effect of plain packaging on stated intentions and subjective impressions.
>
> Multiple studies with the same underlying flaws do not magically remedy those flaws. In such a case, consistency of results provides better evidence of the consistency of the flaws than it does of the accuracy of the general conclusion. *The scientifically honest approach to this literature is to infer that we have no sound evidence about the likely effects of plain packaging on smoking outcomes*".
>
> (Emphasis added)

396. The inference to be drawn from Professor Klick's analysis is that it is scientifically *dishonest* to conclude that the pre-existing literature base has any probative weight whatsoever. Equally damning is the following conclusion:

> "…the proposal to rely on surveys of experts to resolve the irreducible uncertainty on this issue is absurd".

397. His counterblast continues in the same tone:

> "On issues where empirical evidence is wholly absent, consensus does not magically transform speculation into sound science. Studies of forecasts by experts generally find them to be very inaccurate and biased. This has been true across a wide

> range of scientific and social scientific fields. The Department of Health's proposed method of recruitment virtually ensures that any such bias will be compounded as the DOH has conceded it will not seek impartial parties. Its sample of experts will systematically draw from individuals who have demonstrated a willingness to draw conclusions about the efficacy of plain packaging even though none of the existing studies provides a sound basis for such conclusions. Indeed many of the individuals and the sample pool have publically advocated for plain packaging despite the absence of a scientific foundation for such policies".

398. Professor Klick has an impressive academic teaching CV. He has published widely on an array of different topics ranging from terrorism through to mental health insurance. He has however, from a perusal of his CV, no relevant experience in empirical qualitative or quantitative analysis of the effects of advertising upon smoking prevalence or use. As such it is difficult to see how he can properly express a view on the underlying literature base or as to the "*real world*" when he does not even address on any systematic basis the actual literature on the topic. He also, like other experts, fails to engage with the damning findings in the US courts which include a finding that the various sorts of promotional, branding and advertising activities deployed by the tobacco companies do, in the "*real world*", - causally - exert tangible effects, which is exactly what the pre-existing literature base predicts. At the start of his opinion he says that his role is to assess the literature on plain packaging. However he nowhere goes on to do this. There is now a substantial body of peer reviewed pieces of research that exist in the literature base. In his opinion Professor Klick cites just 3 and even then in no detail at all confining himself to setting out only his overall conclusion which is simply that they are flawed. Professor Klick ends with this observation: "*This is not an area where expertise can make up for the dearth of evidence*".

399. The opinion of Professor Klick was prepared in June 2012. It has not been updated. It has not since then been subjected to peer-review. It has however been tendered in the course of this litigation as relevant to the Claimants' proportionality challenges without even a statement of truth being attached to it. It is not CPR compliant. I could have declared it inadmissible. Yet I was invited to accord it real weight in the context of issues arising in this litigation. Had it been peer reviewed then it could well have received a barrage of (critical) comment and had this occurred it is questionable whether it would have been tendered as evidence in this case at all; or if it had it would then have been capable of being benchmarked against such peer review commentary.

400. Professor Hammond makes a number of similar points. First, he points out the inconsistency between the conclusion and Professor Klick's acknowledgement that the purpose of his opinion is not to discuss methodological issues in great depth. Secondly, he points out that the report was dated June 2012 and that a major limitation therein lies in the fact that it is outdated and incomplete because it fails to account for any post-implementation evidence or peer-reviewed literature released in the past three years. Thirdly, he points out that the features of the underlying research which are described by Professor Klick as weaknesses are in fact, according to

standard (i.e. normally accepted) benchmarks, indicators of quality. Fourthly, he points out that a number of Professor Klick's recommendations for research design would be described by researchers in the field as "*completely unfeasible*". He states:

> "Klick's threshold for acceptable behavioural outcomes is completely unfeasible and his recommendations for collecting this data verge on absurdity".

(viii) Faber

401. Professor Hammond also challenges the methodological approach of the Faber Report prepared on behalf of BAT which discusses the role of trade marks and the brands that they represent. The conclusion of Professor Faber is that trade marks are a key element in branding that assist consumers to identify brands and distinguish between competing brands and that they play an important role in forming brand identity. The thrust of the report is that advertising can stimulate primary demand when a consumer product category is relatively new but ceases to do so in "mature" markets that have reached a sufficiently large size such that incremental growth is less likely. There is a considerable amount of this report that Professor Hammond does not challenge. However, he points out that the report's conclusions, as applied to standardised packaging, fail to address or take account of relevant evidential matters such as the impact of the FCTC or the fact that no other consumer product has been subjected to the same type of marketing restrictions as have tobacco products and that accordingly the general marketing principles upon which Faber relies are inapplicable or largely inapplicable to the effects of marketing and branding for cigarettes. He then says this about the data sources relied upon by Professor Faber:

> "The only source of empirical evidence that can bear on this question is from the cigarette market itself. Unfortunately, Faber has not provided any analysis specific to changes in the tobacco market or any citations to comprehensive reviews of the effect of marketing restrictions for tobacco products. These reviews conclude that comprehensive advertising restrictions are indeed responsible for reductions in primary demand".

402. Professor Hammond points out that there is extensive scientific data relating to the extent of exposure of adolescents to cigarette advertising; the extent to which adolescents find advertising appealing; the effect of advertising upon prevalence and use; and, the effect of advertising upon the desire of adolescents to smoke. From my own review of the background literature sources this is a correct conclusion. Professor Hammond points out that this literature has not been addressed by Professor Faber. Elsewhere, Professor Hammond criticises Professor Faber (for example, in relation to the question of whether brand differentiation under standardised packaging would lead to lower prices and would impact upon demand), upon the basis that Professor Faber is neither an expert in this particular area nor, to plug any gap in expertise, has he reviewed the relevant literature. His conclusion is that: "*Faber's opinion on the effects of standardised packaging amounts to speculation without empirical justification*".

(ix) This Court's cross-referencing exercise

403. I repeat that I have not simply accepted Professor Hammond's criticisms without verification. I have come to my own conclusions as to: (a) the applicable best practice standards to apply; and (b), the extent to which the BAT evidence matches up to these standards. I have already set out (see paragraph [344] above) that my own cross-referencing of Professor Hammond's methodological criticisms substantially bears out Professor Hammond's conclusions about methodology.

(8) Conclusions

404. In conclusion I reject the complaint that the Secretary of State acted unlawfully in attributing "*limited*" weight to either the generality of the tobacco industry evidence or more specifically BAT's evidence during the consultation process. I am of the conclusion that, measured against internationally accepted research and evidence standards, that evidence, as a generality, was materially below par. However I am also of the conclusion that even if there had been an error of evaluation by civil servants of that evidence, including that specifically tendered by BAT, it could not or did not affect the decision making process leading up to promulgation of the Regulations by Parliament.

G. GROUND 3: PROPORTIONALITY – THE REGULATIONS ARE INAPPROPRIATE

(1) The issue

405. The Claimants advance 3 discrete challenges based on the proportionality test. I address the first one only in this section and the other two as Grounds 4 and 5 in Sections H and I below. The first ground is that the Regulations are a disproportionate restriction on the Claimants' fundamental rights and freedoms because they will fail to meet their stated objective of improving public health and as such they fail to satisfy the appropriateness limb of the proportionality test. The Claimants raise proportionality as a free-standing ground of challenge but it also plays an important part in their grounds relating to the alleged unlawful expropriation of property (under EU and ECHR law) dealt with under Grounds 6 and 7 below.

(2) The Claimants' submissions in outline

406. In broad terms the Claimants put their case on proportionality in the following way:

> "The Claimants' case is that the Defendant has failed to discharge the burden he bears of proving that the Regulations are proportionate. In particular:
>
> (a) The objective of the Regulations is "*improving public health by reducing smoking*". The Defendant has failed to demonstrate that the Regulations are suitable or appropriate to meet this objective because it has failed to establish that the Regulations will cause a material decrease in smoking rather than an increase".

The Claimants submit that the Defendant must (the burden being upon him) prove to the requisite (civil) standard that:

> "(a) The Regulations are, on the balance of probabilities, more likely to cause a decrease in smoking than an increase".

407. The Claimants submit that the empirical evidence on the impact of smoking in Australia post-implementation of standardised packaging rules demonstrates that: (a) standardised packaging has caused downtrading to increase at record rates; (b) it is several times more likely that standardised packaging has caused smoking in Australia to increase than to decrease; and (c), the 2014 Impact Assessment's estimate of the likely effect of standardised packaging was wrong. It is submitted that Australian post-implementation evidence is both compelling and ousts and renders irrelevant all pre-existing qualitative research.

(3) The test to be applied to the evidence and its practical application

408. In this area the law has developed significantly in recent years. It was agreed between the parties (and as I set out below) that on the basis of this law: it was for the Court to decide upon the application of the proportionality principle to the facts; that it should do this upon the basis of the best up to date scientific information and evidence; that there was a margin of discretion to be afforded to the decision maker; and, that the extent of that margin was context specific. There is also no serious dispute to the proposition that the Court must examine the facts in detail and that this judicial task is not to be confused with the intensity of review: A Court might have to work very hard in order to come to the conclusion that the margin of appreciation was broad and that the decision taken was within that margin. The level of detail into which a Court delves, and the "margin of appreciation", are two quite different things.

409. Before setting out the relevant legal principles I start with a practical issue, which is *how* as a matter of *actual practice* and *process* a Court in a judicial review is to approach the evaluation of what may be a voluminous and complex body of technical evidence. The question arises because the standard starting approach of Courts in the past has been to "label" the case according to the test to be applied to the evidence, for instance a test of "*manifest inappropriateness*". Once this categorisation exercise had been undertaken that in large measure governed the intensity of the review that followed and often dictated the result. However, in a series of recent judgments from the Supreme Court and the Court of Justice it has been confirmed that in a proportionality case the Court must decide the question for itself based upon the most up to date scientific evidence. A number of judgments of the Supreme Court have emphasised that the evaluation to be performed by the Court is "*exacting*" and thorough. Yet at the same time the Court is to have regard to the appropriate margin of appreciation. The Courts have not, however, then gone on to explain how, in workaday practical terms, this is to be performed, especially in circumstances (such as arise in the present case) where substantial new evidence has emerged which, in consequence, the decision maker has not addressed prior to taking the decision.

410. In this case there was a debate as to the proper label for the test that I should apply. The Claimants eschewed any test of manifest in/appropriateness. They pointed out that in *Lumsdon*, at paragraph [38], the Supreme Court identified a category of case which they said covered the present facts namely where: "*Member States rely on*

reservations or derogations in EU legislation in order to introduce measures restricting fundamental freedoms". In such cases the Supreme Court observed that: "*proportionality is generally applied more strictly, subject to the qualification we have mentioned*". The "qualification" referred to concerned cases: "*Where member states adopt measures implementing EU legislation, they are generally contributing towards the integration of the internal market, rather than seeking to limit it in their national interests*".

411. In this case, and in particular in relation to the first proportionality challenge, the parties have placed before the Court an enormous volume of psychological, sociological, economic and econometric analysis and commentary thereupon. Much of this (and in particular the econometric analysis) was tendered only shortly before the hearing. Some is based upon complex maths, some amounts to narrative which describes detailed econometric analysis which was conducted by the experts in question off-line, some describes the results of psychological or biometric analysis or research, and some relates to conclusions from surveys, focus groups and elicitation studies. Only a small portion was in fact made the subject of detailed oral submissions. A good deal of it was referred to only in written submissions or in footnotes. I have however read it *all*, in detail.

412. During the course of oral argument I posed to the parties the question of <u>how</u> a Court was to be expected to absorb and then process material of this volume and complexity. This question resulted in helpful analysis from the parties of how overarching principles of judicial review translated in the context of Court proceedings into practical, nuts and bolts, forensic analysis. The question was at its most acute in relation to the extensive econometric regression analyses submitted by the parties. As to this the Claimants submitted that it was the <u>only</u> evidence before the Court which was capable of "*going to the critical point*" - "*the regressions are all that is before the Court*". And it was the "*only*" evidence in the view of the Claimants because it was based upon actual market developments in Australia following implementation there of standardised packaging measures and it thus stood in sharp contrast to the evidence relied upon by the Secretary of State prior to the promulgation of the Regulations which was in large measure based upon flimsy and insubstantial predictive qualitative and soft-edged research about possible or likely consumer reactions to changes in branding and design but which did not measure <u>actual</u> outcomes.

413. In relation to the judicial task the Claimants were however clear: "*We are not asking the Court to decide what the effect of [standardised packaging] has in fact been in Australia*".

414. Instead the Claimants invited the Court "*... to find that the Defendant has not discharged the burden on it of demonstrating that the regulations are a suitable measure for improving public health*". And in this context they invited the Court to accept the quantitative econometric analysis conducted by their principal econometric expert (Professor Mulligan) and to reject the quantitative evidence submitted by the expert acting for the Secretary of State (Professor Chaloupka) upon the basis that it "*...is flawed and [the Defendant has] no reasonable answer to the evidence of Professor Mulligan*".

415. With regard to the dispute between the expert evidence of Professor Mulligan and that of Professor Chaloupka the Claimants acknowledged that there were many aspects of the dispute about which reasonable experts could disagree and that therefore it was not unreasonable for the Secretary of State to rely upon Professor Chaloupka in those particular respects. However, they also submitted that there were certain errors in the analysis and reasoning of Professor Chaloupka which were so obvious that they were "*hard edged*" and capable of being categorised as such by the Court. The submission (in a form characterised by the Secretary of State to which the Claimants then responded) boiled down to this:

> "Models 2 and 3 are so fundamentally flawed for "hard edged" reasons so they can be disregarded. These "hard edged" reasons are that:
>
> > (a) Professor Chaloupka's model does not provide for any dynamic adjustment of prevalence in response to price. Without accounting for the time lag impact of changes in prices his models fail to correctly take account of the impact of price changes.
> >
> > (b) Professor Chaloupka's arguments that applying highly correlated measures to the same models creates confounding effects can be dismissed because all that need to be ensured in that packaging effects are not confounded with price effects.
> >
> > (c) Professor Chaloupka's points on the impact of including highly correlated points is only a criticisms of Professor Mulligan's band aid solution – and not a reasonable defence of his own model for the time lag impact of changes in prices.
>
> It is a pure question of who is right and who is wrong".

416. The Claimants explained further what they meant by a "*hard edged*" error of reasoning and did so in terms which, in fact, provided a broader set of terms of reference for a judicial review in this area:

> "Our case is that, at the very least, if we have raised a question or identified a flaw which (i) appears to the Court to be reasonable, and (ii) is material to the proportionality of the Regulations, then the Court must require that the Defendant provide a response to that point and must review the reasonableness of that response. If there is no (adequate) response or the response is not reasonable, then the Court must quash the measure. This is what we mean by a hard edged point. Anything less than that is no judicial review at all".

417. The approach adopted by the Claimants has much to commend it at least as a starting point, especially where the evidence base is in large measure based upon experts instructed by the parties. The approach reflects the fact that the State has the initial

burden of proof. It also accepts that the Court cannot be asked to decide the merits or demerits of the underlying dispute save where there are clear and unequivocal black/white, right/wrong, answers. These are what the Claimants describe as the "hard edged" issues or errors. They include: straightforward mathematical errors[15]; common sense errors (including common sense economic errors[16]); errors of logic[17]; errors in the inferences that may be drawn from primary facts; failures on the part of the decision maker to take into account relevant material; and, errors on the part of the decision maker in taking into account irrelevant matters. This list of examples is not intended to be exhaustive.

418. A Court might also grant relief not because of any obvious howling error but because, having worked its way through the proportionality test and applied a proper margin of appreciation, it simply comes to the end result that the measure fails the test (see *Gibraltar Betting & Gaming* (ibid) paragraphs [100]-[101]). A case might also be decided simply upon the view of the Court as to the probative balance of the evidence. In weighing up admissible evidence the Court can (and in my judgment should) take account of the extent to which expert research evidence and material meets accepted methodological standards and norms. In a case where there is conflicting evidence it may be wholly rational to prefer and endorse one set of evidence upon the basis that it is methodologically superior to a material degree to the competing evidence. In this case I have found fault on this score with the Claimants' evidence. But in another case it is possible that a claimant's evidence will far outshine in probative value that of the decision maker and that might also be a reason for granting relief. I can see little reason why a decision maker's margin of appreciation should extend to basing a decision upon evidence which on analysis falls materially short of normal, acceptable, standards of evidence.

419. The Secretary of State did not significantly disagree with this overall approach. He did not for instance argue that the exacting methodological standards that his own experts espoused should not be applied equally to experts supporting tobacco control. In his written submissions he also submitted that it was not necessary for the Court to decide on the merits of the disputes arising between the competing expert economists and econometrician: "*It is sufficient that Professor Chaloupka and Hammond have shown that the issue in dispute, concerning the future effects of the Regulations on the behaviour of children and adults in the UK, are issues on which reasonable experts may disagree on reasonable grounds"*. It followed, in the submission of the Secretary of State, that they did not have to prove that the expert evidence upon which they relied was "*more accurate*" than that of the Claimants' experts, only that it was reasonable.

420. At base the Court is assessing the reasonableness of the evidence advanced by the State to justify the disputed measure. This is not classic broad brush "*Wednesbury*"

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[15] See e.g. *R v Gibraltar Betting & Gaming association Ltd v Secretary of State for Culture Media and Sport* [2014] EWHC 3236 (Admin) at paragraph [100]: "*An error in the placing of a decimal point may exert profound consequences upon the logic of a measure*" and may be manifestly inappropriate for that reason even though the error is exceedingly difficulty to unearth.

[16] See e.g. *R (British Academy of Songwriters, Composers and Authors et ors) v Secretary of State for Business, Innovation and Skills* [2015] EWHC 28 at paragraphs [245] – [270].

[17] See e.g. the Court of Justice in *Scotch Whisky* (ibid) in relation to the nexus between tax and minimum price measures for alcohol. The Court did not (because it was a reference from a national court) decide the case but it nonetheless made its position as to the facts clear.

reasonableness; it is a rationality challenge the intensity of which is calibrated according to a range of variable policy factors which are context specific but it is a challenge which nonetheless requires detailed judicial engagement with the facts.

421. The margin of appreciation is not ignored in this process. Factors relevant to it are fed into the assessment of rationality/reasonableness. For instance, it is more reasonable for a decision maker to take a decision upon the basis of a relatively underdeveloped evidence base if the case can properly be categorised as "precautionary"; or, where there are planned reviews within a relatively short period of time when a more substantial and mature evidence base can be assessed. Equally, if the Court is examining new scientific evidence which was not therefore in front of the decision maker then a Court would give less weight to the fact that the decision maker was the legislature[18].

422. There is one further point by way of preface to make: In a complex area, how does the Court actually work out whether in fact there are "hard edged" errors? As to this I agree with the Claimants that if, to test the argument, there *are* such hard edged and material errors in the reasoning which led to the adoption of the disputed measure then a Court should not reject the case just because it is complex and the answer difficult to unearth. This was the tenor of the point also made by the Supreme Court in *Lumsdon* at paragraph [44]. In some cases the hard edged errors can be deduced through logic or elementary common sense. But often the howling error might involve the Court understanding complex scientific or economic evidence before its flawed nature comes to light. But parties to litigation have to recognise that Courts have limits. The legal teams representing complex arguments to a Court will have spent months if not years with their clients and the experts in preparation. They are, by the very nature of the trial preparation process, further up the learning curve than the Court might ever be. Further, the success or failure of a judicial review should not (cannot) depend upon the particular ability of an *individual* judge to grapple with complex economic and technical evidence. The answer in my view has to lie in process.

423. To enable a Court, confidently, to resolve such issues it is incumbent upon the parties to engage in a detailed and if needs be exhaustive pre-hearing process which breaks down all of the issues and which results in the highest degree of agreement possible between the parties. The aim and object of this process must be to place before the Court the smallest possible number of real and material unresolved disputes, together with a clear road map as to how the Court is to resolve them. If necessary outstanding disputes between the parties could be subjected to third party expert review or opinion in order to assist the Court. If some process such as this is not engaged in I have a real fear that otherwise strong and viable judicial review challenges will fail simply because the demands placed upon the Court are too great. I have addressed this is greater detail at paragraphs [630] – [648] below.

(4) General principles of law governing the principle of proportionality to be applied under EU and ECHR law

(i) Proportionality

[18] This seems to me to be consistent with the approach of the Supreme Court in *R(Lord Carlisle of Berriew QC et ors) v SSHD* [2014] UKSC 60 per Lord Sumption at paragraph [34].

424. In this part of the judgment, and notwithstanding that this section addresses only the first of the Claimants' 3 proportionality challenges, I have set out my conclusions on the law of proportionality fully. In particular I set out the approach to be adopted to the evidence and the types of factors which are capable in a case such as this of affecting the margin of appreciation which govern the intensity of review. I deal with supplementary legal points relevant to other aspects of the test in the sections dealing with the other proportionality challenges.

425. The test to be applied is that of proportionality. Proportionality is a general principle of EU law enshrined in the Treaties and it is inherent in the application of the ECHR. Article 3(6) Treaty on European Union ("TEU") states:

> "The Union shall pursue its objectives by appropriate means commensurate with the competences which are conferred upon it in the Treaties".

Article 5(4) TEU of the states:

> "Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties".

426. The principle has been subject to extensive but not always consistent exegesis in the case law of both the Court of Justice in Luxembourg and the European Court of Human Rights in Strasbourg. The Supreme Court has pointed out that the test is different under EU law and under the ECHR. This is not particularly helpful in a case such as the present where the Claimants invoke overlapping proportionality challenges under both EU law (including the Fundamental Charter) and under the ECHR in relation to exactly the same facts. Given that under EU law the Fundamental Charter must be construed in accordance with the ECHR the judicial exercise becomes one of intellectual gymnastics if the two tests are different but must be construed to be consistent. In the event, for the reasons that I set out below, I do not believe that the differences are significant and I have found that the same result arises regardless of which jurisprudential regime applies.

(ii) The position under EU law

427. The principle as it applies under EU law was considered by the Supreme Court in the case of *R (on the application of Lumsdon) v Legal Services Board* [2015] UKSC 41 ("*Lumsdon"*).

428. According to the jurisprudence proportionality as a general principle of EU law involves a consideration of two questions. First, whether the measure in question is suitable or appropriate to achieve the objective pursued (the Appropriateness test). Second, whether the measure is necessary to achieve that objective, or whether it could be attained by a less onerous method (the Necessity test). Each of these questions implicitly contains other questions. For example, the first question necessarily involves identifying the objective pursued and determining that it is a legitimate objective in and of itself to pursue. If the objective sought to be pursued is illegitimate it can hardly be rendered legitimate simply because the means adopted to achieve that (*ex hypothesi*) illegitimate end are "appropriate". This means that any

Court ruling upon the issue must in fact consider (i) the aims of the measure and its legitimacy; (ii) whether the measure in question is *suitable* or *appropriate* to achieve the (legitimate) aims pursued; and (iii) whether the measure is *necessary* to achieve that objective, i.e. determining whether if there is a choice of equally effective alternative measures which would achieve the aim that the least restrictive measure has been adopted.

429. Some debate exists as to whether there is a further (fourth) question ("proportionality *stricto sensu*") which is whether the burden imposed by the measure is disproportionate to the benefits secured. In some cases, the Court of Justice has omitted this question from its formulation of the proportionality principle but, as was noted by the Supreme Court in *Lumsdon*, where the question has been argued the Court tends to include it in its formulation and addresses it separately: see e.g. Case C-331/88 *R v Minister for Agriculture, Fisheries and Food, Ex p Fedesa* [1990] ECR I-4023. It was also addressed in *Philip Morris* (see paragraphs [271] – [272] above). This is the basis of the third of the Claimants' proportionality challenges: See Ground 5 below, Section I at paragraphs [680ff].

430. It can thus be seen that although it has been said that there are only 2 limbs in fact there are either 3 or 4 limbs to the EU test.

(iii) The position under ECHR law

431. The test under the Human Rights Act 1998 and the ECHR contains four parts. It was articulated by the Supreme Court in *Bank Mellat v Her Majesty's Treasury (No 2)* [2013] UKSC 39 by Lord Sumption (giving the judgment of the majority) in relation to the justification under domestic law (in particular, under the Human Rights Act 1998) of interferences with fundamental rights. Lord Sumption (at paragraph [20]), having cited relevant case law stated the following:

> "20. Their effect can be sufficiently summarised for present purposes by saying that the question depends on an exacting analysis of the factual case advanced in defence of the measure, in order to determine (i) whether its objective is sufficiently important to justify the limitation of a fundamental right; (ii) whether it is rationally connected to the objective; (iii) whether a less intrusive measure could have been used; and (iv) whether, having regard to these matters and to the severity of the consequences, a fair balance has been struck between the rights of the individual and the interests of the community. These four requirements are logically separate, but in practice they inevitably overlap because the same facts are likely to be relevant to more than one of them".

Thus the four component parts of the test are: First, whether the objective of the measure is sufficiently important to justify limiting a fundamental right (i.e. the *legitimacy* of the aim); second, whether the measure adopted is rationally connected to the objective; third, whether the measure goes no further than is necessary to achieve the objective, or whether a less intrusive measure could have been chosen which would achieve the objective to the same extent; and fourth, whether the impact of the rights infringement is disproportionate to the likely benefit of the impugned

measure (or in other words, whether, having regard to the severity of the consequences, a fair balance has been struck between the rights of the individual and the interests of the community). It is recognised that although the parts can be separately identified in practice the evidence relevant to each may overlap.

432. The test under the ECHR is strongly reflective of the test in EU law if (a) it is accepted that the first part of the EU test does involve an analysis of the objective being pursued and its legitimacy and (b) the so-called proportionality *stricto sensu* component of the test is applied and amounts in practice to the ECHR "fair balance" test.

(iv) Intensity of the application of the test: Avoiding an excessively schematic approach

433. A significant issue in the present case is the intensity with which the Court must apply the proportionality test to the facts. In *Lumsdon* the Court was influenced by the categorisation of the rights said to be trespassed upon by the impugned measure. Thus the Court divided up its analysis into various categories such as: challenges to measures of EU institutions (cf. paragraphs [40ff]); national measures derogating from fundamental freedoms (paragraphs [50ff]); and national measures implementing EU measures (paragraphs [73ff]). *However*, and in my view importantly and correctly, the Court was careful to emphasise that the analysis was always fact and context sensitive and that the true starting point was the rationale of the underlying rule and the context. As such the classification of cases under different headings was no more than a convenient and useful *aide* to analysis. The Court took the following as its critical point of departure:

> "34. … the other critical aspect of the principle of proportionality is the intensity with which it is applied. In that regard, the court has been influenced by a wide range of factors, and the intensity with which the principle has been applied has varied accordingly. It is possible to distinguish certain broad categories of case. It is however important to avoid an excessively schematic approach, since the jurisprudence indicates that the principle of proportionality is flexible in its application. The court's case law applying the principle in one context cannot necessarily be treated as a reliable guide to how the principle will be applied in another context: it is necessary to examine how in practice the court has applied the principle in the particular context in question".

434. The sorts of broad considerations which the Court identified, from case law, as relevant (on the facts of that case) included: (i) the nature and importance of the "private interest" being derogated or departed from (paragraph [36]); (ii) the importance of the public interest being prayed in aid to justify the departure from the competing private right; (iii) the need in an EU case to prevent unnecessary barriers to free movement and market integration (paragraph [37]); (iv) the extent to which the alleged derogation itself furthered a recognised social policy of the EU (paragraph [37]); (v) the extent to which the national measure derogated from free movement in an area where the EU had not legislated but where it was said that the derogating measure furthered an important consumer protection policy in the Member State (such

as the protection of the consumer against gambling in the case of *Gibraltar Betting & Gaming Association Ltd v Secretary of State for Culture Media and Sport* [2014] EWHC 3236 (Admin) ("*Gibraltar Betting*") cited with apparent approval in *Lumsdon* ibid at paragraph [38]).

435. The point, that an overly rigid schematic approach should be eschewed, is important in this case because it does not fit easily into the scheme of case types identified by the Supreme Court. I have set out the sorts of considerations that do affect this case below.

(v) The date upon which the evidence is to be assessed

436. In *Scotch Whisky* the Court of Justice was considering how a national Court should review a decision of a national legislature which was taken within the broad context of EU law. The Court stated (ibid paragraph [62]) that EU law had to be complied with at all relevant times, including at adoption, or implementation if later than adoption.

437. The Court must assess the compatibility of the measure on the date on which it gives its ruling (*Scotch Whisky* paragraph [63]). In that assessment, the Court must take into consideration "*any*" relevant information, evidence or other material of which it has knowledge under the conditions laid down by national law (ibid paragraph [64]). In the present case, this is an important point and it bears upon the weight that is to be attributed to other factors which are relevant to the scope of the margin of appreciation. In *Scotch Whisky* (at paragraph [64]) the Court of Justice thus stated that where a legislature has promulgated a measure "*…where there appears to be scientific uncertainty*" the duty on the Court that, subsequently, hears the case is to take into account "*any relevant information, evidence or material of which it has knowledge*". This serves to exemplify the point that factors which were relevant, in the past, to the decision maker's margin of appreciation may become less so over time. This has obvious implications for the relationship between the Courts and legislatures. But in my judgment it does not imply that the margin of appreciation is irrelevant. To the contrary, it means that the reviewing Court must modify the factors so that they are current and up to date but the Court must still remember that it is measuring the legality of a legislative or administrative measure. The process remains judicial review not a *de novo* merits hearing.

(vi) The importance of public health considerations

438. The Regulations are health measures. This is an area of legislative activity to which immense importance is attached and legislatures and decision makers are habitually accorded a wide margin of appreciation. Health is recognized as a fundamental right. Article 35 of the Fundamental Charter identifies access to health care as a fundamental right but <u>also</u> makes a statement as to the weight to be attached to this right, namely "high":

> "Health care
>
> Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of

> human health protection shall be ensured in the definition and implementation of all Union policies and activities".

439. The adoption of policies by the state to avoid and prevent consumer products causing medical problems is itself recognised as important: Article 38 of the Fundamental Charter states:

> "Consumer protection
>
> Union policies shall ensure a high level of consumer protection".

440. The TFEU makes clear that the Union has competence, in conjunction with the Member States, for the adoption of measures to promote public health and, moreover, that these are important obligations and can, indeed, take precedence over other "fundamental" rights contained in the Treaty. Article 4(k) TFEU identifies public health matters as an area of shared competence between the European Union and the Member States. Article 6 confers upon the EU competence to carry out actions to support, coordinate or supplement the actions of Member States in, *inter alia*, the area of "*protection and improvement of human health"*. Article 9 TFEU buttresses this objective by requiring the Union in the formulation of all of its policies to protect public health. Article 36 TFEU expressly sanctions and condones derogations from the free movement of goods on grounds of public health. Article 45 TFEU permits derogations from the free movement of workers on grounds, inter alia, of "*public health*", and, equivalent derogations are found from the right of freedom of establishment in Article 52 TFEU. Article 114(3) TFEU makes clear that when adopting legislative measures relating to the internal market the Union shall take a high level of health protection as its starting point.

441. Articles 168 TFEU (on public health) and 169 TFEU (on consumer protection) are especially important. They emphasise how the protection of public health is to be placed at the epicentre of policy making and also how the setting of EU policy is to take account of the work of international organisations (which obviously includes the WHO) and how "*all*" EU policies must ensure a "*high level of human health protection*". The Member States retain a high degree of discretion:

> "*Article 168*
>
> 1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities. Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health. The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas. Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.

3. The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:

> (a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;
>
> (b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;
>
> (c) measures setting high standards of quality and safety for medicinal products and devices for medical use.

5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.

> 6. The Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.
>
> 7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.
>
> Article 169
>
> 1. In order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests.
>
> 2. The Union shall contribute to the attainment of the objectives referred to in paragraph 1 through:
>
> > a) measures adopted pursuant to Article 114 in the context of the completion of the internal market;
> >
> > (b) measures which support, supplement and monitor the policy pursued by the Member States.
>
> 3. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, shall adopt the measures referred to in paragraph 2(b).
>
> 4. Measures adopted pursuant to paragraph 3 shall not prevent any Member State from maintaining or introducing more stringent protective measures. Such measures must be compatible with the Treaties. The Commission shall be notified of them".

(vii) Detailed assessment regardless of the level of intensity of review / rolling the judicial sleeves up

442. I have already observed that in *Lumsdon* (ibid paragraph [44]) the Supreme Court distinguished between the judicial task and the margin of appreciation; see also *Gibraltar Betting* (ibid) at paragraphs [96] – [98] to the same effect. Even in cases where the margin of appreciation is at its highest (such as where the test for striking down a measure is that it is *"manifestly inappropriate*") it is wrong to suppose that the Court's scrutiny of the justification for the measure is cursory or perfunctory. While the Court might be slow to substitute its own evaluative judgment for that of

the primary decision-maker it will still need to consider in appropriate depth the factual foundation and reasoning underlying the proportionality of the impugned measure. In *Bank Mellat* (ibid) Lord Sumption referred to an "*exacting analysis*" of the facts advanced by the State to justify a measure (cf. paragraph [20]).

(viii) The prospective nature of the decision

443. The consultative exercise conducted by the Secretary of State prior to the laying of draft Regulations before Parliament was prospective; it sought to predict the health outcomes in a future counterfactual market where advertising or branding on packaging and on products was substantially outlawed. The United Kingdom, along with Australia, is an "early adopter" of such prohibitive rules so that unless it can be said that either (i) evidence from Australia is not only compelling but also an apt comparator to the United Kingdom or (ii) the answer is one which is in any event capable of exact computation, then inevitably Parliament was making a judgment call based upon advice about consequences which were inherently uncertain. The same applies to the approach to be adopted by this Court though, since time to some degree has marched on, the evaluation may be less prospective than it was when performed by the initial decision maker.

444. In *Jippes v Minister van Landblow Natuurbehere en Visserif* [2001] ECR I-5689 the Court of Justice, albeit in a case involving the Community legislature, stated at paragraph [84]:

> "Where the Community legislature is obliged to assess the future effects of rules to be adopted and those effects cannot be accurately foreseen, its assessment is open to criticism only if it appears manifestly incorrect in the light of the information available to it at the time of the adoption of the rules in question".

445. The logic of the point applies equally when legislative measures are being taken by national legislatures, especially when that is in the context of supportive international and EU law. Where there are uncertainties in the state of scientific knowledge this serves to broaden the margin of appreciation enjoyed by the State and this is especially the case in the area of public health: See e.g. Case 174/82 *Sandoz* [1983] ECR 2445; Case 174/84 *Commission v Federal Republic of Germany* [1987] ECR 1262. In *Lumsdon* at paragraph [43] the Supreme Court in similar vein stated: "*... the legality of an EU measure cannot depend on a retrospective check on a predictive assessment*". It is no good being wise in hindsight. And the Court of Justice endorsed the same point in *Scotch Whisky* (ibid at paragraph [57]) which *was* concerned with national (not EU) legislative measures.

(ix) Areas of partial harmonisation

446. In *Lumsdon* the Court expressly acknowledged the existence of a margin of appreciation in the area of partially harmonised health measures:

> "The court has also accepted that, where a relevant public interest is engaged in an area where EU law has not imposed complete harmonisation, the Member State possesses

> "discretion" (or, as it has sometimes said, a "margin of appreciation") not only in choosing an appropriate measure but also in deciding on the level of protection to be given to the public interest in question. This can be seen, for example, in cases where the public interest relied on is the protection of human life and health, such as *Apothekerkammer des Saarlandes v Saarland and Ministerium für Justiz, Gesundheit und Soziales* (Joined Cases C-171/07 and C-172/07) [2009] ECR I-4171, which concerned a rule restricting the ownership of pharmacies. The Court stated:
>
> > "... it is for the member states to determine the level of protection which they wish to afford to public health and the way in which that level is to be achieved. Since the level may vary from one member state to another, member states must be allowed discretion". (para 19)

447. The Court of Justice has, in the past, been unimpressed, in areas of activity where Member States enjoy this kind of discretion by arguments that one Member State's regulatory scheme is disproportionate because another's is less restrictive. This is illustrated by the case of Case C-110/05 *Commission of the European Communities v Italian Republic* [2009] ECR I-519, which was concerned with a ban on a type of trailer, on the ground of road safety. The Court said:

> "61. In the absence of fully harmonising provisions at Community level, it is for the member states to decide upon the level at which they wish to ensure road safety in their territory, whilst taking account of the requirements of the free movement of goods within the European Community ...
>
> 65. With regard ... to whether the said prohibition is necessary, account must be taken of the fact that, in accordance with the case-law of the court referred to in para 61 of the present judgment, in the field of road safety a member state may determine the degree of protection which it wishes to apply in regard to such safety and the way in which that degree of protection is to be achieved. Since that degree of protection may vary from one member state to the other, member states must be allowed a margin of appreciation and, consequently, the fact that one member state imposes less strict rules than another member state does not mean that the latter's rules are disproportionate".

(x) Complex evaluations involving political, economic or social choices

448. Where the evaluation is a complex economic or social or scientific one this also feeds into the breadth of the margin of appreciation. To the extent that the Member State exercises a discretion involving political, economic or social choices, especially where a complex assessment is required, the reviewing Court may be slow to interfere with that evaluation. In applying the proportionality test in circumstances of that nature, the Court of Justice has applied a "manifestly disproportionate" test: see, for

example, Case C-44/94 *R v Minister of Agriculture, Fisheries and Food, Ex p National Federation of Fishermen's Organisations and Others* [1995] ECR I-3115, paragraph [58]. The Court may nevertheless examine the underlying facts and reasoning: see, for example, Case C-120/97 *Upjohn Ltd v Licensing Authority established by the Medicines Act 1968* [1999] ECR I-223, paragraphs [34] – [35]. The Supreme Court in *Lumsdon* was doubtful whether a manifest error approach was proper. There is an inconsistency in the way that the Courts have labelled the test to be applied. As I have explained above in my view, a far more helpful approach is to adopt a fact and context sensitive approach as the Supreme Court in *Lumsdon* recognised was in fact the way to proceed.

449. In *Lumsdon* the Supreme Court disagreed with the majority of the Court of Appeal in *R (Sinclair Collis Ltd) v Secretary of State for Health* [2011] EWCA Civ 437 ("*Sinclair Collis*") that in cases of public health the test was always one of manifest inappropriateness. They agreed with the conclusions of the Lord Justice Clerk, Lord Carloway, in the Scottish *Sinclair Collis Ltd v Lord Advocate* [2012] CSIH 80; 2013 SC 221 ("*Sinclair Collis Ltd*") who stated:

> "... 'manifestly inappropriate' is language used by the ECJ in relation to testing EU institution measures (or national measures implementing EU law) (see e.g. *R* v *Secretary of State for Health, Ex p British American Tobacco (Investments)* [2002] ECR I-11453, para 123). There the balance is between private and public interests. It is not applicable when testing the legitimacy of state measures against fundamental principles contained in the EU Treaties where the balance is between EU and state interests". (para 56)

At the same time, Lord Carloway recognised that there was "*a margin of appreciation*" afforded to the state not only in determining the general health objective of reducing smoking but also in selecting the manner in which the reduction in health risk is to be achieved.

(xi) The status of the decision maker

450. The decision maker here is Parliament promulgating the Regulations by affirmative resolution. In *Gibraltar Betting* (ibid) I stated that a factor relevant to the margin of appreciation was the status of the decision maker. I drew a distinction between those cases where the alleged error was on the part of Parliament in respect of a clear point of law and those where the challenge was to policy choices for regulation. The issue in that case was whether an *ex ante* regulatory regime based upon place of consumption of the service in issue (consumers of gambling received in the United Kingdom) in contrast to regulation based upon place of supply (i.e. Gibraltar) was valid. I recognised that even in such cases a challenge could occur but that the standard of proof was high. I stated:

> "112. The GA 2005 as amended is an Act of Parliament: This case is not a "*Factortame*" type case where it is said that the Act of Parliament is flawed in a clear and legally identifiable way because (as there) it discriminated on grounds of nationality. Here the challenge is to structural policy choices

> made for the purpose of regulation. All of the case law underscores the point that an Act of Parliament is at the apex of the exercise of the democratic decision making process. A court should only interfere with the GA 2005 if there are fundamental errors or where the policy choices adopted are wholly unsupported by evidence or unconnected with any lawful policy objective and cannot on any logical or sensible basis be said to be consistent with the various limbs of the proportionality test".

451. In *Sinclair Collis* the Court of Appeal accepted that the strictness with which the EU proportionality principle was applied to a national measure restricting a fundamental freedom could depend on the identity of the national decision-maker (whether, for example, it was a minister or Parliament) (see paragraph [136]). However Lord Carloway in the Scottish equivalent case (*Sinclair Collis Ltd*) questioned the proposition that the strictness with which the EU proportionality principle was applied to a national measure restricting a fundamental freedom should depend on the identity of the national decision-maker. Lord Carloway commented (at paragraph [59]):

> "... the court has reservations about whether the margin can vary in accordance with the nature of the particular organ of the state which creates or implements the measure. It might appear strange if the manner in which a EU member state elects to organise government within its borders were capable of increasing or decreasing the margin of appreciation available to that state relative to measures challenged as infringing one of the EU Treaties' fundamental principles. The legality of a measure ought not to depend upon whether a measure is passed by a central, national, provincial or local government legislature or determined by an official or subsidiary body under delegated authority from such a legislature".

452. In *Lumsdon* the Supreme Court, albeit with a degree of circumspection, left the issue open (ibid at paragraph [81]):

> "There is force in the point made by Lord Carloway; and it is difficult to discern in the court's case law any clear indication that the identity or status of the national authority whose action is under review is a factor which influences the intensity of scrutiny. On the other hand, we would not rule out the possibility that whether, for example, a measure has been taken at the apex of democratic decision-making within a member state might, at least in some contexts, be relevant to an assessment of its proportionality, particularly in relation to the level of protection considered to be appropriate and the choice of method for ensuring it. It is however unnecessary to resolve that question for the purposes of the present appeal".

453. In *Bank Mellat* (ibid) the Supreme Court under the ECHR adopted a slightly different view in relation to measures adopted by affirmative resolution calling for

"*considerable caution*" before a Court intervenes; this was later endorsed by the Supreme Court in *SG & Ors* (ibid); See paragraph [149] above.

454. It seems to me that the fact that the Regulations are adopted by Parliament by affirmative resolution purporting to exercise a power conferred by the Council of Ministers and the Parliament of the EU in the TPD and which is intended to apply *erga omnes* across Europe and which is itself contemplated by an International law Convention promulgated by the WHO and to which the United Kingdom and the EU are signatory, might just be the sort of case which attracts some added gravitational pull in the proportionality scales. If it does not in a case such as this it is hard to imagine circumstances where it ever could. The force of the point is, however, diluted somewhat because I am required to assess evidence that was not before the decision maker so that it never exercised a margin of appreciation over that evidence. In my view, this does not, however, strip the consideration of all of its relevance. In any event a substantial part of the evidence relied upon by the Secretary of State in the litigation was in existence when Parliament legislated.

(xii) Review within five years

455. The TPD sets out a mandatory review of the legislation in the light of experience within 5 years. The Regulations do likewise. See paragraph [250] above. It is a relevant consideration that the Regulations are not set in stone. If for instance at the end of five years' experience in the UK and in Australia pointed unequivocally to the conclusion that standardised packaging was counterproductive to health then one would expect the relevant provisions of the TPD and/or Regulations to be reviewed and possibly revoked or at least modified.

456. In the present case, the 2014 Impact Assessment indicated that there would be a review. It pointed out that upon implementation monitoring could occur of the consequences and effects and that this on-going review would enable adjustments and other measures designed to mitigate any unintended consequences (such as impact on cross border trade or the size of the illicit market): See 2014 Impact Assessment at paragraph [38].

457. The willingness of the State to review the efficacy of a measure against the posited objectives has been recognised by the Courts as a factor militating in favour of the proportionality of an impugned measure. Logic dictates that the margin of appreciation of a State that is committed to reviewing efficacy should be greater than for one that intends resolutely to lay down a rigid and immutable policy within no acknowledged possibility of future review.

458. In *Gibraltar Betting* (ibid) the fact that the decision maker was prepared to review the decision within a reasonable period of time was a factor which militated in favour of a conclusion that the decision was proportionate (ibid paragraph [117]). This is because, in a case where it is not possible with exactitude or certainty to quantify in advance of the introduction of a policy what the impact will be, there can be no certainty that the expected policy benefits will necessarily obtain. As such, and if they do not transpire, hindsight may establish that the measure was disproportionate. Accordingly it is good administrative practice for such decisions to be subject to a review process to ensure that a decision that is ostensibly reasonable and proportionate on day zero, can be kept under review as the evidence base solidifies.

459. The same point was acknowledged as relevant in *Lumsdon* (ibid). At paragraph [60] the Court stated: "*Particularly in situations where a measure is introduced on a precautionary basis, with correspondingly less by way of an evidential base to support the particular restrictions imposed, it may well be relevant to its proportionality to consider whether it is subject to review in the light of experience*". The Court noted that the "QASA" scheme under challenge (which concerned a scheme to assess the quality of advocacy in the criminal Courts) was to be reviewed in due course (ibid paragraphs [100] and [110]) and this was a relevant consideration in favour of its ultimate conclusion that the decision to introduce the scheme was proportionate.

460. In *Scotch Whisky* the Court of Justice treated as (favourably) relevant to proportionality the existence of a six year sunset mechanism on a minimum price measure. The logic is that a measure that has a limited lifespan, and, *a fortiori* will be periodically reviewed, is intrinsically less restrictive than a permanent measure (ibid paragraph [57]).

(xiii) The views of the European Commission

461. In previous case law the view of the European Commission has been held to have some possible, though limited, significance. In *Gibraltar Betting* (ibid) the High Court, citing an observation by Lady Justice Arden in *Sinclair Collis* stated:

> "123. Views of the European Commission: Mr Beal QC referred me to the fact that the Commission, being fully cognizant of the dispute, has not proceeded against the United Kingdom in infraction proceedings for breach of Article 56 TFEU or otherwise objected. The Government has placed before the Commission all of the principal documents that were before this Court. The Commission has also been the recipient of complaints from the Claimant association and from the State of Malta and the Commission has received justification from the Government. In my view a Court can place some modest weight upon this. But the mere fact that the Commission has not objected does not necessarily mean that a clean bill of health has been given to the United Kingdom. It is well known that the Commission prioritises its complaints and does not commence infraction proceedings in relation to every violation that it suspects has occurred. In *Sinclair Collis* Lady Justice Arden observed (ibid para [113]) that it was "*…not completely without significance*" that the Commission had not taken action against the United Kingdom. I think that this limited statement is about as far as this point goes".

462. The position in the present case is somewhat different. Under Article 24(2) TPD the United Kingdom was under a duty to notify the European Commission in draft of its proposed implementation of standardised packaging rules. It did this pursuant to both Article 24(2) and the Technical Standards Directive well before the deadline and the Commission did not in any way object (see paragraphs [121] – [124] above). A procedure exists whereby other Member States can express their views and the Commission can then issue an opinion, for example, objecting to the proposed

measure. The position of the Secretary of State is that Commission silence is deemed to amount to approval albeit of a qualified type which does not in the future preclude the Commission from taking action against the Member State and nor does it preclude national Courts from deciding whether the measure infringes EU law.

463. In my judgment this is an accurate reflection of the status of the Commission silence. It is notable in this regard that the TPD was adopted pursuant to Article 114 TFEU which sets out a formal procedure whereby at the end of six months following notification if there has been no objection from the Commission the measure is "approved". It is common ground in this case that the formal Treaty procedure does not apply. Nonetheless Article 24(2) is adopted pursuant to that Treaty provision and as such it is capable of providing some guidance as to the status of the procedure under the TPD. Read in the light of Article 114 it could have been argued that silence by the Commission created a harder edged approval but the Secretary of State does not so contend. For present purposes I am content to adopt the softer edged approach of the Secretary of State. Nonetheless, it is evident that the ability of Member States to introduce standardised packaging is one that is subject to close supervision by the Commission and it is equally clear that the Commission has not objected. The fact remains that even though the Commission received a number of conflicting opinions from the Member States, including objections, it has not expressed any hostility towards the adoption by the United Kingdom of the Regulations. A distinction can be drawn between the facts of the present case and those arising in *Scotch Whisky* (ibid) where a notification of the minimum price measure was notified to the Commission under the Technical Standards Directive and the Commission objected upon the basis that the measure was not justified on public health grounds (ibid paragraph [10]). Clearly every case must be considered according to its own merits but the distinction in treatment between the two cases highlights that the process of Commission scrutiny in this case has been real and meaningful.

(xiv) The consensus position adopted at the level of international law

464. This case is singular in that Parliament has acted in accordance with a consensus formed at the broadest of international levels, i.e. amongst 180 states worldwide and in accordance with an EU directive giving formal legislative expression to that consensus. That consensus is that standardised packaging will contribute to enhanced public health. This area of health regulation is not a policy blank canvass. It is true that the FCTC did not mandate the adoption of standardised packaging and nor has the TPD; but the message conveyed by the Guidelines to the FCTC is clear: standardised packaging is a positive step in the fight to reduce smoking. It is EU policy to reflect the FCTC and the Guidelines. This is a factor which affects and broadens the margin of appreciation. The Court of Justice has in its consistent case law attached considerable weight to the views and opinions on health issues of the WHO: see for example: Case 174/84 *Commission v Federal Republic of Germany* [1987] ECR 1262 at paragraphs [41], [44] and [52]; and Case C-473/98 *Kemikalieinspektionen v Toolex Alpha AB* [2000] ECR I 5702 at paragraph [42]. In *Philip Morris* the Court of Justice attached great weight to the fact that the FCTC was based on best scientific evidence and experience as was "*adopted by consensus*". Even, therefore, the Guidelines could bear "*decisive influence*" on the content of the rules in issue (ibid paragraphs [111] – [113]).

(xv) The precautionary principle

465. The present case illustrates the application of the precautionary principle. Cases involving the protection of public health are seen as paradigm illustrations of sectors where the precautionary principle arises and public health ranks "*foremost*" in the list of interests which may justify impediments to free trade and other fundamental principles: See for example: Case C-473/98 *Kemikalieinspektionen v Toolex Alpha AB* (ibid) at paragraph [38] (which concerned the outright prohibition on the industrial use of a particular chemical).

466. Advocate General Kokott in *Philip Morris* made the same point in the specific context of the TPD: See paragraph [269] above.

467. What is the precautionary principle? This principle states that where the public interest concerns the protection of the public from harm the decision maker may justifiably take a decision to act now rather than to await further information. In *Lumsdon* (ibid) the Court explained how the precautionary principle impacted specifically upon the nature and the quality of the evidence that would suffice to justify a decision to act. The Court explained that in precautionary cases the evidence did not need to be as firmly established or conclusive as it might be in other scenarios. The Court articulated the point in the following way:

> "57. Where goods or services present known and serious risks to the public, the precautionary principle permits member states to forestall anticipated harm, without having to wait until actual harm is demonstrated. The point is illustrated by the case of *Commission of the European Communities v Kingdom of the Netherlands* (Case C-41/02) [2004] ECR I-11375, which concerned a prohibition on the sale of foodstuffs fortified with additives, the justification being the protection of public health. The court held that the existence of risks to health had to be established on the basis of the latest scientific data available at the date of the adoption of the decision. Although, in accordance with the precautionary principle, a member state could take protective measures without having to wait until the existence and gravity of the risks became fully apparent, the risk assessment could not be based on purely hypothetical considerations.
>
> 58. In a case concerned with an authorisation scheme designed to protect public health, the court required it to ensure that authorisation could be refused only if a genuine risk to public health was demonstrated by a detailed assessment using the most reliable scientific data available and the most recent results of international research: *Criminal Proceedings against Greenham and Abel* (Case C-95/01) [2004] ECR I-1333, paras 40-42. As in *Commission of the European Communities v Kingdom of the Netherlands,* the Court acknowledged that such an assessment could reveal uncertainty as to the existence or extent of real risks, and that in such circumstances a member state could take protective measures without having to wait

> until the existence and gravity of those risks were fully demonstrated. The risk assessment could not however be based on purely hypothetical considerations. The approach adopted in these cases is analogous to that adopted in relation to EU measures establishing authorisation schemes designed to protect public health, as for example in the *Alliance for Natural Health* case, discussed earlier.
>
> 59. It is not, however, necessary to establish that the measure was adopted on the basis of studies which justified its adoption: see, for example, *Stoß v Wetteraukreis* (Case C-316/07) [2010] ECR I-8069, para 72".

468. In *Lumsdon* the Court held that the precautionary principle was appropriately applied in the case of standards of criminal advocacy. The Court stated that the core feature of QASA was that every criminal advocate without exception, who wished to practise at one of the upper levels, was required to undertake judicial assessment at the outset. No criminal advocate, competent or incompetent, could slip through that net, and every client therefore had the protection that whoever represented him in a case at an upper level would have been subject to such assessment. As such:

> "115. A precautionary scheme of this kind provides a high level of public protection, precisely because it involves an individual assessment of each provider wishing to practise at an upper level, and it places a corresponding burden on those affected by it. Whether such a level of protection should be provided is exactly the sort of question about which the national decision maker is allowed to exercise its judgment within a margin of appreciation: see paras 64-65 above".

469. With particular regard to the criticism made by the applicants in that case that the evidence base relied upon by the decision maker was inadequate the Court stated:

> "116. It is perfectly true that the evidence did not enable the level of risk to be quantified with any approach to precision, but that did not preclude the Board from considering that it was unacceptable. We do not regard the judgment made by the Board in that regard as falling outside the appropriate margin of appreciation. Since the only way of reducing the risk, so as to provide the desired level of protection for all members of the public involved in criminal proceedings at an upper level, was to have a scheme of the kind proposed by the JAG, it follows that the scheme was proportionate to the objective, notwithstanding the inconvenience caused to competent members of the profession".

470. In *Gibraltar Betting* (ibid) the Court endorsed the use of the precautionary principle in a case involving the protection of consumers from the consequences of on-line gambling. One criticism had been that the evidence base for the use of the principle was inadequate. The Court rejected this approach on the basis of an actual assessment of the evidence which underpinned the challenged decision in order to see whether it

was sufficient, albeit to the lower level required in case where the precautionary principle was in play: See (ibid) paragraphs [155]-[157].

471. The 2014 Impact Assessment provides clear evidence that the precautionary principle was considered by the Secretary of State to be applicable. For instance at paragraph [38] the following is found which reflects both the desirability of acting sooner rather than later notwithstanding the uncertainties arising and which also takes account (in the final bullet point) of the ability to monitor the situation over time and make adjustments:

> "38. The intervention is worth pursuing now, notwithstanding these costs and risks. We believe that the cost of delaying a decision on whether to implement the intervention (Option 3) is too great in public health terms, particularly in view of the following considerations:
>
> - we can already benefit from the experience of Australia in determining the detail of any legislation and in implementing the intervention:
> - the potential health gains are very substantial and dramatically outweigh quantified costs;
> - the deferral of such gains would adversely affect the life expectancy of large cohorts of children and adult would-be quitters in every year of deferral;
> - if the true impact of standardised packaging is substantially smaller than assumed in this IA (but not zero) it would still be net beneficial to act now;
> - evidence from Australia is valuable, but there are considerable uncertainties that will remain;
> - if standardised packaging is implemented, monitoring of extent of impacts, such as any impact on cross-border shopping or the size of the illicit market would identify where mitigating action is needed; the information conveyed by such monitoring is likely to be much more directly pertinent to the policy context in the UK than that which can be gathered from other countries that have implemented the intervention (such as Australia)".

See also Impact Assessment paragraph [315].

472. In my view the precautionary principle applies and it therefore magnifies the margin of appreciation. I can briefly summarise the main reasons: (i) the objective of the measures is public health; (ii) the aim is to reduce the prevalence and use of a product that is recognised at the international law level to be causative of a health epidemic (so the risk of causation is high); (iii) the Secretary of State acknowledges that there are uncertainties about the way in which the Regulations will work in practice and as

to their impact but, on balance, considers that, upon the basis of the evidence as it stands the number of young lives saved or improved will be significant and that this societal gain warrants the introduction of the curative measures now rather than later. In such cases the margin of appreciation extends "*… not only in choosing an appropriate measure but also in deciding on the level of protection to be given to the public interest in question*" (*Lumsdon* (ibid) paragraph [64]).

(5) Proportionality: The components of the Claimants' economic case

473. I turn now to consider the evidence in relation to this limb of the proportionality test. I start by setting out the main components of the Claimants' case. They submit that the case for the Regulations must be established upon the basis of empirical evidence *only* and in particular evidence from Australia which is now available to the Court and which proves the Claimants' case that the Regulations will stimulate demand not suppress it. Parliament adopted the Regulations lacking empirical data and its assessment was therefore inadequate. However since the Court must take into account the most up to date data the new evidence must be considered. Boiled down to bare essentials the Claimants' economic case can be summarised as follows.

474. **Propensity to downtrading**: Standardised packaging has a propensity to increase downtrading. This is where consumers switch to cheaper packs as a consequence of the absence of package branding and advertising. Downtrading causes consumers to pay less, on average, for cigarettes than they would have paid in the absence of downtrading. Consumers switch from buying more expensive cigarettes to cheaper alternatives and it follows that the average price that they pay must be lower.

475. **Absence of competitive discounting**: Downtrading will occur even in the absence of any competitive discounting by the tobacco suppliers i.e. even assuming that unit brand prices remain unchanged (but see below).

476. **Downtrading stimulates demand**: If standardised packaging causes downtrading, and downtrading causes consumers to pay less on average, then, all else being equal, standardised packaging can be expected to result in increased smoking. Smokers will respond to the restrictions by purchasing more cigarettes of a lesser quality.

477. **Illicit trade**: In any event the Regulations will lead to an increase in illicit imports.

478. **Inter-brand competition**: Further, (and based upon the experience in Australia) unit prices are likely to fall as a result of increased inter-brand competition between the manufacturers and this discounting will again "all things being equal" lead to price competition which will also serve to reduce prices and stimulate demand.

479. **No offsetting effects**: The stimulant effect upon demand will not be counteracted and offset by other "intermediary effects" either at all (because they are unproven) or (if they do exist) sufficiently to prevent the net effect of the Regulations being an increase in use/consumption.

480. The Claimants submit that the above points flow from the application of ordinary economic principles and they tendered the evidence of experts (in particular Mr Dryden on behalf of BAT) to establish them. However they also submit that economic theory is irrelevant if one has, in effect, a fully fledged set of data based

upon real life experience which tells one, after the event, what actually happened when standardised packaging was introduced. As to this the Claimants submit that they do have just such data emanating from Australia following implementation there in 2012 of standardised packaging. And they submit that when one subjects this data to (regression) analysis, it shows, to a high degree of statistical confidence, that standardised packaging will prove counterproductive and will hamper and not advance attempts to reduce prevalence and use of tobacco.

481. A good deal of argument thus centred upon the use and relevance of regression analyses in order to prove the extent to which the Australian measure, following implementation, had (or had not) adversely impacted upon use and prevalence of tobacco. The Claimants submit that expert regression analysis conducted by their experts showed clearly and unequivocally that standardised packaging was several times more likely to produce adverse effects than beneficial effects. This was directly relevant to the proportionality test because it demonstrated that the measures were not suitable or appropriate, i.e. not fit for purpose and they would, in actual fact, be counter-productive. Further, this type of regression analysis was the only robust and credible evidence available to the Court. It is based upon actual experience in Australia which is accepted by all to be a valid comparable. It is also based upon hard data generated by public agencies in Australia which can be taken to be reliable. Given its quality it is compelling evidence and ousts the probative value of all other evidence which either predates the Australian experience or which is based upon less thorough and directly relevant evidence. The Defendant's evidence is in contrast low grade. It is predominately based upon qualitative pre-Australian material such as survey results. And in so far as it is based upon post-Australian quantitative regression analyses (such as those performed by Professor Chaloupka) it was riddled through with obvious errors and could confidently be disregarded.

482. Professor Mulligan, who led the quantitative expert evidence case for the Claimants, stated (in his Reply report) that *"... it is not possible to assess what the true effects of the policy will be without considering empirical data on how real consumers have reacted to standardised packaging*". In his First report he criticised the value of qualitative evidence upon the basis that it reflected transient feelings which might never be translated into action. He considered that this point rendered the evidence worthless: *"The basic problem with the majority of the evidence relied on by the Impact Assessment is that it relates to attitudes and beliefs about smoking, or perceptions about the possible impact of standardised packaging. However, attitudes, beliefs and perceptions do not, by themselves, prevent or reduce smoking-related illnesses. Only changes in individual smoking behaviour can do that. .... A focus group or survey participant can talk freely about their intention to quit smoking without making any of the sacrifices that accompany actually quitting*". The proposition that good intentions might not be translated into action is no doubt true as an abstract principle; but whether that means that evidence of attitudes is irrelevant as a predictor of future behaviour is quite another matter. I address this issue at paragraphs [561] – [568] below.

(6) Terminology: Counterfactuals, qualitative and quantitative evidence, and regression analysis

483. The expert evidence was replete with technical terms. I do not in this judgment provide any sort of an explanation of these terms. However, to aid comprehension I

do need to explain some very basic terms. I start by providing a broad explanation of some key expressions.

484. **"Counterfactuals"**: The appraisal that has to occur is generally called a "counterfactual analysis" – it examines how something (e.g. a particular market) will occur in a future altered environment. Counterfactual analysis is routine in regulatory decision making. For example when competition regulators consider how two companies will behave in a market for a particular good or service once they have merged to form a single entity they have to postulate how the new (merged) entity will act if the merger is allowed to proceed and is not blocked. The regulator must decide whether, for instance, consumers will be better or worse off because in the hypothetical market prices will rise and product or service quality will deteriorate. The decision maker must ask whether the state of competition in this new and hypothetical market will be such as to maintain on the new merged entity sufficient competitive pressure to ensure that it keeps prices down and quality of goods and services up. Similar sorts of counterfactual analysis occurs in the field of planning and environmental development: how will a local environment react (e.g. in respect of pollution or noise) if a development is permitted?

485. **"Quantitative" and "qualitative" evidence**: "Quantitative" and "qualitative" as descriptions of evidence are loose terms. "Quantitative" data refers generally to observations and research results expressed in numbers. "Qualitative" evidence is evidence based upon matters other than numbers such as surveys or focus groups' comments, or reports of human reactions to scientific or psychological experiments or tests. Because quantitative evidence is based upon numbers it is capable of being verified and its probative value or reliability can therefore become a function of the robustness of the methodology used in the research. If the methodology is watertight and all of the underlying assumptions are verifiable and correct then the end result may be said to be very reliable. Qualitative evidence may of course be generated through methodologies which are more or less robust, such as the number of persons in the sample, or whether it is "cross-sectional" or "longitudinal"[19].

486. **Regression analysis**: The term "regression" in common parlance suggests some form of backward looking movement towards a previous and generally worse or more primitive state or condition. In fact in the present context it is used in an essentially prospective sense and asks whether and how a situation market will move (regress) into the future under assumed variable scenarios[20].

487. Regression analysis is a common statistical tool used to investigate relationships between variables. The investigator will seek to ascertain the causal effect of one variable upon another. A classic illustration is the impact of a price increase upon demand. In order to conduct this inquiry the compiler assembles data on the relevant

[19] Longitudinal surveys refer to surveys of the same person over time and are usually considered to have a higher degree of reliability attached to them than cross-sectional surveys which relate to surveys of different people at the same time but not subsequently repeated.

[20] The expression "regression" was first used in the mid 19th century by biologists to explain how over time (measured by successive generations) the heights of those descending from tall forbears tended to reduce down to the average height (regression to the mean). The earliest use of regression analysis was at the start of the 19th century by scientists who used it predict the orbit of bodies (comets and minor planets) around the sun.

underlying variables and then employs regression to estimate the quantitative effect of the causal variables upon the variable that they influence. The inquiry will also normally assess the "statistical significance" of the estimated relationships i.e. the degree of confidence that the true relationship is close to the estimated relationship. In the present case the counterfactual being assessed is the use and prevalence of tobacco in a market where standardised packaging as mandated by the Regulations is operative. Many factors operate upon use and prevalence: tax and excise duty; prior regulatory restrictions; the pricing policies of individual tobacco companies; etc. Regression analysis seeks to disentangle these divergent and variable forces in order to measure how only one such force or impetus is working.

488. A complication in the present case lies in the fact that due to the combined effect of existing anti-smoking measures general rates of prevalence and use are declining. The question therefore, in relation to standardised packaging, is not whether the new measures will actually increase prevalence or use rates, but whether the existing rate of decline will accelerate with the advent of the new Regulations (the Defendant's position) or whether it will stall or retard (the Claimants' position). In this judgment when I refer to an increase in prevalence or use in relation to the Claimants' case, or a decrease in relation to the Secretary of State's case, I do so in this particular context.

(7) Qualitative evidence relied upon by the Secretary of State of the existence of intermediate effects

489. In his case before the Court the Secretary of State relied upon both quantitative and qualitative evidence. It is important to set out this evidence because the Secretary of State bears the initial burden of proof. In the text below I summarise both types of evidence in order to determine whether, *prima facie* (i.e. before the application of any other consideration such as margin of appreciation or methodological considerations), the Secretary of State has established that the Regulations are appropriate and suitable to achieve the avowed objective.

490. I start with the qualitative evidence. This evidence is directed at two matters. First, whether there are so called "intermediate" effects, i.e. reduced prevalence due to the increased efficacy of health warnings and/or the reduced appeal of packaging. Second (and critically), whether if there *are* such intermediate effects they would be of sufficient magnitude to offset any negative effects flowing from downtrading. It would only be if this second effect also eventuated that one could then conclude that the overall, or net, effect of standardised packaging would create a positive health effect. In this section I address the first type of evidence, i.e. that relating to the existence of intermediate effects.

491. The Defendant relies upon the expert report of Professor David Hammond (12th September 2015). In that report he, *inter alia*, addressed evidence relating to both the existence of intermediate effects, and, whether such effects were sufficient to offset any, hypothesised, downtrading which led to an increase in use and/or prevalence.

492. In relation to the existence of intermediate effects Professor Hammond reviewed 73 original empirical articles of which 66 concerned the outer packaging of cigarettes and 7 concerned the cigarette sticks themselves. One concerned both outer packaging and cigarette sticks. He summarised each article and included that analysis as an appendix to his report. The research articles derived from a variety of jurisdictions: 15

emanated from Australia, 15 from Canada, 13 from the United Kingdom, 4 from France, 8 from New Zealand, 5 from the United States, 8 from Scotland, 3 from Norway, and one from each of Belgium, Greece and Brazil. Thirty five of the studies included samples of youth prevalence and/ or use and 48 related to adults. Articles in the review consisted of 54 quantitative studies, 13 qualitative studies and 4 studies with both quantitative and qualitative components. In selecting the articles to review Professor Hammond excluded public opinion articles, reviews, and commentaries.

493. In addition Professor Hammond examined 25 published studies relating to the impact of standardised packaging in Australia since the introduction of legislation there. In relation to the Australian literature Professor Hammond divided the material into six types: health warnings; perceptions of risk; consumer appeal; measures of consumer demand and smoking behaviour; post-implementation research from Australia; and research on differences in standardised packaging colours. I set out below, briefly, the conclusions arrived at in relation to this literature.

494. **Enhancement of saliency/effectiveness of health warnings**: First, in relation to the enhancement of the saliency and effectiveness of health warnings three qualitative studies examined how consumer perceptions of health warnings changed when displayed upon standardised packaging. Qualitative research with youth in New Zealand found that pictorial warnings increased the attention paid to graphic warning labels and overall perceptions of harm caused by cigarette smoking and reduced the social appeal of smoking. A second qualitative study relating to youth in Belgium found that health warnings 'catch the eye' more strongly when presented on standardised rather than branded packaging. Qualitative analysis conducted in Australia also concluded that consumers felt that standardised packaging would strengthen the impact of health messages. Five experimental studies examined recall of health warnings. For instance, an experiment amongst Canadian university students in 2013 found that students exhibited greater recall for health warnings on standardised relative to branded packaging. The more up to date literature was consistent with earlier quantitative and qualitative studies from the 1990s. Four studies used eye-tracking objective physiological techniques to assess the impact of standardised packaging on visual attention to health warnings. An eye-tracking experiment conducted in the United Kingdom with young adults involved the number of saccades (i.e. eye movements) towards health warnings in order to assess visual attention. The study concluded that increased visual attention was paid towards health warnings when presented on standardised packaging relative to branded packaging. The effect was observed among non-smokers and weekly smokers but not daily smokers. A second study of eye-tracking in the United Kingdom found similar results among youth. Other studies conducted in the United Kingdom found less of a distinction between daily and other smokers. The impact of standardised packaging on health warnings was assessed on a 'naturalistic' experiment in which young Scottish female smokers used standardised packs for a two week period. The authors found no material difference between pack types in terms on perceived seriousness or believability of health warnings but participants reported looking more intensely at the warning on standardised packaging and reported greater levels of cognitive processing of the message content. Eight studies examined the effect of branding and different types or sizes of health warning. These studies sought to determine whether larger health warnings (leaving less space for branded information) attenuated the effect of branding. Two studies in Canada in 2008 involving both adults and youths

indicated that smoker and product image associations persisted but the significant differences in most outcomes were not observed until the pictorial health warning reached 90% of the principal display area of pack. Research conducted in Australia found that the effect of branding was observable even in the context of large pictorial health warnings. Experiments conducted in New Zealand suggested that standardised packaging and health warnings exerted independent effects upon measures of consumer appeal. A study in New Zealand with young adults found that health warnings exerted a positive, interactive effect with standardised packaging i.e. larger warnings and standardised packaging resulted in lower levels of consumer appeal and demand relative to smaller warnings and standardised packaging. Two experiments conducted in Australia concluded that the largest reductions in consumer appeal were produced when standardised packaging had larger pictorial health warnings. Similar findings were found with respect to perceptions of risk. The conclusion in relation to this particular topic was in the following terms:

> "7.2.7 overall, the evidence suggests that health warnings on standardised packs are more noticeable, are associated with greater recall of health messages, and may lead to greater cognitive processing, particularly among youth non-smokers. The evidence also indicates the effects of package branding persists even in the context of large pictorial warnings, and that standardised packaging and health warnings have complimentary, but independent, effects on consumer perceptions".

495. **Consumer perceptions of risk**: Professor Hammond then turned to the literature that addressed the impact on consumer perceptions of risk. His report focussed upon research specific to perception of risk associated with standardised packaging and pack colour. A number of qualitative studies from New Zealand and Scotland found the consumer perceptions of the relative harm and strength of cigarette branding were associated with pack colour. Qualitative surveys amongst youth in the United Kingdom found similar results. Equally the results of these studies were consistent with a series of qualitative and quantitative studies commissioned by the Australian government prior to the implementation of standardised packaging which found consistent associations with colours. Packs with darker colours were perceived to contain cigarettes which are more 'harmful to health' and 'harder to quit' but packs with lighter colours were seen to be less 'harmful to health' and 'easier to quit' and therefore lower risk. Similar results were found in adult smokers and non-smokers in the United States and France. Pack colour was significantly associated with ratings of reduced risk and tar and standardised packaging were associated with fewer false beliefs about the relative risks of different brands. Equally within-subject experimentation conducted with adult and youth smokers and non-smokers in the United Kingdom found that fewer false health beliefs were associated with standardised packaging. Similar results were found from experiments in Canada, Norway and Brazil. Two studies deployed experimentally-manipulated packaging to assess associations with weight-related beliefs. An experiment with young adult females in Canada found that women who viewed fully-branded female oriented packs were more likely to believe that smoking helped control appetite relative to women who viewed non-female oriented packs or female oriented packs without descriptors or colours. A study in the United States found that branded packs were

significantly more likely to be associated with smoker-image trait 'slimness' than standardised packs. In the United Kingdom an experiment between standardised packaging and health warnings was conducted using function magnetic resonance imaging (MRI) brain scans. When standardised packages were viewed these produced a different pattern of brain activity in areas related to threat (amygdela) and reward (nucleus accumbens), compared to viewing branded packages. The authors concluded that the findings were consistent with eye-tracking studies and supported the efficacy of standardised packaging which indicated that daily cigarette smokers actively avoided cigarette package health warnings. The conclusion in relation to this particular issue was as follows:

> "7.3.8 Many consumers continue to hold false beliefs that some cigarette brands are less harmful than others, despite scientific evidence to the contrary. Pack design and colour promote false beliefs about the relative risks between brands. A variety of experimental studies indicate that standardised packaging is associated with fewer false health beliefs".

496. **Standardised packaging and consumer appeal**: The next issue considered by Professor Hammond was the impact upon consumer appeal. Qualitative research with youths and young adults was conducted in New Zealand, Canada, France, Scotland and Belgium. Focus groups amongst youths in the United States and Canada indicated that standardised packaging was 'uglier' and about one third of the youth in the same study believe that standardised packaging would make non-smokers 'less likely to start'; approximately one quarter believed standardised packaging would make young smokers 'smoke less'. Qualitative and survey based research in New Zealand, Norway, Australia and Canada indicated that the removal of brand imagery diminished positive association with product characteristics and smokers of standardised package cigarettes rated the cigarette less highly than smokers of branded products. Perception analyses were conducted in Australia, the United Kingdom, Norway, the United States and Brazil. For instance a study of young females in Canada found that fully branded packs were significantly more likely to be associated with glamour, slimness and sophistication. An experiment in Australia in which the brand was removed resulted in smokers articulating unfavourable appraisals. In summary Professor Hammond stated as follows:

> "7.4.7 The evidence unequivocally demonstrates that standardised packaging is perceived as less attractive and less appealing, particularly among youth and young adults, including smokers and non-smokers. Standardised packaging was also associated with less positive brand imagery. Overall the findings suggest that standardised packaging is less socially desirable and limits the ability of packaging to target sub-groups of youth and young adults".

497. **Standardised packaging and consumer demand**: Professor Hammond then turned to measures of consumer demand and smoking behaviour. A growing number of studies examined the association between standardised packaging and measures of consumer demand. A study in Canada found that pack type was an important attribute in the reasons given by adults and youth smokers for quitting, particularly when paired with a pictorial warning. Discrete methodology was also used to assess

consumer demand among young smokers in New Zealand where pack options with fewer branding elements were associated with less demand and were more likely to elicit cessation behaviour. A similar discrete choice experiment conducted in Canada in 2013 with young female adults led to similar results. Standardised packaging had a significant effect upon intentions to try a product and perceptions of taste. In the United States an experimental auction study was conducted to examine changes in consumer demand associated with health warnings and standardised packaging. Such studies are an established methodology in the field of economics for assessing consumer behaviour. In this particular study smokers participated in a 'real' auction to purchase cigarettes and were assigned to different experimental conditions including a standardised and branded pack condition. The study found that standardised packaging reduced the demand for cigarettes over and above the effect of pictorial health warnings. Four different studies used a so-called 'pack-offer' methodology pursuant to which youth participants were offered a choice of packs at the conclusion of a study. No cigarettes were actually distributed as a part of the studies but the participants believed that they would be receiving a pack when they made their selection. This sort of experimentation had been conducted in the United States from 1995 onwards. When asked which pack they would like to take home the vast majority of youth (in one study 80%) chose an established branded pack. 17% chose a novel branded pack and only 3% chose the standardised pack. Similar conclusions were found from a pack-offer experiment conducted with young women in Brazil. Similar results were found from naturalistic studies of standardised packaging in Scotland and in the United Kingdom. Professor Hammond also reviewed literature relating to clinical studies which indicated that environmental cues played a strong role in smoking relapse and that cigarette packaging served as a salient cue for smokers. In summary, Professor Hammond stated:

> "7.5.8 Evidence from a range of methodologies indicates that standardised packaging reduces consumer demand. Evidence from a limited number of naturalistic studies suggests that standardised packaging may promote smoking cessation among established smokers, although additional studies are required to demonstrate this effect. Findings from clinical studies also indicated that branded tobacco packaging is a reliable cue for smoking and can prompt urges to smoke among former smokers, and that exposure to standardised packages reduces urges and motivation to smoke compared to branded packages".

498. **Colour**: Professor Hammond then turned to the impact of studies relating to standardised pack colour. The studies were consistent in demonstrating that darker, non-white colours were perceived as significantly less appealing. By way of example a study conducted amongst United Kingdom youth and adults demonstrated that standardised brown packs were seen as less appealing than standardised white packs and were associated with high perceptions of risk. Similar results were found from experiments conducted in Scotland and Australia.

499. **Impact of branding on cigarette sticks**: Professor Hammond also examined the issue of branding on cigarette sticks. He pointed out that the Regulations restricted brand imagery on cigarette sticks themselves and in particular prohibited colours

other than plain white in the cigarette paper, casing, filter or material other than the tobacco, with the exception of 'cork' coloured tipping paper which was permitted. He observed the brand names and variants were permitted on sticks subject to restrictions on font type and size. Six studies examined branding and information on sticks apart from their outer packaging emanating from Australia, Greece and Scotland. He also referred to conference presentations reporting on findings from a study in New Zealand. The evidence in relation to advertising on sticks was consistent with the conclusions about findings of exterior packaging. Qualitative research in Scotland using focus groups comprising smoking and non-smoking participants led to the conclusion that participants perceived slim and super slim cigarettes with white filter tips and decorative features as most attractive with the slimmer diameters of these cigarettes communicating weaker taste and less harm. In contrast longer brown cigarettes were viewed as unattractive and associated with greater strength and harm. The Australian Government conducted qualitative research in 2011. This involved focus group discussions using three sets of stimuli one of which was cigarette sticks. Participants were shown four separate boards displaying cigarette sticks of various brands depicting four types: cork tips, white tips, slim cigarettes and fancy cigarette varieties. The results of the experiment exhibited strong associations with different stick colours and differentiating factors such as patterned tips. Internal industry documents demonstrated that colour and brand imagery on cigarette sticks operated in a similar fashion to that on exterior packaging. For instance Philip Morris consumer tested an 'ultra light' product and concluded:

> "A red pack with cork tipping will position Marlboro Ultra Lights closely to Marlboro's flavour heritage. A blue/grey pack with white tipping, although distant from the Marlboro flavour heritage, provides traditional ultra low tar reassurance. A red pack with white tipping represents a middle ground position with a flavour linked to Marlboro via the red pack and ultra low tar reassurance via white tipping".

500. In 1985 RJR Reynolds researchers undertook a similar analysis to examine whether colour of the tipping paper affected perceptions of light cigarette brands. The conclusion of these internal producer studies was that manufacturers can promote deceptions of mildness by using different colours of tipping paper. The conclusion of Professor Hammond was in the following terms:

> "7.7.11 There was less independent research examining branding on cigarettes themselves; however the literature that exists is highly consistent with findings on exterior packaging. In addition, industry documents demonstrate an association between branding elements, such as the colour of the tipping paper, and consumer perceptions of 'light' cigarettes and reduced harm. Collectively, this literature indicates that the appearance of cigarettes themselves, in addition to the packaging, can alter consumer perceptions of appeal and harm".

(8) Qualitative evidence relied upon by the Secretary of State on the existence of offsetting effects.

501. In this section I summarise the principal pieces of evidence cited by the Secretary of State to support the proposition that standardised packaging has been successful at reducing consumption of tobacco in Australia. There is a general downward trend in consumption and prevalence in Australia. Therefore the impact of standardised packaging in Australia is measured against a background of declining use and prevalence.

502. Evidence was tendered to the Court in the form of a Witness Statement dated 15th September 2015 from Mr Martin Bowles, Secretary of the Department of Heath in Australia. His evidence represented the views and knowledge of the Department of Health and that more generally of the Australian Government. Mr Bowles is the most senior civil servant employed by the Department and is responsible for leading and overseeing its work as a whole. He summarised the conclusions of certain qualitative studies on appeal, health warning saliency, and quitting interest, in the following terms:

> "The department expects that the effects of the tobacco plain packaging measure will be greatest and most clearly observable in the long term. However, studies into the efficacy of the tobacco plain packaging measure indicate that it is already contributing to its objectives with respect to both current and potential smokers.
>
> Research in Victoria found a reduction in the appeal of smoking products of the phase-in period of tobacco plain packaging. Compared with smokers using fully branded packs, smokers using plain packs perceived their cigarettes to be of lower quality and less appealing, and reported being more likely to think about and prioritise quitting.
>
> A study undertaken for the Cancer Institute New South Wales compared the promotional appeal of tobacco packs before and after the introduction of tobacco plain packaging. The study associated the introduction of tobacco plain packaging and larger GHWs with a significant increase in the proportion of smokers reporting strong cognitive and emotional responses to the health warnings on packs. There was also a significant increase in the proportion of smokers strongly disagreeing that their packs are attractive, fashionable, and influenced their choice of brand.
>
> A study published in the Medical Journal of Australia investigated the impact of the introduction of the tobacco plain packaging on the number of calls made to the 'Quitline', a smoking cessation support service. The study found a 78% increase in the number of calls to the quit line associated the introduction of the tobacco plain packaging".

503. Mr Bowles also referred to a special supplement, published by the British Medical Journal, of its publication 'Tobacco Control 'BMJ Supplement''. This contained 15 peer reviewed articles by various authors on the results of the first comprehensive evaluation of standardised packaging. The Department considered that this published research indicated that standardised packaging was efficacious. Articles published included the following key findings:

- An analysis of survey responses from Australian smokers indicated a reduction in the appeal of tobacco packs one year after implementation of the measure. Compared with survey responses prior to its implementation, more smokers disliked their pack, perceived lower appeal, lower cigarette quality, lower satisfaction, and lower value, and disagreed that brands differed in prestige.

- Seven to twelve months after the introduction of the measure, the appeal of cigarettes and brands to adolescents who had seen packs in the previous six months had decreased significantly.

- There was increased appreciation after tobacco plain packaging that brands do not differ in harm.

- The introduction of the measure was associated with more smokers thinking about quitting.

- Observations of tobacco packs displayed by people in outdoor café strips showed a decrease in the number of packs that were visible on tables and a decrease in the number of patrons smoking, particularly in the presence of children.

504. Mr Bowles considered that in the light of the emerging evidence the criticism advanced by the tobacco companies was unjustified. This criticism had included that: there was an insufficient evidence base to suggest that standardised packaging would reduce the prevalence of smoking and consumption of tobacco in Australia; the removal of branding would mean that companies would be forced to compete primarily upon price which would lead to a reduction in tobacco product prices and down trading and a consequential increase in consumption; standardised packaging would stimulate illicit trades including through counterfeiting and unlawful import; and standardised packaging would adversely impact upon small retailers including by causing confusion for retail staff and impeding their ability to serve customers quickly driving customers away to large supermarket chains and causing difficulties with stock management.

505. Mr Bowles also cited data disseminated by the Australian Institute of Health and Welfare (AIHW) released in the NDSHS Detailed Report which was based upon a survey of approximately 24,000 people conducted between the 31st July and 1st December 2013 following the introduction of standardised packaging. The report includes findings upon tobacco use and attitudes amongst the general population. It also compares findings relative to findings issued in earlier years. The Report made the following findings:

- That the proportion of daily smokers aged 14 or older had significantly decreased from 15.1% in 2010 to 12.8% in 2013;

- That the number of people smoking daily in 2013 fell by approximately 200,000 people;

- That smokers smoked fewer cigarettes per week on average in 2013 (96) compared to 2010 (111);

- That the proportion of people reporting never smoking rose from 58% in 2010 to 60% in 2013;

- And, that the majority of smokers attempted to make a change to their smoking behaviour in the previous year.

506. The Australian evidence was considered in the 2014 Impact Assessment. The analysis contained within the NDSHS Detailed Report was referred to. Nonetheless, the limitations in the data available from Australia were recognised, in view of the fact that standardised packaging had only recently been implemented there. The 2014 Impact Assessment concluded:

> "At this time it is difficult to conclude what the impact of Standardised Packaging on Australian smoking prevalence has been, due to confounding issues of a general decreasing trend and changes to tobacco prices. There are also general difficulties when investigating impacts that are expected to be relatively small, where there is variation in observations due to the sampling process. Also the policy is at an early stage and data on medium and longer term trends do not exist yet. However, the evidence that is available is consistent with a hypothesis that the policy would contribute to a modest decrease in prevalence".

507. The conclusion of the Australian Government was therefore that whilst the full effects of the standardised packaging measures would be measurable over the long term current research was consistent with the conclusion that standardised packaging was contributing to a reduction in tobacco consumption and prevalence as part of the Government's comprehensive suite of tobacco control measures. The Australian Government was also of the conclusion that there was no reliable evidence that plain packaging had caused downtrading or had led to an increase in illicit trade or impacted upon small retailers in an adverse way.

508. The policy adopted by the Secretary of State to view standardised packaging as one component of a wider series of deterrents is echoed by the policy adopted in Australia. Mr Bowles explained that in Australia they adopted the '*comprehensive'* approach to tobacco control advocated in the FCTC which refers to contracting states using '*comprehensive multisectoral national tobacco control policies, plans and programmes*.' The standardised packaging measures in Australia were simply one of a range of measures introduced at the Commonwealth, state and territory levels to restrict the marketing, advertising and promotion of tobacco products. Prior to the introduction of the standardised packaging measures most forms of advertising had

already been banned by virtue of the Tobacco Advertising Prohibition Act 1992. The standardised packaging measures '*targeted one of the last forms of advertising, marketing and promotion that remained available to the tobacco industry… being the packaging of tobacco products and the products themselves*'..

(9) Quantitative evidence relied upon by the Secretary of State: Post Australian implementation - Professor Chaloupka and the 2016 Australian Government Post-Implementation review

(i) Professor Chaloupka's regression analyses

509. I turn now to the quantitative evidence. That of the Secretary of State was largely responsive to that of the Claimants (and in particular that of Professor Mulligan). Professor Chaloupka presented six regression models based upon prevalence data from Roy Morgan and ten regression models based upon IMS data relating to shipments from manufacturers. In his first report Professor Chaloupka came to the conclusion that both prevalence and consumption data supported the effectiveness of standardised packaging in Australia. These reports were subjected to some fierce criticism by Professor Mulligan. It is not necessary to go into detail. In a nutshell Professor Mulligan in his first report had used a "linear time trend"; but Professor Chaloupka replaced these in his models with "year indicators" in an attempt to capture the effect on impact of non-price factors. Professor Mulligan commented that the variable used by Professor Chaloupka did not however measure what it was intended to measure. When, in a regression model, a change of behaviour is noted between two time points the model will attribute responsibility (causality) to the variables that have changed over the time period. Professor Chaloupka's original models had separate time year indicators for each year in addition to an "indicator for plain packaging" that applied to every month from December 2012 onwards. Professor Mulligan was of the opinion that if consumption were to decline from December 2012 to January 2013 because both months are plain packaging months but December 2012 is a year indicator for 2012 and January 2013 is a year indicator for 2013 then the model assumes that the change in behaviour is causally attributed to the 2013 year indicator and not to standardised packaging. As such the model would simply explain how prevalence and consumption for December 2012 differed from the other 11 months of 2012 but it would not indicate anything about the new packaging rules.

510. In his second report Professor Chaloupka recognised the force of some of the criticisms made by Professor Mulligan as "*useful*". The Claimants say that Professor Chaloupka accepted that in truth his work was "*so fundamentally flawed as to be meaningless*". Of course, Professor Chaloupka acknowledges no such thing and merely says that he accepted that in an incremental process he recognised that there were improvements which could be made to his models. He then set about perfecting his models and using linear time trends and these models, in his view, showed "*consistently negative effects of standardised packaging on smoking prevalence and on cigarette shipments*". He concluded that statistically the results were significant. Whilst he was of the view that the data was promising and showed a significant effect on prevalence and use he nonetheless said:

> " … neither my analysis nor those of Professor Mulligan can provide definitive evidence on the effects of standardised

> packaging on tobacco use in Australia, given the limitations of the data used in these analysis and the relatively short post-implementation period covered by these data and it will likely require several more years before strong evidence is available one way or the other."

511. The Claimants say, in the light of the final position adopted by Professor Chaloupka, that his final regression analyses, using linear time trends, are still blighted by errors that are in fact so "hard edged" that they are readily susceptible to judicial review, according to any applicable test. They are black and white howlers. I deal with these at paragraphs [575] – [584] below.

(ii) The Australian Government "Post-Implementation Review - Tobacco Plain Packaging" 2016 (the "PIR") / qualitative and quantitative evidence

512. **The Report**: The Secretary of State also relies upon a post-implementation report dated 2016 prepared by the Government of Australia on the impact of plain packaging in Australia. He emphasised his primary case which was that there was sufficient evidence to support the Regulations regardless of the PIR; and he therefore relied upon the PIR only as supporting and confirmatory. The PIR examined the post-implementation evidence, data and analysis of the broader costs and benefits to industry, government and the wider community in order to evaluate the efficiency and effectiveness of the tobacco plain packaging measure. This was in accordance with the Australian Government Office of Best Practice Regulation, "*Guidance Note: Post-Implementation Reviews"* (July 2014).

513. **Procedure adopted in these proceedings**: This report was served on the Court after the completion of the oral hearing. I permitted submissions to be made about this Report including the preparation of an expert critique prepared on behalf of the Claimants. I did not permit the Claimants to submit further, new, quantitative evidence in rebuttal of the PIR for two reasons. First, because the tobacco companies had already been given a chance to submit detailed new evidence in Australia as part of the review process leading up to the PIR and hence the PIR was the culmination of that process; accordingly I was of the view that enabling the Claimants to submit both written legal submissions and an economic critique was a sufficient and proportionate right of response. The second reason was that from a case management perspective given the time constraints (namely the growing imminence of the date for the coming into effect of the Regulations) and my view that the rights that I had given to the tobacco companies would enable them effectively to represent their views, it was not sensible or possible to re-open the entire evidential dispute. In the event the Claimants submitted both legal submissions and a very detailed critique prepared by Professor Mulligan.

514. **Relevance**: The PIR is relevant to both the existence of intermediate effects and to whether they are capable of generating a net incremental downward pressure on prevalence and use.

515. **The evidence relied upon**: The PIR is based upon literature reviews, consultation responses from external stakeholders (the tobacco industry including tobacco companies, wholesalers and importers and packaging manufacturers, retailers, public health organisations and experts, NGOs, Government departments and agencies,

consumers/individuals), and regression analyses submitted by the tobacco companies and by an expert instructed by the Australian Government.

516. **Basic conclusions**: The basic conclusions of the PIR were: First, tobacco use was harmful and a key health risk factor and remained one of the leading causes of preventable disease and premature death in Australia; second, despite a broad range of extant regulatory measures to reduce tobacco use, the number of smokers remained unacceptably high; third, to maintain or increase future declines in tobacco use a comprehensive and regularly updated approach to tobacco control was required; fourth, that as part of this comprehensive and dynamic approach the advertising and promotion of tobacco products had been increasingly restricted yet tobacco product packaging was considered to be one of the last remaining avenues for tobacco companies to promote use of their products; and fifth, that the packaging of tobacco products could be used to increase their appeal, distract from the effectiveness of the health warnings and create misperceptions about the relative health of tobacco products.

517. The full beneficial effects were expected to be realised over time. Citing from a report prepared for the Government by Dr Chipty - *Study of the Impact of the Tobacco Plain Packaging Measure on Smoking Prevalence in Australia* (January 2016) (the "*Chipty Report*") - the PIR states:

> "… the evidence examined in this PIR suggests that the measure is achieving its aims. This evidence shows that tobacco plain packaging is having a positive impact on its specific mechanisms as envisaged in the TPP Act. All of the major datasets examined also showed on-going drops in national smoking prevalence in Australia. These decreases cannot be entirely attributed to plain packaging given the range of tobacco control measures in place in Australia, including media campaigns and Australia's tobacco excise regime. However, analysis of Roy Morgan Single Source Survey Data shows that the 2012 packaging changes (plain packaging combined with enhanced graphic health warnings) have contributed to declines in smoking prevalence, even at this early time after implementation. The analysis estimated that the 2012 packaging changes resulted in a "statistically significant decline in smoking prevalence [among Australians aged 14 years and over] of 0.55 percentage points over the post-implementation period, relative to what the prevalence would have been without the packaging changes". This decline accounts for approximately one quarter of the total decline in average prevalence rates observed between the 34 months prior to implementation of the measure and the 34 months following the implementation of the measure (the total decline between the two periods was estimated as being 2.2 percentage points, with average prevalence falling from 19.4% to 17.2%). The analysis concludes that, "given the ways in which the TPP Act was intended to work, the policy's effects on overall smoking

> prevalence and tobacco consumption are likely to grow over time"."

518. **Limitations on evidence collection**: The Review addressed the limitations of the evidence it relied upon.

519. First, in relation to results of the survey that had been conducted it set out the facts which led it to acknowledge that those results might not be fully representative: See ibid paragraphs [43ff].

520. Second, in relation to both quantitative and qualitative conclusions the PIR stated that there had been no comprehensive review of the experimental evidence available on the effectiveness of tobacco plain packaging but that the authors simply used such reviews to inform the conclusions arrived at. The PIR focused only on peer reviewed studies that had been published in leading medical journals.

521. Third, in relation to the evidence as a whole and to its adherence to best practice standards the PIR states:

> "64. The PIR required a holistic assessment of the measure, such that the accuracy of the claims made by stakeholders and the various strengths and quality of the sources relied upon have been considered as part of the analysis of the stakeholder consultations. This includes in particular: the independence of a source, the authority or credentials of its authors, the public or confidential nature of data relied upon, its peer reviewed status and the consistency of the findings of a source with the entire body of evidence."

Peer-review was defined as: "*a multiple filtering process articles go through before being published in academic journals. This process includes the work being evaluated by experts in relevant fields to ensure it is rigorous and coherent before it is published, as is recognised as best standard in academic publishing."*

522. **Best practice limitations of the evidence submitted by the tobacco industry**: The PIR records that it received evidence from the tobacco industry. This evidence was discounted upon the basis that it was not peer reviewed, was unverifiable, and swam against the strong tide of independent expert evidence:

> "During consultations one tobacco company stakeholder provided three reports prepared by SLG Economics, which the tobacco company had commissioned. The most recent of the SLG reports criticised a number of the findings summarised above including:
>
> (i) In relation to the appeal of tobacco products, the SLG report concluded that a number of different measures from the National Tracking Survey and NDSHS suggest that tobacco plain packaging was not successful in reducing the appeal of tobacco products and that the evidence was mixed in relation to the effectiveness of health warnings;

> (ii) in relation to effectiveness of health warnings, the SLG report compares NSW Tracking Survey data from 2012 to 2014, critiques the peer-reviewed study of the NSW Tracking Survey data described above, and states that the data does not show an increase in the effectiveness of health warnings following the implementation of tobacco plain packaging;
>
> (iii) in relation to the ability of the packaging to mislead about the harms of smoking, the SLG report concluded that the results from the National Tracking Survey do not point to a strong impact of tobacco plain packaging in either direction;
>
> The SLG reports provided limited information on the methodology used and contradicts the findings of peer-reviewed and published academic studies that have been prepared by recognised experts in public health and tobacco control."

523. **Monetised cost / benefit analysis**: It was not possible to assess the monetised benefits of the measure precisely because the new rules were long term measures with benefits "*...expected to be realised in the long term*". However, the PIR recorded that the evidence indicated that even very small impacts on tobacco prevalence attributable to the measure would result in *"... very large monetised health benefits once realised. Indeed, even a drop in smoking prevalence of 0.07 percentage points (or 15,057 people) evenly distributed over ten years would generate an estimated monetary value equivalent to $273 million*".

524. **Evidence shows causality between advertising and branding and consumer behaviour**: The PIR concluded (thereby rejecting the contrary submissions of the tobacco companies) that there was strong evidence of causality between advertising and promotion and smoking related behaviour. The Australian National Preventative Health Taskforce ("NPHT") recognised a causal relationship between the promotion of tobacco and increased tobacco use. The link between advertising and smoking-related behaviours, including starting smoking, quitting smoking and relapse of tobacco use, has been confirmed by successive authoritative reviews of the evidence, including by reports of the United States Surgeons General, the United States National Cancer Institute, the United States Institute of Medicine, and the WHO. All of these reports reviewed substantial amounts of scientific evidence, from various fields, concerning the relationship between tobacco advertising and smoking-related behaviours. The overall conclusion to be drawn from this evidence was described in a 2012 US Surgeon General report:

> "The total weight of the evidence from extensive and increasingly sophisticated research conducted over the past few decades shows that the industry's marketing activities have been a key factor in leading young people to take up tobacco, keeping some users from quitting, and achieving greater consumption among users".

525. The PIR also cited internal tobacco company documents which also supported the conclusion that there was causality between advertising and promotion and consumer behaviour and that tobacco company promotional efforts were targeted at children:

> "19. There is also extensive evidence, including in tobacco industry documents, which shows that the tobacco industry uses tobacco packaging (including logos, imagery and colour) to create positive brand associations in order to promote and reinforce smoking. Industry documents confirm that tobacco companies have invested heavily in pack design, including innovative packaging, in order to communicate messages about brand identity and to appeal to specific demographic groups, especially young smokers."

526. For instance a BAT document was cited from 2001 which stated:

> "In some key markets legislative restrictions mean that the only medium available to communicate with consumers is via packaging. The pack becomes the primary communication vehicle for conveying the brand essence. In order to ensure the brand remains relevant to target consumers, particularly in these darkening markets, it is essential that the pack itself generates the optimum level of modernity, youthful image and appeal amongst ASU30 [Adult Smokers Under 30] consumers."

The Review also cites the conclusion of the NPHT which came to the following conclusion about the impact of advertising upon consumers:

> "24. The NPHT identified the need to address the remaining forms of tobacco advertising and promotion in Australia, including tobacco packaging. This included the recommendation that tobacco plain packaging be implemented, based on evidence demonstrating that:
>
> - young adult smokers associate cigarette brand names and package design with positive personal characteristics, social identity and aspirations;
>
> - packaging can create misperceptions about the relative strength, level of tar and health risks of tobacco products;
>
> - decreasing the number of design elements on cigarette packs reduces their appeal and perceptions about the likely enjoyment and desirability of smoking; and
>
> - plain packaging of tobacco products would increase the salience of health warnings, make the packaging less attractive, and reduce the propensity of packaging to mislead consumers about the harmful effects of tobacco products."

527. At the time of the introduction of the new measures research had established a link between three specific (intermediate) effects of plain packaging (reducing the appeal of tobacco products, increasing the effectiveness of graphic health warnings and reducing the ability of the packet to mislead consumers) and positive public health outcomes. For example: (i) in relation to the link between reducing the appeal of tobacco products and public health outcomes, research showed that a reduction in appeal and positive perceptions is associated with stronger intentions to quit using tobacco products and reduced intentions to start using tobacco products. The long standing view of the US Surgeon General and the WHO is that there is a "*strong relationship*" between advertising bans and changes in behaviours relating to smoking, including preventing youth initiation and encouraging quitting; (ii) in relation to the link between the effectiveness of graphic health warnings and public health outcomes, there was a significant body of evidence supporting the view that such warnings were effective in changing the behaviour of smokers and that increasing the effectiveness of graphic health warnings did in fact influence potential customers to resist initiation and increase quitting rates.

528. Further in relation to the link between reducing the ability of retail packaging to mislead consumers regarding the harmful effects of using tobacco products and public health outcomes, a published review of tobacco industry documents concluded that many smokers were in fact misled by pack design into thinking that some cigarettes may be "safer" and that advertising and branding had been effective.

529. **The uses of a comprehensive multi-partite tobacco control policy**: The PIR endorsed the comprehensive multifactor approach to tobacco control which combined advertising and branding restrictions with excise and tax measures: See paragraph [3.2].

530. **Evidence from Regression analysis**: The PIR relies upon the Chipty Report. She was asked to analyse individual-level survey data, over the period January 2001 to September 2015, from Roy Morgan Research, an independent entity that collects nationally representative information on the smoking behaviour of Australians aged 14 and above. These data, which span time periods both before and after plain packaging, enabled her to study the early effects of plain packaging on smoking prevalence in Australia. Her conclusion was:

> "… it is my opinion that the evidence is consistent with the conclusion that the TPP Act is having its intended effect. The evidence indicates clearly that the combination of plain packaging and updated and enlarged graphic health warnings is succeeding in reducing smoking prevalence. Specifically, I estimate a statistically significant decline in smoking prevalence of 0.55 percentage points over the post-implementation period, relative to what the prevalence would have been without the packaging changes. The 95 percent confidence interval around the estimated reduction in smoking prevalence is -0.095 to -1.01 percentage points. Because plain packaging is intended to deter smoking initiation, promote cessation, and deter relapse, the benefits of the packaging changes will likely grow over time."

531. Her conclusion was based upon a "before – after regression analysis":

> "My analysis relates an individual's decision to smoke to a set of explanatory variables, including socio-demographic factors and controls for tobacco control policies (including the policies governing plain packaging and enlarged graphic health warnings) that are widely believed to influence individuals' decisions to smoke. There are two important features of this analysis. First, it disentangles the effects of multiple factors that may simultaneously be influencing the observed outcome. Second, it identifies the effect of the packaging changes by comparing smoking behaviour before the policy to smoking behaviour after. A finding that the packaging changes had a negative and statistically significant effect on smoking prevalence, controlling for changes in other factors, would provide support for the conclusion that the packaging changes are having their intended effect. Moreover, the estimation results can be used to determine what smoking prevalence would have been absent the packaging changes."

532. The PIR conclusion as to the effect of standardised packaging post implementation based upon quantitative analysis of relevant data sources is as follows:

> "180. The major relevant datasets all show drops in national prevalence rates since 2012. For example, data from Roy Morgan Research, the ABS and AIHW relating to tobacco prevalence, as well as data relating to tobacco excise and duty clearances, and household expenditure, all show continuing declines in recent years. Dr Chipty's modelling also estimated a 0.55 percentage point drop in smoking prevalence in Australia, over 34 months following implementation, attributable to the 2012 packaging changes. This strong result, that is "likely understated", is expected to grow into the future as the full effects of the 2012 packaging changes are realised over the longer term. In light of all of the above, it is the conclusion of this PIR that the measure has begun to achieve its public health objectives of reducing smoking and exposure to tobacco smoke in Australia and it is expected to continue to do so into the future".

533. It is right to point out that the Claimants did not have a chance in *this* litigation to review the data underpinning Dr Chipty's report or subject it to their own detailed analysis. On the other hand, the PIR, as recorded above, *did* receive detailed evidence from the tobacco companies and it was rejected for lack of peer review and being inconsistent with the evidence from non-affiliated sources. In other words the conclusion of the Australian Government was taken with full knowledge of the new analyses conducted by the tobacco companies; it was not therefore a conclusion formed in a vacuum.

534. **Conclusion**: The PIR supports the Secretary of State's case. It is the most up to date evidence of post-implementation effects in Australia. It supports the conclusion of the Secretary of State that (i) restrictions on standardised packaging will, through the

posited intermediate effects, exert a downward pressure on prevalence and consumption; and (ii), this conclusion, which flows from a review of the qualitative literature base, is corroborated by the quantitative regression analysis conducted by an expert instructed by the Australian Government which indicates, on a conservative basis, that the measure is in actual fact working. Nonetheless the fact that this was not evidence tendered or tested in this litigation is a reason to exercise at least some degree of caution over these results and conclusions.

(10) The quantitative regression analysis evidence submitted by the Claimants

(i) Professor Mulligan

535. In this section I summarise the principal pieces of expert evidence relied upon by the Claimants. As with the evidence of the Secretary of State I set out the evidence in summary form. The Claimants rely upon a series of regression analyses prepared by Professor Mulligan. He produced a number of reports in this litigation. In his first report he presented a regression analysis using consumption data from the Australian National Accounts ("National Accounts") in order to estimate the impact of standardised packaging. In his view the National Accounts are a valuable source of information because they draw on data from a range of sources such as business, government agencies and households and are produced according to a rigorous and transparent methodology. The data also comes with information on tobacco prices which is useful for conducting regression analysis. He acknowledges, however, that the cigarette volume data used does not correspond directly to the number of cigarettes consumed in the market but, instead, to a quality-adjusted measure of the volume of cigarettes. Through this process of quality adjustment more expensive cigarettes are given greater weight in the data than cheaper cigarettes. Professor Mulligan considers that it is straightforward to use data on brand-level prices and market shares to modify the National Accounts measure of volume into a measure of actual consumption. Having performed this adjustment Professor Mulligan used the "forecast" method to evaluate the impact of standardised packaging upon consumption in Australia. In his report (at paragraph [80a]) he explained the method in the following way:

> "Building a model of how consumption evolves over time and reacts to various other factors (most importantly, price) in the period prior to the introduction of standardised packaging, and then using that model to predict what would have happened to consumption after the introduction of standardised packaging based on the real-world values of those other factors (such as price) during that time. In this method, the impact of standardised packaging is measured as the difference between the actual level of consumption for the years after standardised packaging was introduced, and the level of consumption predicted by the model for those years".

536. Professor Mulligan used quarterly data from Q1 2001 to Q4 2012 to construct the model and to estimate the relationship between consumption and "explanatory variables" such as price. Professor Mulligan then used the model to predict the level of consumption that would have been observed in Australia in 2013 and 2014 in the absence of standardised packaging. He considered that his model produced a "central"

or best estimate and a range of plausible consumption levels. He acknowledged that the data and the model were unavoidably imperfect and there was no way of knowing for certain precisely what would have happened in the absence of standardised packaging.

537. In his first report he set out, in a series of graphs, the range of what he considered to be plausible impacts of standardised packaging as estimated by his model. According to Figure 5A of his first Report his view was that the most likely outcome is that standardised packaging would increase consumption by 2 - 2.5% compared with the level of consumption that would have been observed in the absence of the new rules. His Figure 5A also makes clear that a range of other outcomes, including that the new measures would exert no or even a small negative impact upon consumption, were also consistent with the data.

538. It was the opinion of Professor Mulligan that, as was evident by his Figure 5B, the probability that standardised packaging would reduce consumption was only 9% whereas the probability that it would increase consumption was 91%.

539. Professor Mulligan conducted a similar analysis to that which he applied to the National Accounts data using IMS data. In his view such IMS data is not as informative as National Accounts data because it relates to shipments from manufacturers, rather than consumption, and does not cover the entire market since it relates only to the large tobacco companies' brands. Using IMS data Professor Mulligan, nonetheless, reached the same quantitative conclusion, namely that standardised packaging was more likely to increase than decrease consumption.

540. In his Reply Report dated 26th October 2015 Professor Mulligan set out a further series of regression analyses using data on tobacco clearances that had been acquired by PMI from the Australian Government through Freedom of Information requests. These regression models used a different technique known as the "dummy variable" method. The dummy variable model involves the same regression models used by Professor Mulligan in his First Report save that the new model included data from the years following the introduction of standardised packaging as well as the period before the introduction of standardised packaging. And it also included a "dummy variable" that was used to measure the average difference between consumption in the years with and years without standardised packaging, after taking into consideration the other differences between those years. It is the view of Professor Mulligan that both approaches (forecast and dummy variable) were reasonable. He accepted that both have strengths and weaknesses. He considered that the forecast method was superior at taking into account the possibility that model parameters (such as the underlying rate of decline of smoking) might be different after standardised packaging than before; whereas in his view the dummy variable method was superior at taking into consideration temporary disruptions or transitions that occurred in the market at about the time of the introduction of the new rules. This would have included events such as stock-piling of packs or returning packs that could not be sold after the legislation was introduced.

541. In addition, in his Reply Report Professor Mulligan set out four regression analyses. Two of these deployed National Accounts data only and two combined National Accounts data with the up to date clearance data. Each pair of regressions adopted a different approach to controlling for any disruption that might have occurred in the

second half of 2012 which was associated with the introduction of the new rules. Professor Mulligan concluded: that all of these regression analyses contradicted the Pechey Estimates with at least 99% confidence; all four analyses estimated that standardised packaging had resulted in an increase in consumption by approximately 2%; and all four regression analyses found that it was several times more likely that standardised packaging had increased consumption than it had decreased consumption.

(ii) Mr Dryden

542. The Claimants also rely upon regression analyses conducted by Mr Dryden in a report dated 6th March 2015 which was submitted to the Department of Health following publication of the 2014 Impact Assessment (i.e. prior to promulgation of the Regulations). He reviewed the extant data on Australian consumption. However, he deployed a different set of data based on retail sales and a different methodology. His modelling is known as "differences in differences". He did not set out to measure the extent to which consumption in Australia after the introduction of standardised packaging differed from consumption in Australia prior to the introduction of such rules. Instead, he used data from New Zealand (which has not adopted standardised packaging) as a benchmark comparator to analyse the impact of standardised packaging in Australia. His models also seek to control for the differences between Australian and New Zealand trends unconnected with standardised packaging, such as different tax policies. The key results arrived at by Mr Dryden are set out in his Reply Report dated 26th October 2015. In this report he sets out results of a series of models controlling for prices and other potential determinants for consumption in a variety of ways. Nonetheless, he finds that each of the models produce the same result: standardised packaging is associated with an increase in consumption of cigarettes in Australia relative to New Zealand. He states that the conclusion of the Pechey Elicitation Studies that two years post-implementation prevalence would reduce 1% for adults and 3% for children (11-15) is refuted by 2 years' worth of Australian data.

(iii) The Claimants' critique of the PIR Report

543. The Claimants submitted a detailed response to the PIR which included a Third expert report from Professor Mulligan. In the text below I set out some of the main objections made by the Claimants and my comments thereupon.

544. Generally the Claimants were very critical of the PIR. JTI, in a press release dated 26th February 2016, stated that the Australian Government Report "*jumps to conclusions to mask failure of plain packaging*". It described the conclusions as "*shaky*" and the report a "*desperate effort to justify the branding ban*". The analysis was replete with shortcuts and was "*designed to fulfil the political agenda*". In their written legal submission to this Court on the PIR the Claimants considered that a sense of "*marking one's own homework*" pervaded the analysis of the Australian Government.

545. In relation to the report of Dr Chipty it was pointed out that she had worked as an expert for the Australian Government in the WTO dispute proceedings, the implicit criticism being that she was partisan. Some of the most trenchant objections were methodological:

> "…it would be wrong for the Court in these proceedings to give weight to this evidence in circumstances where (i) the Secretary of State has refused to disclose the reports served in reply to Dr Chipty's reports in the WTO proceedings (to which it has access), (ii) Dr Chipty has not disclosed or referred to any criticisms made of her reports and how, if at all, her latest report responds to or addresses any such criticism, and (iii) the Tobacco Claimants have not been afforded access to Dr Chipty's underlying data and models and have therefore not had the same opportunity to respond as has been afforded to the parties to the WTO proceedings".

546. And also:

> "…the Chipty Report has not even been tested in the context of a public consultation because it was not disclosed until the PIR was released on 26 February 2016. The failure to offer the Chipty Report for consultation and response is particularly inexcusable and unfair in circumstances where, as mentioned above, Dr Chipty has been submitting testimony on behalf of Australia throughout 2015".

547. And if the Secretary State wishes to rely upon Chipty:

> "To allow the Defendant to rely on the PIR at this late stage, in circumstances where part of the Tobacco Claimants' case is that the decision to introduce the Regulations should not have been made without this evidence being available and properly consulted on, is obviously unfair. If the Defendant seeks to place any weight on the PIR, the proper course is to quash the Regulations and to remit the decision to the Defendant so that (without prejudice to the other grounds advanced by the Tobacco Claimants) a proper consultation can take place, allowing stakeholders sufficient time and provision of underlying materials, to enable them to make informed responses to it".

548. The Claimants also place the Chipty analysis into the context of Ground 11 (the alleged error in the application of Article 24(2)). They repeat their point about the high standard of proof:

> "As the Tobacco Claimants submitted at the hearing, the Defendant must show that the measures that it wishes to introduce are justified because there is evidence that they will achieve a higher level of health protection above and beyond those effects that are said to be achieved by the GHWs (and other) measures implemented in TPD2".

549. **Comment**: For the reasons that I have given elsewhere in this judgment the Claimants are of course entitled to rely upon methodological criticism of the evidence relied upon by the Secretary of State. The Claimants do not however in this response

address the criticisms made by the Australian Government of *their* evidence submitted to the review for methodological weaknesses. What the views of the Australian Government and the response of the Claimants do highlight is the real importance of adherence to best research and methodological practices. Nonetheless, the case before the High Court concerns the UK not Australia and some care is required in placing too much reliance on the PIR. The Secretary State in his written submissions responding to the PIR stated that the PIR "…*was not evidence that the Secretary State needs to rely upon in order to succeed in this case*". It is then simply observed that the PIR conclusions are consistent with the evidence adduced in the UK proceedings by the Secretary of State and it is treated as corroborative or supporting evidence.

550. I turn now to the specific analysis conducted by Professor Mulligan. Professor Mulligan was not able to verify the data underlying Dr Chipty's report. A request had been made to the Secretary of State for the underlying data but it was made clear to the Claimants that this data was not in the possession of the Defendant, but was in the possession of Dr Chipty and the Australian Department of Health. A Freedom of Information request had been made to the Department in Australia but the data had not been forthcoming in time. Professor Mulligan expressed the opinion that Dr Chipty's report was "*fundamentally flawed*". I set out below some (but not all) of the main objections raised by Professor Mulligan and my comments upon each. These bear a significant resemblance to the challenges made to the analysis of Professor Chaloupka.

551. **Use of tax as a proxy for price**: Professor Mulligan says that Dr Chipty's decision to control for taxes instead of prices is inappropriate and results in a flawed analysis. Dr Chipty's regressions included three indicator variables that controlled for tax changes instead of price changes. This approach was flawed because prices can change without changes in tax and because consumers respond to changes in overall prices, rather than changes in taxes. For that reason, if price changes during the relevant period differed substantially (in amounts and/or timing) from tax changes, Dr Chipty's approach would produce misleading results. He argued that *"... any model on the effect of standardised packaging on prevalence or consumption that neglects to properly consider price, especially when inflation-adjusted cigarette prices are readily and publically available, is inappropriate and unreliable*." He also argued that even were it proper to control for price through tax Dr Chipty had not actually controlled for tax levels but had instead used indicator variables to control for three changes in excise tax rates that occurred in 2010, 2013 and 2014. Professor Mulligan said that in actual fact there had been 14 separate occasions between 2010 and 2015, not just three, when tax changed. In any event, Dr Chipty's decision to use indicator variables rather than actual price levels was not supported by her own data analysis.

552. **Comment**: The approach adopted by Dr Chipty is on a par with that adopted by Professor Chaloupka. I have set out my views on this point at paragraphs [577] – [579]. Dr Chipty stated that she used indicator variables as "*a more flexible way to account for the effect of price increases on smoking prevalence*" because the effect on smoking prevalence would not necessarily be proportionate to the size of a tax increase. Dr Chipty also stated (cf. paragraph [35]) that she had tested the robustness of her conclusion by using different models. Professor Mulligan said of this that there was no reference to the benchmarking exercise in her paper so it could not be verified.

However, there is no reason which has been placed before this Court to suggest that this benchmarking exercise conducted by Dr Chipty was unreliable or not supportive of her main conclusions.

553. **Failure to account for dynamic adjustments**: Professor Mulligan criticises Dr Chipty for failing to account for dynamic adjustments when controlling for monthly changes in price (or taxes) and he says that it is essential to allow for dynamic adjustments. Dr Chipty's models (like Professor Chaloupka's) implicitly assume that the probability that a particular person is a smoker in any particular month depends only on the tax in that month, and not on the tax in any previous month. Dr Chipty thus, it is argued, fails to identify the quitting that results from the cumulative impact of increased price over more than one month. Dr Chipty's approach is in any event incapable of taking into account the fact that smoking behaviour can be influenced by tax and prices not just in any one month but also in the prior months thereto. As was evident from Professor Chaloupka's analysis, this failure biases the conclusion of the analysis by misinterpreting price effects as packaging effects.

554. **Comment**: This complaint, like many others, is illustrative of the process of forensic ping pong that has occurred in this case as between the experts. Professor Mulligan employs an unforgiving approach which never admits of even the possibility of error on his part whilst simultaneously taking the view that any and all opposing experts' reports are flawed. Perhaps he is right? But I return to the basic objection that I have with the approach adopted in this case which is that it provides the Court with virtually no assistance whatsoever as to how the myriad complaints boil down to properly justiciable issues. At base when I read in detail the various conflicting experts opinions on this issue (shorn of their purely adjectival attacks) I am driven to the conclusion that the alleged errors and flaws are in truth disputes about variations in empirical and statistical techniques about which the experts simply disagree. I am of the view that there are strengths and weaknesses in the (reasonable) approaches of all of the experts. I do not conclude that any truly vitiating errors have been identified or proven.

555. **Failure to cross check RMSS data with other data:** Dr Chipty was instructed to consider only RMSS data and it is argued that she erred by failing to consider the reliability of the RMSS data, including by reference to other sources. There is no reference in the Chipty Report to any assessment of the reliability of the RMSS data which is, argues Professor Mulligan, "*troubling*" given that the RMSS data has a propensity to underreport smoking. It is Professor Mulligan's view that the RMSS data appears to consistently underreport smoking behaviour when compared to IMS data; RMSS survey respondents admit to smoking too little to account for the number of cigarettes that are actually shipped to Australia. Of particular note is the fact that the RMSS underreporting in 2013 and 2014 (the first two full years of standardised packaging) exceeds the underreporting that occurred in 2011 and 2012. Whenever the survey's propensity to underreport increases, the RMSS data gives the false impression that smoking is decreasing more than it really is. As such it is better to rely on market data that reflect what people do (such as the consumption data) than on data from focus groups or questionnaires that only reflect what people say. The magnitude of the RMSS' underreporting may suffice to mask fully the counterproductive effects of standardised packaging on increasing consumption. Even if it were appropriate for Dr Chipty to consider only one source of data and the RMSS

data were considered an appropriate source Dr Chipty's conclusions should have been qualified and it should have been explained that whilst the RMSS data recorded a reduction in smoking prevalence, other prevalence data suggested that prevalence may be increasing. The fact that other prevalence data points in the opposite direction shows that it is not safe to draw conclusions on the impact of standardised packaging on prevalence based exclusively on an analysis of the RMSS data.

556. **Comment**: This is a dispute about the strengths and weakness of different data sources. There may be strengths and weaknesses in many of the data sets being used. This is not one-way traffic. The Defendant's experts identified what they considered to be weaknesses in the data relied upon by Professor Mulligan and Mr Dryden (amongst others). Indeed, the limitations of different types of data were often acknowledged by the experts who relied upon them. To overcome limitations the experts frequently make adjustments to the data. And accordingly any imperfections which the data set exhibited at the outset might have been overcome. This is, in my judgment, *par excellence,* an area where reasonable experts can reasonably disagree. At the very least no party placed before this Court any route map or model which would have enabled me to come to a firm conclusion that, for instance, the RMSS data set was ***so*** unreliable that I should exclude results premised upon it, or that the data sets used by the Claimants were so reliable that I could safely adopt conclusions based upon them without question or qualification. And when, where data was manipulated or perfected to increase robustness, the experts then used assumptions and new techniques to modify the data, there was no assistance given to me to enable me to differentiate as between the accuracy or reliability of those assumptions or as to the materiality of the end conclusions to the outcome of the grounds of challenge raised.

557. **Dr Chipty's margins of error are misstated:** This brings me to margins of error. Professor Mulligan accepted that economists use many techniques to mitigate gaps in the available data and minimise measurement errors and that notwithstanding measurement errors will inevitably remain. He also accepted that economists then had to "*estimate an appropriate margin of error in order to take account of how statistically confident*" one could be about a particular conclusion. Professor Mulligan argued that the "Huber/White/Sandwich" methodology" - used by Professor Chaloupka - was inappropriate because it required that errors of measurement and specification must, among other things, be "independent" (as confirmed in the STATA manual). Dr Chipty has, it is contended, made the same mistake because several factors in her approach render her errors dependent rather than independent. For example, the price left out in one month was correlated with the price left out in the previous month, because prices were correlated over time. Both Dr Chipty and Professor Chaloupka should have adopted a more sophisticated modelling technique, such as the statistical nonparametric bootstrap procedure. Professor Mulligan stated that: "*One would need access to the Chipty Data in order to see in detail how Dr Chipty has estimated her margin of error*". Professor Mulligan then proceeds to perform his own substitute margin of error analysis using RMSS and other data and he finds that Dr Chipty has erred in using an overly simplistic margin of error.

558. **Comment**: To accept Professor Mulligan's submissions I must (a) find that use of the Huber/ White/ Sandwich test is outwith the bands of reasonableness (even though the Defendant's experts have independently come to the conclusion that it is reasonable to

use this approach); and (b) that the error is material to the end result. This is one illustration (from amongst a multiplicity) where the Claimants seek to assert an end result and expect the Court to find in their favour without giving the Court the tools to do so.

559. **Correcting for Dr Chipty's errors might dramatically alter her conclusions:** Professor Mulligan asserted that the cumulative effect of the errors identified meant that Dr Chipty's analysis was flawed and her conclusions were unreliable. However, having taken this robust stance he then said that because he did not have access to the Chipty Data he could not run alternative versions of her models to correct for the errors. The best that he could do in the circumstances was to cross-refer to his analogous exercise conducted upon Professor Chaloupka's regression analyses, which he said proved his point.

560. **Comment**: Professor Mulligan is in substance extolling the virtues of iterative peer review, where different and successive experts and researchers deconstruct and take apart the analysis performed by their predecessor and then seek to perfect the analysis. A running complaint throughout Professor Mulligan's analysis is that he has not had access to the underlying data so he has not been able to verify his conclusions. There is thus in this regard a striking difference between the entirely logical desire of Professor Mulligan to keep "working the data" and the rooted objection to transparent peer review which the Claimants have throughout in this litigation advanced as a reason not to reject that part of *their* evidence which is <u>not</u> peer reviewed and to give precedence to the worldwide research base which <u>has</u> been peer reviewed and upon which the Secretary of State relies. Once again, I repeat the process point made at paragraphs [630ff]. There is simply no way that a Court can accept this analysis in its present form. Even on Professor Mulligan's own case the analysis is in any event unripe and incomplete.

(11) The Claimants' view of the pre-existing evidence base

561. I turn now to the position adopted by the Claimants to qualitative evidence relied upon by the Secretary of State. The Claimants challenge the reliance, by the Secretary of State, upon the pre-existing literature upon the basis that it is not capable of answering the question whether the impact of standardised packaging on intermediate effects will translate into reduced smoking rates either at all, or, to a degree which would outweigh the demand stimulant effect of downtrading caused by standardised packaging. In particular, the Claimants rely upon expert reports from Professor Devinney, Professor Klick, Mr Gibson, Professor Viscusi, and Dr McKeganey. These reports challenge the existing research base at a high level of abstraction. I set out below some of the principal criticisms which they level at this research. They say that their own research shows that standardised packaging is unlikely to have any of the claimed effects on intermediate outcomes and that the Secretary of State (and *a fortiori* Parliament) have proceeded on the false assumption that there will be such an effect. The Claimants' experts highlight, for instance, the small sample sizes and repeated variances of prior studies in which, it is said, the same flawed approaches were applied time and time again by the same authors to support a false confidence based upon a preponderance of evidence from their own repeated flawed studies (a virtue deficient circle).

562. The Claimants rely in this litigation upon the expert opinion report of Dr Gregory Mitchell. He is a professor of law with a PhD and (from his CV) some limited professional experience in psychology. His report is dated 30th July 2014. It was tendered in the course of this litigation without an expert declaration or any acknowledgement that the report is intended to be consistent with the CPR. He was instructed by BAT, during the consultation process, to offer his observations on the Chantler Report, the draft Regulations and the first version of the Impact Assessment. His conclusion was that the Chantler Report supplied no theoretical basis for the view that standardised packaging would have a beneficial effect. He said that there was no direct empirical evidence to support the claim and that the Chantler Report ignored established risk factors for adolescent smoking of which branded packaging was not one. He said also that the Chantler Report was based upon flawed speculation about potential behavioural effects of a move to standardised packaging. It ignored the crucial problem which is that there is no justification for the belief that differentiated packaging can have only positive causal effects upon smoking decisions and standardised packaging have only negative causal effects. In relation to children he expressed the opinion that measures such as increased prices or stricter enforcement of age restrictions on purchasing were likely to have a greater negative impact upon consumption and prevalence but that regulators should acknowledge that short of complete bans the demand for cigarettes amongst youth smokers was difficult to reduce because adolescents desire risk experiment and norm-testing behaviours.

563. I have a number of difficulties with this opinion, over and above the fact that it has been tendered in the course of litigation in the United Kingdom without the normal professional safeguards that are required by the CPR. This is not a mere formalistic criticism. It is a serious point which goes to the weight that should be attached to the evidence insofar as it is relied upon in this litigation. I could have ruled it inadmissible. I have however considered it.

564. Dr Mitchell is scathing about the existing literature base. He states that a number of surveys, focus group studies and experiments examine reactions to standardised versus non-standardised packaging but none examines the effects of standardised packaging on behaviour in the field. He concludes that the Chantler Report is based upon speculation. He says, further, that the Report fails to engage with any "*contemporary theories of adolescent health behaviour and never provides research that can support the claim that branded cigarette packages unconsciously influence adolescents to smoke*". In paragraph [15] he cites, by way of concise summary, five pieces of research, cited in Chantler but then says this:

> "The Chantler Report's facile invocation of unconscious processes as an influence on adolescent decisions and behaviour reveals a lack of understanding of adolescent theories of health behaviour and of the limits of the research into unconscious causes of behaviour".

565. Notwithstanding that Dr Mitchell is so critical of the "*facile*" acceptance by Chantler of the existing literature base, nowhere does Dr Mitchell specifically engage with the nuts and bolts of that existing literature. As I have already set out the literature is substantial and overwhelmingly one directional; the preponderant portion of researchers worldwide have found that consumers, whether youth or adult, do respond

to precisely the sorts of marketing, branding and advertising signals that the tobacco companies actively use wherever they can.

566. I also find the failure to address the question of the tobacco companies' internal documents unsatisfactory. In paragraph [27] Dr Mitchell states:

> "27. The primary argument in favour of a move to standardised packaging is that use of drab, uniform packaging will negatively affect attitudes towards cigarette packages, the cigarettes within those packages, and presumably the act of smoking. As support for this argument, the Chantler Report cites experiments, surveys, and focus group studies in which participants rate drab packaging as less appealing than branded packaging. The Chantler Report also cites as support tobacco industry documents indicating that tobacco companies have treated the cigarette package as a means of advertising and that cigarette brands and packaging have been developed to appeal to particular segments of the market. For instance, a number of brands have been packaged in ways to make them more appealing to women.
>
> 28. This body of evidence is portrayed as supporting the conclusion that standardised packaging will render cigarettes in general less attractive, but that contention makes the fundamental mistake of confusing reductions in the appeal of *some* cigarette brands with reductions in the appeal of *all* cigarette brands. None of the existing research demonstrates that a move to standardised packaging will render all cigarettes equally unappealing, cause the act of smoking in general to become less attractive or common, or lead to a reduction in the incidence of smoking".

567. This is the nearest that Dr Mitchell ever comes to acknowledging that internal tobacco company documents may run counter to the direction of analysis advanced by their experts. In the unique circumstances of the present case it is, in my judgment, simply inadequate to sweep aside as implicitly irrelevant the entirety of the internal thought processes of the tobacco companies particularly when he has not had sight of that internal documentation. This is particularly so because, after a 9 month trial, the US Federal Court, in the *US Judgment*, found as a fact that the tobacco companies' advertising and promotional activities, including branding, did materially influence consumer behaviour, including that of children: See paragraph [3298] of the Judgment cited at paragraph [310] above. That ruling was based on all of the evidence, including internal documents. In other words, internal documents acknowledged the correctness of the conclusions arrived at by the external research community. And it follows, *a fortiori*, that if branding does stimulate demand, proscribing it will depress demand. Dr Mitchell's refutation in the light of the *US Judgment* (which I am entitled to assume he is aware of) can carry scant, if any, weight.

568. In relation to adolescent initiation Dr Mitchell's central thesis is that adolescents are generally aware of the health risks associated with smoking and do not believe that they are immune to the negative consequences thereof, including youth in the United

Kingdom. He opines that even younger smokers perceive higher risks of their experiencing smoking-related negative outcomes than their non-smoking peers, at times overestimating their objective risk of disease and early mortality. Dr Mitchell continues with this theme for a relatively small portion of his overall report. Nowhere does he address the very substantial body of evidence which fundamentally contradicts his conclusions. In short, I found this evidence unsatisfactory at almost every level.

(12) The criticisms of the Claimants' quantitative evidence by the Secretary of State: challenged assumptions

569. I was told in oral argument, in response to my questions on this issue, that Professor Mulligan's assumptions were set out in Schedules to his reports. A difficulty that I had with Professor Mulligan's work was that the assumptions which underpinned it were not readily ascertainable. Having read (and re-read) the schedules and stumbled over the maths, I was only a very little the wiser at the end of my reading. In an ideal world the experts would, in a form and in language comprehensible to a non-expert, set out all of the assumptions that have been relied upon. This would enable them to be properly scrutinised and assessed (see my observations at paragraph [638] below). The experts who gave evidence for the Secretary of State challenged the statistical regression analyses conducted by Professor Mulligan upon the basis that they relied upon a number of faulty or at least controversial assumptions which the experts deduced from Professor Mulligan's analysis and which it was said made Professor Mulligan's conclusions unreliable and which go to the point that the Australian data is far from being mature or robust. I set out below a sample of the main criticisms.

570. **The assumption that prevalence would decline at a constant rate**: The first assumption is that smoking prevalence in Australia would continue to decrease at the same rate as in the pre-implementation period in the absence of any new regulatory measures. However evidence adduced by the Defendant's experts (such as Professor Hammond) suggested that historical smoking trends in Australia indicated the opposite and that reductions in smoking were not self-sustaining and could taper off and plateau in the absence of new measures. Professor Hammond accepted that Professor Mulligan had sought to adjust for pre-implementation time periods (which he acknowledged was reasonable for modelling changes over time). However he concluded that this was reasonable only in outcomes that have only one primary determinant or, in those cases where the outcome may have multiple determinants, where the determinants could be measured and incorporated into the model. However Professor Hammond concluded that neither of these conditions was applicable in the present case. He accepted that Professor Mulligan's model adjusted for price effects but he pointed out that it disregarded all other tobacco control measures implemented prior to December 2012 in Australia. These included comprehensive bans on point of sale displays, a ban on electronic advertising as well as a comprehensive mass media campaign. For standardised packaging to be statistically significant in Professor Mulligan's models the effect of such packaging had to exceed the combined effect of the measures implemented in the pre-implementation period i.e. prevalence post implementation could not simply decline; the decline had to exceed the rate observable in the pre-implementation period - it had to accelerate the decline. Therefore, he was of the view that if standardised packaging reduced prevalence significantly but by less than in the pre-implementation period Professor Mulligan's

models would conclude that standardised packaging was counter-productive and was to be associated with an increase in smoking prevalence. Professor Hammond considered that it was an unreasonable assumption but, more particularly, "*...an untenable one over time, as these models require constant accretion with each consequent intervention which is implemented*". He pointed out that the assumption disregarded the law of diminishing returns as the proportion of smokers grew smaller over time. In addition the smokers that remained in countries such as Australia were widely believed to reflect a 'hardening' population who were ever increasingly resistant to quitting. Whether right or wrong, Professor Hammond's criticisms identified some of the evidential conundrums that underpinned the modelling assumptions.

571. **The assumption that effects would occur immediately**: A further challenged assumption was as to the immediacy of the effect of standardised packaging. A number of models used by the Claimants assumed a rapid change in smoking prevalence upon implementation of standardised packaging. However the Secretary of State's experts were of the opinion that this assumption was inconsistent with the scientific literature and with some of the internal documents disclosed by the tobacco industry. These suggested that the effect of removing tobacco marketing did not appear immediately but exerted itself over time as brand associations weakened. This was particularly true in the case of youth for whom the effects of reduced marketing occurred gradually as subsequent cohorts of youth entered the age where smoking initiation was affected by the nature and extent of promotion and branding. Equally existing smokers may retain, for a considerable period, residual memories and associations with brands which dwindled only over a lengthy period of time. Indeed, this was the conclusion of the economist instructed by Chantler during his review: See Annex C to the Report, set out at paragraph [116] above.

572. **The assumption that standardised packaging measures were not phased in over time:** The experts for the Secretary of State next pointed out that the regression analyses or models failed to account for the fact that plain packaging was phased in over time in Australia. The deadline for implementation was December 2012. However, only plain packs could be produced from October 2012, and such packs were introduced and taken up over time. This meant that comparing the picture before and after 2012 and taking as the reference data a short period post first implementation blurred the picture making it more difficult to draw robust conclusions as to the long term impact of the policy.

573. **The assumption that addiction was irrelevant:** The Secretary of State's experts also pointed out that the Claimants' analyses failed to take into consideration the fact that tobacco products were harmful and addictive and were not normal goods in relation to which "rational" consumption drivers applied in the same way as they would do when choosing to buy ordinary goods.

574. **The assumption that all data sources were reliable**: Professor Chaloupka, Professor Hammond and Professor Mulligan engaged in a vigorous exchange about the reliability of different data sources. The conclusion of Professor Hammond about Professor Mulligan was in the following terms:

> "11.10.25 The analyses presented in the Mulligan Report purport to show that standardised packaging had a negative

> public health impact by increasing smoking behaviour. However, the analyses are based on flawed assumptions that depict a lack of familiarity with the effects of tobacco control measures, particularly with respect to tobacco marketing restrictions. It is highly unlikely that any tobacco control measures implemented in Australia would be deemed 'effective' given the modelling parameters adopted by Mulligan.
>
> …
>
> 11.10.26 In addition to his own analyses, Mulligan relies upon second-hand reports and data sources that were not designed to measure national-level changes in prevalence. In several cases, Mulligan draws inferences from the second-hand source in the absence of any statistical testing to support his speculations. Overall, in my opinion, the analyses presented in the Mulligan Reports are fundamentally flawed and do not provide appropriate test of standardised packaging regulations in Australia".

(13) The "hard edged reasons": Analysis

575. I turn now to the "hard edged" erroneous reasons alleged to have been perpetrated by Professor Chaloupka and which are said therefore to fatally undermine both his own research analysis and his criticisms of Professor Mulligan. As I have set out above I use the Secretary of State's description of them because this was the way they were formulated in a document to which the Claimants responded. In the text below I set out each alleged false "reason" and the respective positions of the parties. This exercise serves to demonstrate just why these are not "hard edged" errors but complex matters over which reasonable experts may disagree. The gravamen of the dispute focuses upon such issues as: the reliability of data sources; the use and accuracy of proxy information; the extent to which weaknesses in data can be overcome by the use of corrective margins of error; the extent to which chosen components of the models are consistent with the general weight of the literature base or are outliers and *sui generis*; and the extent to which models use assumptions which are subjective and open to debate.

(i) Professor Chaloupka abandoned his regression models

576. The first criticism is not so much an alleged error as a forensic sideswipe. Professor Chaloupka was instructed to critique the Claimants' evidence. In performing this task he conducted a series of his own regression analyses. Over time as he responded to criticisms of these from the Claimants he modified his models. The Claimants attack him upon the basis that he was forced to abandon his initial regressions analyses and this should weigh heavily against him in terms of credibility. Professor Chaloupka responded that he had modified his models in order to perfect them[21] so that his latest

[21] For instance a criticism of Professor Chaloupka was that he used year indicators to seek to distinguish between reductions in smoking that would have occurred in the absence of standardised packaging but that this overlaps with the use of dummy variables. The consequence of this was that Professor Chaloupka's models only measured the difference between December 2012 and the other months of 2012 and this therefore failed to attribute smoking increases to standardised packaging.

models were, in his view, robust and reliable. He also says that his willingness to respond sensibly showed that he acted as a reasonable expert which contrasted with the stance of the Claimants' experts who refused to countenance any conceivable criticism of their own work. Ultimately whether this was sensible evolution or abandonment is simply not to the point. The high water mark of Professor Chaloupka's economic case rested in his final models and these are the ones to concentrate upon.

(ii) Professor Chaloupka's model does not provide for any dynamic adjustment of prevalence in response to price. Without accounting for the time lag impact of changes in prices his models fail to correctly take account of the impact of price changes

577. The issue concerns the impact of price in affecting prevalence of tobacco use. In his models Professor Chaloupka used tax (inflation adjusted monthly excise data) as a proxy for price. Professor Mulligan accepts that tax is a major determinant of price but says that price can alter independently of tax. In his reply Report he says (in a footnote) that in some instances ("*though not this one*") he also would consider using excise tax rates. But he goes on to say that it should be used in conjunction with price data. Professor Chaloupka in response was clear that the use of a tax variable as opposed to a price variable was reasonable. He gave 5 reasons for this. First, the Claimants submitted that the introduction of standardised packaging in Australia led to downtrading which led to a reduction in average cigarette prices. But to the extent that this was correct to include a measure of cigarette prices in the models would make it more difficult to evaluate the full impact of the new measures because the new measure of price if caused by standardised packaging would be attributable to the new measures. The new prices would risk confusing the analysis because they could not be said to be causative of a change as opposed to being a consequence of the new measures. In his view tax was therefore a good proxy for price because it was independent of Standardised Packaging. Second, many research studies used tax rather than price because of concerns about the potential endogeneity of price. He cited the IARC review of hundreds of demand studies from around the world which showed that tax was regularly used as an adequate proxy for price. Third, Professor Mulligan's own analysis of tax changes over time was not accurate because it did not reflect actual changes over time but *"…changes relative to trend*s". Fourth, there was in any event no consistent data on cigarette prices available over the time period covered by the RMSS and IMS data whilst data on the excise duty per stick was readily available. Fifth, using price in any event risked creating measurement error because a price series had to be created (and this is what Professor Mulligan actually did).

578. In response the Claimants argue that to the extent that price data is unreliable or less than complete this could be cured by modelling and by margin of error analysis and to the extent that it was suggested that prices did not change in between tax changes this was refuted by evidence that there had in fact been price changes in between tax changes.

Professor Chaloupka accepted this criticism so focused his models of prevalence using linear time trends which showed, what he considered was a statistically significant reduction in smoking.

579. It is virtually impossible to say who is right and who is wrong. To be able to do this a Court would need to be able to verify and test each of the assumptions underlying the competing propositions and to assess the materiality of any errors found to exist. To take but one illustration. The response of the Claimants to the Defendant's position that tax is a good proxy for price in the models is that price changes occur independently from excise duty increases. Two references to parts of the expert evidence of Professor Mulligan are given in support of this proposition. The first purports to show cigarette price increases occurring between 2010 and 2013. It is stated that by 2013-Q4 inflation adjusted cigarette prices were 23% higher than they were in 2010-Q2. However, there is no attempt to attribute these price increases to tax or anything else. And the second reference which is an annex to the Report purports to show increases in excise duty. This Table suggests that over the same period tax increased by 22% on 29th October 2010; by 8% on 1st December 2012 and by 7% on 1st September 2014. Nothing in this information however provides clear information on price changes between excise duty changes and/or (importantly), nothing indicates whether, even if there were such changes, they would be material to the outcomes of the relevant models.

(iii) Professor Chaloupka's arguments that applying highly correlated measures to the same models creates confounding effects can be dismissed because all that needs to be ensured is that packaging effects are not confounded with price effects

580. Professor Chaloupka argues that the overwhelming majority of studies using cross-sectional survey data use a single measure of tax or price and not a dynamic, changing, measure. Professor Chaloupka thus says that his models and analysis are consistent with widely accepted modelling techniques. This is because complex and longitudinal studies are required to conduct this sort of analysis. But there are no longitudinal studies at the population level which would permit researchers to consider the impact of prices and tobacco control policies on prevalence in Australia. The NTPPTS data includes only smokers and recent quitters and cannot be used reliably to examine prevalence and in any event included insufficient data points for respondents. Equally the ITC Australia data included data on actual smokers so could not be used to evaluate impact on prevalence which focused on those who had not yet taken up smoking. Second, the overwhelming majority of existing research studies using cross-sectional survey results use a single measure of tax or price and accordingly this supports the reliability of Professor Chaloupka's analysis. Professor Chaloupka argued that his approach was consistent with the standard literature and Professor Mulligan's criticism reflected a novel approach that was not supported by standard literature.

581. The Claimants reject this and say that there are no reasons to believe that other studies adopt the same approach. However no evidence is served to refute Professor Chaloupka on this point.

582. Once again the Court has no way of sensibly being able to resolve this dispute and moreover, there is no way of knowing whether (i) adopting a single measure actually accords with reality or (ii) even if it does not by how much it departs from reality and (iii) whether any departure from reality would make any real or material difference to the outcome.

(iv) Professor Chaloupka's points on the impact of including highly correlated points is only a criticism of Professor Mulligan's band aid solution – and not a reasonable defence of his own model for the time lag impact of changes in prices

583. Professor Chaloupka submits that introducing lagged price measures introduced unnecessary correlations which confounded the estimated effects of price and other variables correlated with price. Professor Mulligan's band aid approach was inconsistent with existing literature and said to be entirely novel. This is not the sort of dispute that, certainly on the state of the facts and evidence as presented to this Court, is capable of resolution. I accept the Secretary of State's ultimate point on this which is that this "*is a point over which there is reasonable disagreement between the experts*".

(v) Margins of error

584. Before moving on I will briefly refer to the fact that many other disputes between the parties which were raised as fundamental at one point or another subsided into (begrudging) acceptance that they were not justiciable but in truth areas of legitimate disagreement between experts. For instance, the Claimants initially argued that Professor Chaloupka adopted a deeply and fundamentally flawed approach when estimating the margin of error. As to this Professor Chaloupka was adamant that his use of the "Huber/White sandwich estimator in STATA" was orthodox and beyond criticism. He pointed out that this model for margins of error was "*well specified and consistent with the dozens of peer reviewed published studies used in repeat cross sectional survey data"*. Ms Demetriou QC at one stage sought to persuade me that there was a hard edged error because Professor Chaloupka should have used the methodology set out in "Stata Base Reference Manual (Release 3)" which required the errors to be "independent". But this was, with respect and despite attractive advocacy, a forlorn exercise. It is, and was, manifest that the use by Professor Chaloupka of his method was perfectly reasonable and, as such, the difference between the experts was in truth nothing more than that - a dispute between two reasonable views.

(14) Materiality

585. I have referred throughout this section to the Court not being able to assess the materiality of alleged errors. I will give one additional illustration of why this is a real problem. At one point the Claimants criticised Professor Chaloupka for the manner in which he had modelled controls for stockpiling. Professor Mulligan described this as misattribution. Professor Chaloupka in his Reply report accepted that the criticism was reasonable and reworked his model which then showed that the modification made no material difference to the outcome. The Claimants accept in principle (see paragraph [416] above) that unless an error can be said to be material then this would not warrant a Court interfering. But there has been no analysis of the materiality of alleged errors before the Court. The parties allege multiple errors against each other but do not explain or establish just how relevant or significant the error is (assuming it is proven in the first place). I have no evidence upon which I could conclude that, if there were errors, they were so central as to make any sort of a real difference to the conclusions arrived in the quantitative evidence. In the present case the difference in the conclusions of the Claimants and Defendant is not great:

The Claimants' analysis leads to a small (c. 2%) increase in consumption and the Defendant's to a small (c. 1-3%) decrease.

586. In conclusion I reject the submission that there are any proven "hard edged" errors or reasoning and/or that they are material.

(15) Analysis and conclusions

(i) My conclusion: conservative basis

587. I turn now to my conclusions. In my judgment, on the basis of the evidence before the Court the first limb of the proportionality test is met and the Regulations represent an appropriate and suitable means of achieving the legitimate health objective of reducing smoking prevalence and use. This is a conclusion based upon the most up to date evidence before the Court. This includes, therefore, the evidence adduced by the parties which was not available at the time Parliament promulgated the Regulations.

588. For the avoidance of any doubt I have also formed the clear conclusion that the evidence base upon which Parliament acted also met the first limb of the proportionality test.

589. I have divided the analysis in this section into four parts. First, my conclusion as to the evidence before the Court and whether, *prima facie*, the Secretary of State had been able to advance sufficient evidence to establish the appropriateness and suitability of the Regulations as a means to achieve the stated objective. Second, my conclusions on quantitative evidential issues relating to the quantitative evidence which go to its probative value. Third, methodological considerations. Fourth, broader considerations relevant to the margin of appreciation.

590. I have adopted the approach of forming a *prima facie* conclusion about the adequacy of the Defendant's evidence without applying any latitude to the Secretary of State on account of margin of appreciation or any discount to the Claimants' evidence for methodological weaknesses. My approach is thus conservative and favours the Claimants. When I apply factors relevant to margin of appreciation and methodological consideration it will be seen that my *prima facie* conclusions are reinforced.

(ii) Conclusions about the evidence

591. I turn to the first issue which is to consider, taking all of the evidence at face value, whether the Secretary of State has placed before the Court sufficient evidence to establish that the Regulations are appropriate and suitable.

592. **The Secretary of State's qualitative evidence**: In my judgment the qualitative evidence relied upon by the Secretary State (see paragraphs [489] – [508] above) is cogent, substantial and overwhelmingly one-directional in its conclusion, which is that various types of advertising and branding are effective in influencing consumer reactions. The research has been generated over a number of decades by psychologists, social scientists and others in relevant disciplines. The consistent conclusion of the US Surgeon General, the Australian Government, Chantler, the Chief Medical Officer in the UK, the WHO, and the US courts is that the results

generated by the worldwide research community *are* indicative of how consumers *do* react. The underlying premise is that these reactions correlate to consumption patterns and that advertising and branding restrictions will be efficacious.

593. The Claimants however reject this conclusion. The argument placed at the forefront of their analysis is that there is no necessary nexus between good intentions and good actions (see paragraphs [561] – [568] above). In one sense I accept the logic of this proposition: there is no *inevitable* or *necessary* nexus. But that misses the point. The international research community does not say that *every* person who shows less interest in a pack that has fewer design or branding features or less attractive colours on it will inevitably quit smoking or smoke less or refrain from taking up smoking. Their research shows only that the impact of branding upon consumers is predictable and significant and that it is a reasonable and strongly logical inference to draw that it will influence in a material way prevalence and consumption. In other words it is a proper inference from the research base that restricting advertising and branding will be causally effective, albeit not with every person or to the maximum degree possible.

594. In large measure the Claimants' challenge operates at a high level. It does not in any systematic manner take the research results relied upon by the Secretary of State and subject it, piece by piece, to critical analysis. Various of the Claimants' experts point out limitations and provisos that must be placed upon the results but these are frequently exactly the same limitations and provisos that the researchers themselves recognise and record in the relevant literature. This is why it is the *totality* of the research and the *consistency* of its conclusions over time that is important. Furthermore, as Chantler recorded in his report (paragraph [48]) the tobacco companies have chosen not to "…*present the undoubtedly extensive results of its own internal market research for example focus group research exploring brand switching*…". Chantler suspected, on the basis of the US litigation, that this internal material would contradict the tobacco companies' public utterances. And, moreover, in the *US Judgment* Judge Kessler expressly rejected the equivalent argument advanced there by the tobacco companies and she found, upon the basis of comprehensive evidence which included internal documents, that the tobacco companies were well aware of the strong causal nexus between advertising and consumer reaction. I therefore reject the Claimants' challenge to the qualitative evidence relied upon by the Secretary of State.

595. **The Secretary of State's quantitative evidence:** The Secretary of State relies also on the quantitative regression analyses conducted by Professor Chaloupka and (by way of confirmation or corroboration) upon that contained in the PIR in Australia. This is challenged by the Claimants through, primarily, the evidence of Professor Mulligan but also through the evidence of Mr Dryden. In my judgment the disputes represent reasonable differences between reasonable experts. Professor Chaloupka has advanced models which are entitled to be given material weight. He acknowledges the limitations in this analysis but his conclusion is that the regression analyses nonetheless provide support for the efficacy of the Regulations and the regression analysis conducted by Dr Chipty in Australia as part of the PIR supports this conclusion. I agree. I do not accept that any of the regression analyses adduced by any party is definitive or dispositive and certainly those of the Claimants are not remotely such as to oust the relevance or value of the evidence adduced by the Secretary of State, whether qualitative or quantitative.

596. ***Prima facie* Conclusion**: My *prima facie* conclusion therefore is that the evidence base before the Court clearly establishes that the Regulations are suitable and appropriate as measures designed to achieve the stated objective of reducing prevalence and use of tobacco. I turn now to consider whether this *prima facie* conclusion is affected by other factors relating to the probative value of the Claimants' quantitative evidence and other margin of appreciation factors.

(iii) Reinforcing factors: Factors relating to the quantitative evidence

597. I turn now to consider particular factors relevant to the assessment of the quantitative evidence which are relevant to the *prima facie* conclusion that I have arrived at. The key point is that the quantitative evidence has numerous inherent uncertainties and limitations and must be read in conjunction with other evidence which would include qualitative analyses and (were it available) internal documentation. The analysis below identifies some of the main reasons why the Claimants' quantitative regression analyses do not have the extremely high, compelling, probative value claimed for them.

598. **The intrinsic limits of regression analysis - Economic literature**: The first point concerns the Claimants' submission that the quantitative (regression) analysis ousts prior qualitative evidence, i.e. renders it redundant and irrelevant. I emphatically reject this submission. It is in fact inconsistent with standard economic literature. I do not question the value of regression analysis as a useful statistical and evidential tool, *including* in judicial proceedings. Such analysis is routinely put forward in the course of governmental consultations and moreover is a tool used with increasing frequency in Court and in regulatory proceedings. It is widely used for instance in relation to the quantification of damages. It has been used in the US in litigation with proven effect for over 30 years in a wide variety of litigation contexts including for instance to establish racial bias in death penalty litigation. It is a discipline that has a proper pedigree. But it also has acknowledged limitations.

599. A classic analysis from the literature on the evidential value of regression analysis in litigation is that of Professor Alan Sykes, "*An Introduction to Regression Analysis*"[22]. In this seminal paper in 1993 Professor Sykes pointed out that because regression analysis was based upon hypotheses and assumptions it could be unreliable. He explained that investigative bias could also play a part with investigators working and re-working the data so that the end result conformed to the *a priori* desired result. He describes this as "*data mining*" whereby a researcher or expert "*... tries numerous regression specifications until the desired result appears. An advocate quite naturally may have a tendency to present only those estimates that support the client's position."* He also pointed out that in litigation the results of *prior* workings which were less helpful were often shielded from scrutiny through reliance upon legal privilege. He stated as follows:

> "A key issue that one must confront whenever a regression study is introduced into litigation is the question of how much weight to give it. I hope that the illustrations in this lecture afford some basis for optimism that such studies can be helpful,

[22] Alan O. Sykes, "*An Introduction to Regression Analysis*" (Coase-Sandor Institute for Law & Economics Working Paper No. 20, 1993)

while also suggesting considerable basis for caution in their use.

...

Further, regression analysis is subject to considerable manipulation. It is not obvious precisely which variables should be included in a model, or what proxies to use for included variables that cannot be measured precisely. There is considerable room for experimentation, and this experimentation can become "data mining," whereby an investigator tries numerous regression specifications until the desired result appears. An advocate quite naturally may have a tendency to present only those estimates that support the client's position. Hence, if the best result that an advocate can present contains high standard errors and low statistical significance, it is often plausible to suppose that numerous even less impressive results remain hidden, and conceivably shielded from discovery by the work product doctrine.

For these reasons, those who use regression analysis in litigation tend to report results that satisfy the conventional significance tests—often the 5-percent significance level—and to suppose that less significant results are not terribly interesting. Before most experts would feel comfortable asserting that gender discrimination has been established by a study such as that in our illustration, therefore, they likely would require that the coefficient estimate for the gender dummy be negative and statistically significant.

Even then, they would anticipate a vigorous cross-examination based on a number of matters, many suggested by the discussion above. Still more difficult issues arise when an exact parameter estimate is needed for some purpose, such as for computing damages. The fact that the parameter is "statistically significant" simply means that by conventional tests, one can reject the hypothesis that its true value is zero. But there are surely many other hypotheses about the parameter value that cannot be rejected, and indeed the likelihood that regression will produce a perfectly accurate estimate of any parameter is negligible.

About the only guidance that can be given from a statistical standpoint is the obvious—parameter estimates with proportionally low standard errors are less likely to be wide of the mark than others. Ultimately, therefore, statistics itself does not say how much weight a regression study ought be given, or whether it is reasonable to use a particular parameter estimate for some legal purpose or other. These assessments are inevitably entrusted to triers of fact, whose judgments on the

> matter if well informed are likely as good as those of anyone else".

600. Even in those areas where regression analysis is common place, for example competition law, economists accept that it can be an imprecise science. For example, in the estimable "*Economics for competition lawyers"* (Niels, Jenkins and Kavanagh (2011)) the authors point out that the source of the data used in regression modelling needs to be thoroughly tested according to proper "economic practice" and *even then* there will remain uncertainties:

> "Estimating elasticities through regression analysis is conceptually straight forward, and generally allows for more robust results than simply plotting a line. Nevertheless, there are often pitfalls and complexities with such analysis…High standards need to be met before a regression analysis can be considered robust – economists have developed a reasonably clear idea of what constitutes "good economic practice". The econometrics toolbox may always be something of a black box to you, and debates on which particular econometric method is most appropriate in the case at hand can be rather esoteric, but there are things you can do to shake and rattle the box by asking it critical questions, and see if it still holds together…
>
> First you can ask questions about the data: what is the data coverage in terms of time period and products or market participants? How frequent is the data (monthly, yearly)? How large is the data set? Are there enough observations to estimate elasticity robustly using econometric methods? Is the data of good quality (are there many missing observations or measurement errors)? Data coverage must be sufficient to cover the relevant products and time period, and the more observations (and more variants between them) there are, the greater the likelihood of finding statistically significant results. You can see that in the extreme, if you have only two observations, chances are that the line drawn from one to the other will not accurately reflect the demand curve…Second, you can ask questions about the econometric approach: is the econometric method appropriate for the market concerned and in the light of the available data…What assumptions underlie the econometric approach? Is the equation specified correctly, and is it line with economic theory and market reality? Does it solve the price endogeneity problem? If instruments are used for price, are they appropriate? How do the results vary if alternative approaches or specifications are used? The third category consists of questions about the elasticity estimates: are the estimated elasticity values plausible (is the own-price elasticity negative as theory would predict)? How similar or different are they if compared with other available elasticity estimates? Are the estimated coefficients statistically significant? Testing for statistical significant helps in

> understanding the uncertainty surrounding an estimate and informs about how much weight should be placed on the analysis. You should expect any econometric results to be accompanied by a range of statistical diagnostic tests, which indicate whether the results are statistically significant…and whether they suffer from potential statistical problems such as endogeneity".

601. The authors thus accept that not only is there substantial scope for, as Professor Sykes would have it, "*data mining*" but that even when robust data is used it remains necessary to test the "*assumptions [which] underlie the econometric approach*" and it is accepted that the analysis used must be "*in line*" with "*market reality*". In the present case regression analysis is undoubtedly capable of being useful evidence but I firmly reject the submissions that: (i) it is capable of providing a definitive result and/or (ii) it is the only evidence that is reliable and/or (iii) the qualitative evidence relied upon by the Defendant is rendered irrelevant by it.

602. **International regulatory best practice - Approach to regression analyses**: The economic literature is borne out by the best practice rules of international regulators. I have set out at paragraphs [325] – [329] above the best practices conclusions of the CMA and the European Commission. These set out the limitations of quantitative empirical evidence and how its probative value can only be assessed in the light of a process that guarantees transparency and accountability and which permits of full verification of the research against all the data used and other relevant evidence and information. These best practice rules are relevant because they state that quantitative evidence is rarely if ever determinative of an issue and that it therefore has to be viewed as part of the totality of the evidence which includes qualitative and other evidence. It thus provides powerful support for the conclusion that I have arrived at on the evidence itself that the quantitative evidence is not dispositive. It also provides powerful support for the process point which I address at paragraphs [630] – [648] below.

603. **Disputes over data sources**: As the literature establishes, the reliability of any model is contingent upon the quality of the underlying data. The parties have relied upon a multiplicity of data sources[23]. Each has its limitations. Most have had to be adjusted to be made more relevant. A good deal of debate and argument before the Court centred upon the intrinsic reliability of particular types and sources of data and the extent to which opposing experts had used data which was unreflective or inadequately modified to increase its relevance. A data source might be more (or less) reliable because of such factors as: the date or timeliness of its collection; the frequency (periodicity) of its collection and updating; and its coverage (the number of persons or transactions sampled or surveyed). Where data that is intrinsically less reliable is used then it might be rendered more reliable if it can be effectively

[23] In particular in relation to post implementation Australia the data sources included: (i) the National Drug Strategy Household Survey (NDSHS); (ii) Australian State Prevalence Survey data; (iii) the Cancer Institute of New South Wales Tracking Survey (CITTS); (iv) the National Tobacco Plain Packs Tracking Survey (NTPPTS); (v)In-Market data managed by InfoView Technologies (IMS); (vi) Scanner based sale data collected by Nielsen; (vii) the InfoView exchange of sales data (New Zealand); (vii) OECD Long-run consumption data; (viii) The System of National Accounts data produced by the Australian Bureau of Statistics (National Account data); (ix) Retail sales data produced by Aztec-Dryden Reply data; (x) Roy Morgan Single Source Prevalence data (RMSS); (xi) Roy Morgan Consumer Survey data commissioned by KPMG; (xii) Roy Morgan data set out in Claimants' reply data.

manipulated or modified ("*cleansed"*) to improve its relevance and accuracy but whether this can be achieved will then, in turn, depend upon a range of considerations such as: the type of modelling or analytical methodology being used; the different types of controls used; and the accuracy of the assumptions deployed, etc. The utility of any particular data source therefore depends upon an understanding of its strengths and weaknesses and therefore in not overstating the accuracy of the inferences that may properly be drawn from it. I give two illustrations (out of many) below of the limitations. In neither case was sufficient information or evidence placed before the Court to enable me to determine who was right and who was wrong or whether the differences were material.

604. The first concerned the CITTS and NTPPTS data sets used by Professor Viscusi in their reports on behalf of the Claimants to examine the beliefs and conduct of consumers post-Australian implementation. There is no doubt that this source of data can have *some* value but it is not free from limitations. Mr Derbyshire (for the Secretary of State) pointed out that CITTS data was based upon surveys of recent actual smokers and did not provide evidence on smoking prevalence and did not provide guidance as to the impact of standardised packaging on potential <u>new</u> smokers. Professor Chaloupka pointed out in relation to the use of the NTPPTS data that if one modified (he said improved) the controls for the characteristics of the survey respondents then one could readily show that standardised packaging exerted a positive effect on reducing smoking. This was in particular if one concentrated upon the data which used longitudinal surveys which he considered to be more accurate or indicative (i.e. surveys of the same people over time) as opposed to cross-sectional surveys (which do not follow changing patterns of behaviour in the *same* individuals).

605. Another illustration concerned clearance data. The Defendant's expert witnesses relied upon Australian clearance data (including excise and customs duty) which ostensibly showed that between December 2012 and May 2013 consumption had fallen by 3.4% relative to 2012 when standardised packaging was introduced. Professor Mulligan, for the Claimants, in his second Report (paragraph [76]) complained however that this information had been misinterpreted since the official Australian Government data had not taken account of excise equivalent refunds. He said that clearances could not be taken to indicate consumption *unless* refunds were taken into consideration. Professor Mulligan then sought to provide a calculation of the actual results with refunds factored in. He concluded that this led to a net consumption reduction of 0.2%. Mr Derbyshire for the Secretary of State responded by challenging the relevance of modifying the basic data with refund clearance data pointing out that the Australian Government had already addressed itself to this point. He concluded: "*These growth rates do not take into account refunds of excise equivalent customs duty made under the [relevant scheme] between December 2012 and May 2013. These refunds cannot be related to annual net clearances on a comparable basis to other data used to derive these growth rates*". Mr Derbyshire then explained that the updated equivalent Australian clearance figures showed a decline of 7.9%. He then, in addition, argued that the 0.2% figure arrived at by Professor Mulligan was itself premised upon data from one tobacco manufacturer (PMI) to which the Secretary of State did not have access (as it has not been disclosed). Mr Derbyshire said: *"...neither the Department nor Professor Chaloupka can analyse the data used and the manner in which Professor Mulligan purports to use that data for one manufacturer to assess the impact of the returns on the market*

as a whole". This is typical of many of the disputes which have arisen. The parties rely upon a category of raw data; they then adjust it to make it more reflective of reality; there then arises a dispute about the process of modification or adjustment and whether it is relevant or correctly quantified. This is not the sort of dispute that this Court can readily rule upon, Most of the econometric disputes are of this nature and there are a plethora of them.

606. **Materiality:** The materiality of disagreements about different components of the econometric analysis was not subjected to any detailed analysis. If I had come to the conclusion that there were hard edged errors I would then have had to ask whether they were material to the final outcome. A Court would not strike down the Regulations unless satisfied that an error was material. The Claimants do not dispute this: see paragraph [416] above. The experts did not however in any real way grapple with materiality on an issue by issue basis and there was no proper evidence placed before the Court which would have enabled me to form a conclusion on the Claimants' submission that any error was material.

607. **Uncertainty as to comparability of Australian experience**: There is also the point that whilst it is accepted that evidence from Australia will be valuable it has never been accepted that it is a perfect fit for the United Kingdom. I note that the validity of Australia as a perfect comparator for the United Kingdom was questioned by even the Claimants' own experts. Mr Bezant, for instance, was instructed to prepare a valuation of the loss which would be sustained by PMI if the Regulations came into force. I have referred to his report dated 21st May 2015 at paragraphs [699] - [706] below. For present purposes the relevance is that in Appendix 4, when he is dealing with the so-called "Market Model" for calculating lost value he considered the relevance of the empirical data from Australia. As to this he said: "*I have reviewed data on cigarettes in Australia between 2008 and 2014, for evidence to inform my assumptions on how cigarette manufacturers may respond to SP in the UK. However, given the differences in the Australian and UK cigarette markets, I cannot assume that UK manufacturers will respond in a similar way as they may have done in Australia*".

608. The 2014 Impact Assessment (ibid paragraph [38]) stated:

> "The intervention is worth pursuing now, notwithstanding these costs and risks. We believe that the cost of delaying a decision on whether to implement the intervention (Option 3) is too great in public health terms, particularly in view of the following considerations:
>
> - we can already benefit from the experience of Australia in determining the detail of any legislation and in implementing the intervention;
>
> - the potential health gains are very substantial and dramatically outweigh quantified costs;
>
> - the deferral of such gains would adversely affect the life expectancy of large cohorts of children and adult would-be quitters in every year of deferral;

> • if the true impact of standardised packaging is substantially smaller than assumed in this IA (but not zero) it would still be net beneficial to act now;
>
> • *evidence from Australia is valuable, but there are considerable uncertainties that will remain*;
>
> • if standardised packaging is implemented, monitoring of extent of impacts, such as any impact on cross-border shopping or the size of the illicit market would identify where mitigating action is needed; the information conveyed by such monitoring is likely to be much more directly pertinent to the policy context in the UK than that which can be gathered from other countries that have implemented the intervention (such as Australia)".
>
> (Emphasis added)

609. There are some very obvious differences. Although ultimately the risk of the Regulations increasing illicit trades was not at the oral hearing seriously pursued by the Claimants the risk of illicit trade between Australia and third countries will provide little guidance as to what will happen between (say) the UK and France. Another example cited by one expert was differences in consumer purchasing power.

610. **Comparability and the use of tax to neutralise the depressant effect of downtrading on average prices**: The Claimants' models assume that the Regulations will cause downtrading. This is a critical component part of their models. The position of the UK Government is that it would learn lessons from implementation in the UK and from the Australian experience and use tax policy to neutralise any average price depressant effects of downtrading. So, for instance, if in Australia, downtrading led to (say) a 5% decrease in average prices then using that evidence the Treasury in the United Kingdom could modulate tax so to eradicate or reduce that reduction in average price. On the Claimants' case if there is no or only a limited reduction in average prices then their basic economic model of how the Regulations will be counterproductive is seriously and almost certainly fatally undermined; and if the Government here *does* use the market experience to address downtrading effects then the Australian experience (measured through regression or other quantitative techniques) becomes of far less value as a comparator.

611. **Prematurity and the scheduling of future reviews**: A very important consideration is that in the relatively near future reviews are to be conducted in the UK, the EU and they have already been conducted in Australia (see paragraph [512] – [534] above). This raises the question whether a national Court should pre-empt those reviews, which will examine the evidence base as it *then* exists, which will necessarily be more complete and mature than it is *now*. A Court can also take into account that the evidence which will be collected during these reviews is likely to be of a broader nature than that which is placed before a Court in the course of litigation, so that the conclusions arising from those specialist reviews might be superior to that arising from a Court. And a Court can also take into account further that the fact that reviews have been scheduled-in through legislation and are mandatory is an expression of the

legislature's considered intention that the planned review is the appropriate point in time at which to take stock.

612. These are all considerations which strongly support the submission of the Secretary of State that the evidence is unripe and incomplete and that the Claimants' submission that the current evidence placed before the Court (i.e. their evidence) is sufficiently robust and definitive cannot be accepted.

613. That view is shared by others. The Director General of the WHO expressed the view to the Parliamentary Under-Secretary of State for Public Health in a letter sent on 3rd September 2015 that "… *The Australian measures were fully implemented in December 2012 and it remains too soon to assess the impacts of plain packaging in Australia in a comprehensive manner".* The Director General then cited new emerging evidence on the impact of standardised packaging in Australia and stated that this was "… *consistent with the broader body of evidence discussed in the brief, and provides additional support for the conclusions contained therein*". The "brief" referred to was the brief submitted by the WHO to the WTO dispute panel that had been convened to challenge the new laws in Australia. This remains the position of the Australian Government in 2016 as set out in the PIR (see paragraph [532] above). Chantler also took the view that it would take a lengthy period of experience from Australia to be able to draw robust conclusions. This is the position adopted in this litigation by the Secretary of State and by his experts. Mr Derbyshire took the view that even if there was 10 years' worth of Australian data there would remain a significant "*subjective*" element of the data which would require judgments to be made - there would *"always be uncertainties in the analysis*".

614. **Other uncertainties in the evidence base:** In my judgment the Defendant's argument that there is still insufficient evidence upon which to form a concluded position is a proper, logical and correct conclusion. There now exists just about 3 years' worth of data from Australia. There are, evident in this litigation, a multiplicity of live disputes about the adequacy of the Australian data based upon uncertainty as to *when* the impact of new measures will begin to "bite" and take effect. These temporal uncertainties cover: when the Regulations might begin to become effective after first coming into effect; whether their efficacy will be constant or variable over time; and how the efficacy of other measures will be affected by the introduction of the Regulations, etc. These uncertainties mean that the data might take a long time to become settled and reliable as an indicator of efficacy or before which the true underlying trends can be identified. I set out some examples of these temporal complications below.

a) **The masking effect of the combined effect of simultaneously acting measures**: The point in time at which the Regulations might become effective is complicated by the fact that the new standardised packaging measures are being introduced to act in a complementary manner with a series of parallel counter-measures. There is therefore an inherent masking effect on the potency of each measure created by the combined effect of the suite of other measures acting simultaneously. The efficacy of each individual measure in this suite is uncertain: some have been in force longer than others and their principal effects may taper off over time yet they will still work in parallel with newer measures which might be at their most potent but which might themselves taper in due course. The rate of overall decline in prevalence and

use is not therefore guaranteed to be either stable or durable. Accordingly, a new measure, such as standardised packaging, can be expected to affect (one way or another) the overall downward pressure on usage but, again, the impact of the new measure might not become evident immediately and even when it does kick in its effect might evolve over time and that evolution itself might be variable. There are, of course, econometric techniques which can attempt to measure the impact of a new measure in the context of other variables acting in conjunction with each other but, as the standard literature on regression analysis explains (see paragraphs [598] – [601]), these models are subject to the vicissitudes of the data they deploy and the assumptions that are built into the models. Any air of certainty that a model exudes in the hands of a skilled expert can in actual fact mask real uncertainty.

b) **The complications caused by unpredictable consumer reactions / the effect of addiction**: The point in time at which a measure will prove effective is also dependant upon consumer reactions which, as the research worldwide demonstrates, is subjective and not always predictable. For instance, many consumers are addicts and do not react to supply and demand factors as if the product in question were an ordinary consumer product, such as eggs or bananas. The rate at which addicts may become receptive to the new measures will depend upon subjective factors such as the degree of addiction, the desire to quit, and the strength of the addict's willpower to persevere with a quitting strategy. I deal more generally with addiction below.

c) **Hard core non-quitters**: There is also a body of literature which seeks to identify what are called "hard-core non-quitters". This describes a group of consumers who are resistant to efforts to deter their smoking. The thinking is that as deterrent measures pick off those susceptible to persuasion the residual pool of smokers becomes ever more concentrated with stubborn smokers. The literature suggests therefore that the rate of decline in smoking might not be linear but will taper off in the absence of new, ever harder-hitting, counter measures. This is a complicating factor in assessing, in isolation, the point in time at which a new measure such as standardised packaging may become effective.

d) **The durability of smokers' brand loyalty**: Long term smokers may have durable memories and their allegiances to brand names might take a considerable period of time to weaken especially as under the Regulations the brand name can still be used (a point made also by Chantler: See quotation at paragraph [116] above).

e) **Delayed impact on adolescent initiation**: The literature suggests that the efficacy of deterrent measures on the initiation rate of adolescents may only reveal itself after a series of cohorts of children have reached and passed through adolescence.

615. **Uncertainty in supply and demand**: A further complication arises from the fact that the way in which supply and demand operates is itself complex since the object and purpose of regulation in this field is to distort normal patterns of supply and demand. So by way of illustration upon introduction of the TPD pack sizes may not contain less than 20 cigarettes; this is to deter the making of single or smaller unit number

purchases. If average prices reduce and consumers save money that saving will not in all likelihood be enough to pay for a new unit pack of cigarettes. Packs of cigarettes can cost circa £9 or £10; a saving of (say) 50 pence or even £1 does not enable the consumer to go out and buy a new unit pack. He or she must save up the 50p's in order to purchase a new pack. And in the interim the consumer might spend that saving on something else. This was a point recognised as a possibility in the 2014 Impact Assessment at paragraph [28] (set out in paragraph [138] above). Since the TPD is not yet in force there is no evidence to indicate how in practice this will impact on the supposed stimulant effect of downtrading.

616. **Addiction:** Addiction also means that a "30 a day" smoker might not need more than that to satisfy the craving especially if he or she is torn between a craving to smoke and a desire to quit. In short the fact that the product is consumed by addicts means that the effect of downtrading is an inherently difficult thing to predict. A theme running throughout the Secretary of State's criticisms of the Claimants' experts was their failure properly or at all to address the impact of addiction upon consumer behaviour. There is a significant body of research literature upon this.[24] A minority of researchers have taken the view[25] that smoking is a rational activity and that therefore addicted smokers must be taken to be fully aware of the consequences that smoking will have upon their future economic conduct. However, the preponderant weight of research adopts a more nuanced position which is that addicted smokers apply inconsistent standards of conduct and behaviour at different points in time reflecting, for instance, their internal struggle both to quit and to consume nicotine.[26] Econometric modelling which ignores the highly complex and subjective impact of addiction risks materially skewing research outcomes. Some of the expert analysis relied upon most heavily by the Claimants does not even mention the impact of addiction at all.

617. **Tobacco companies pricing policies**: Into this mix one also has to predict the behaviour of the tobacco companies. In their basic economic theory (summarised at paragraph [478] above) the Claimants assume either that the tobacco companies will not react to the reduction in average prices caused by downtrading, or, that if they do react they will compete the prices down even further in order to retain market share. But there is another possibility which they have not addressed which is that the tobacco companies manage to increase prices in order to recoup lost profits. Downtrading strips the Claimants of profit and they could seek to counter this by raising unit prices of the (now) unbranded products in order to recover some of the losses. In oligopolistic markets where a small number of suppliers collectively dominate supplies non-collusive "coordinated effects" (or "conscious parallelism") can arise which leads to price increases. The market characteristics described in the Claimants' downtrading counterfactual are: greater product homogeneity and high levels of price transparency. Standard economic theory postulates the possibility that in such markets prices can rise.[27] I would find it hard to believe that internally the tobacco companies have not given consideration to the impact of downtrading on pricing strategy and profit recoupment policies. Yet their policy of not disclosing internal documents means that this is an issue they have not addressed in these

[24] Summarised in paragraphs 134ff and the related footnotes of the 2015 Impact assessment.
[25] cf. 2015 Impact Assessment paragraph [135]
[26] Ibid paragraphs [135]ff
[27] See for example Whish & Bailey Competition Law (2015) pp 598ff; Niels, Jenkins and Kavanagh, Economics for Competition Lawyers (2011) pp 147-149.

proceedings and their internal thought processes are not transparent to this Court. This means that their instructed experts can hypothesise about price movements without the risk of their theories and opinions being undermined by internal "real life" thinking. For present purposes I need do no more than postulate that one or more tobacco companies would or might seek (in a perfectly lawful non-collusive manner) to raise prices to counter profits lost from downtrading. Whether this would succeed in this market remains to be seen. But it is sufficient that it is a possibility that makes modelling future price movements with any degree of precision very difficult indeed.

(iv) Methodological considerations.

618. In my judgment a variety of methodological considerations also confirm my *prima facie* conclusion set out above. I have set out in the context of Ground 2 my conclusions on the relevance of adherence to methodological standards and I do not repeat them here. These considerations apply to the evidence adduced by the parties in relation to the proportionality challenge. Pulling threads together the following points emerge: (i) none of the regression analyses have been subjected to peer review or to any alternative process by which they could be subjected to any comprehensive verification process; (ii) there is a general lack of transparency about the expert regression analyses. The assumptions which underpin these reports are opaque. It was argued for instance that the assumptions made by Professor Mulligan were set out in annexes to his reports. An analysis of these annexes does not lay bare the assumptions made and many are cloaked in and subsumed by inpenetrable maths; (iii) none of the expert opinions were capable of being verified or cross-checked against internal documents and on the basis of conclusions reached by the WHO and the US courts about those internal documents there is a strong likelihood that a proper disclosure process could have generated inconsistent evidence which would have forced the experts to alter and modify their views and at the very least would have provided ammunition to the Secretary of State's experts which could have been used to challenge the Claimants' experts' opinions. Importantly, the internal documents are relevant to both the new quantitative analysis but <u>also</u> the older pre-Australian qualitative evidence. I accept that the methodological criteria apply to all of the evidence, from all sides. But in this case it applies with greater force to the Claimants' evidence because their case has predominantly been advanced through a large number of experts. This is their chosen method of attack. I note also that the Australian Government took the same view in relation to evidence submitted by the tobacco companies in relation to the PIR (see paragraph [522] above). I now set out below some particular points which elaborate upon these conclusions.

619. **The absence of peer review**: The quantitative evidence was almost wholly free from peer review and was not subjected to any systematic, fully transparent, process of verification which could have acted as a proxy or substitute. An illustration of the benefits of a process which subjects complex quantitative analysis to external peer review is found in the approach of the parties to the research of Kaul & Wolf (see paragraph [291] above). The Claimants' experts relied upon this research which suggested that the available data from Australia demonstrated that standardised packaging led to adverse health results. It appears (see quotation below) that this research was funded by Philip Morris. The Secretary of State however relied upon a subsequent research paper by Diethelm & Farley, "Refuting tobacco-industry funded research: empirical data shows decline in smoking prevalence following introduction

of plain packaging in Australia" (November 2015). This set out to "correct" Kaul & Wolf and to provide an assessment which they said was "independent" of the tobacco industry. Under the methodology used monthly smoking prevalence and sample sizes from repeat cross-sectional surveys were reconstructed from published working papers using an original reverse-engineering technique that achieved (they said) nearly 100% accuracy. This was analysed as a time series using logistic regression analysis. Indicator variables were chosen reflecting comprehensive smoke-free policies, graphic health warnings, a 25% taxation increase, and the introduction of plain packaging. The result was that smoking prevalence declined from 25% to 18% over the 3 year period – an overall 28% relative reduction or average 2.8% (95% confidence interval 2.6% - 2.9%) annual reduction. A significantly improved fit was obtained by the full model which included terms for tax increase (4.8%, 2.7% - 6.8% reduction), a comprehensive smoke-free policy (4.5%, 1.7% - 7.2% reduction) and plain packaging (3.7%, 1.1% - 6.2% reduction) in addition to an adjusted average annual reduction of 1.7% (1.3% - 2.2%).

620. The conclusion was expressed in the following way:

> "Conclusions:
> A significant decline in smoking prevalence in Australia followed introduction of plain packaging after adjustment for the impact of other tobacco control measures. This conclusion is in marked contrast to that from the industry-funded analysis".

621. The authors sought not to overstate the result:

> "While it is not possible to conclude that the decrease in smoking prevalence was *caused* by plain packaging, it remains that the new tobacco packaging policy constitutes, at least partly, one of the most plausible explanations for the observed decrease. Another factor which may have also induced a decrease in smoking prevalence is the enlarged and enhanced health warnings, which appeared on cigarette packs conjointly with the requirement for standardized packaging. It is however difficult to completely separate these two measures from each other as the larger health warnings are an integral part of the new pack design.
>
> If further data confirm the observed decline in smoking prevalence noted in the 14 months from November 2012, this would indicate that the measure is associated with a stronger effect than anticipated".

622. The researchers declared that they were free from any conflict of interest and did not have any specific grant from any funding agency in the public, commercial or not-for-profit sectors. The researchers took the evidence base used by Kaul & Wolf and subjected it to a full regression analysis. It is worth setting out the background to this in full:

> "The multinational tobacco companies are intensively opposing the measure on several fronts, notably using international trade

law and bilateral investment treaties to challenge Australia and threatening the other countries with large lawsuits and the spectre of billion-dollar financial compensations. One key legal argument used by these companies invokes the principle of proportionality, which requires that any limitation on the exercise of rights and freedom may be made only if it is *suitable* to achieve its aim. In spite of mounting evidence to the contrary, they claim this condition is not met in the case of plain packaging, contending that evidence of effectiveness of the measure is lacking.

They even go further, resorting to the classical *ad ignorantiam* argument, shifting from absence-of-evidence to evidence-of-absence. In their response to the UK Department of Health's consultation on plain packaging, British American Tobacco (BAT) states that "the evidence to date from Australia shows that more than 18 months after its introduction, Plain Packaging has not had any effect on smoking behaviours beneficial to public health," referring to the Roy Morgan population survey data as evidence. Similarly, JTI declared in its submission to the consultation that after 18 months, "the evidence actually emerging from Australia reinforces the fact that plain packaging does not work", citing two studies by A. Kaul and M. Wolf published on the web-site of the University of Zurich, which "have found that plain packaging has had no effect on smoking prevalence, either among minors or adults" and a report by a UK consultancy company, all three funded by Philip Morris. A closer inspection reveals that the Roy Morgan population data cited by BAT designates the same two studies. In its response to the consultation, Philip Morris also refers to these studies, saying that "the experts found no evidence that 'standardised packaging' had had an effect on smoking prevalence among Australians," adding that they "confirmed that if there had been an effect in reality … it would have been reflected in the data.

These two studies are presented by one of their authors as the only papers on plain packaging "based on real-world data." The authors also claimed that their methodology is the most apt at finding an effect associated with plain packaging: "Altogether, we have applied quite liberal inference techniques, that is, our analysis, if anything, is slightly biased in favor of finding a statistically significant (negative) effect [...]. Nevertheless, no such evidence has been discovered. More conservative statistical inference methods would only reinforce this conclusion." The two papers, which use nearly identical approaches, have been criticized for their methodological flaws. Most critiques related to the first study (on minors), except Laverty et al. who looked at the second study (on adults). None was based on a re-analysis of the data used by the

> authors. In this article, we complement these critiques by re-analysing the data set used in the paper on smoking prevalence in adults using a more appropriate method of analysis.
>
> The two authors further assume that in Australia, like in "all the OECD countries," there is a continuous downward trend in smoking prevalence which is best modelled by a declining straight line. They explain that "we see essentially the same line in all countries" regardless of whether they have "heavy anti-smoking measures" with a "minus 0.4 percentage point effect per year." Accordingly, this decline in prevalence observed over the past 15 years across OECD countries is the result of a "pre-existing" continuous and uniform trend. Two studies published in peer-reviewed journals contradict this assumption and strongly suggest that the evolution of smoking prevalence over periods which largely overlap the period considered by Kaul and Wolf was associated with the introduction of tobacco control measures.
>
> Our objective hence was to assess the effect of plain packaging on smoking prevalence among adults in Australia based on the same data as Kaul and Wolf using a more appropriate statistical method and accounting for the potential effect of other key tobacco control measures".

623. It was observed that when Kaul & Wolf noticed that there were discrepancies in their data (the so called discrepancy between the Loess trend and the time trend for the first three years): "*Rather than questioning the validity of their linear model, they simply cut off the first 42 months of observation, retaining only months 43-156 for their analysis."* And also:

> "The conclusion reached by Kaul and Wolf in their two papers was based on a subtle circular reasoning. They posited that the decrease of smoking prevalence observed in OECD countries, including Australia, follows a "pre-existing" linear trend which is independent of tobacco control policies. Starting from the hypothesis that all tobacco control measures are ineffective, they arrived at the conclusion that there was no evidence of the effectiveness of one of them, plain packaging.
>
> Using the same data set as Kaul and Wolf, we have shown in this paper that with the more realistic assumption that tobacco control measures can be potentially effective – as was shown by Wakefield et al - we arrive at the conclusion that three key tobacco control measures that were introduced during the 13-year period under study, namely comprehensive smoke-free policies, the large tax increase of April 2010 and plain packaging, were all associated with a clear and statistically significant reduction in smoking prevalence. This suggests consequently that all these measures were effective. In particular, the reduction in smoking prevalence that followed

> the introduction of plain packaging appears to have been even greater than expected".

624. In her closing submissions Ms Demetriou QC skilfully subjected Diethelm & Farley to sustained criticism. I am not in this judgment expressing a conclusion on who is right and who is wrong. The criticisms of Kaul & Wolf seem persuasive. However, ultimately this episode demonstrates that much of the evidence in this area is as yet undercooked. It has not been subject to peer review or to any proxy process whereby it can be robustly tested.

625. **The inability to cross-check expert's analysis against internal documents**: I have set out the importance of access to internal documents at paragraphs [292] – [293] and [311] – [319] above and I do not repeat here those considerations. There has been no ability to cross check any of the assumptions underpinning the Claimants' expert reports against internal documents. It is argued by the Claimants that there were no such documents which are of relevance to the quantitative analyses. This submission however is not based upon any of the lawyers having conduct of this case having undertaken a full disclosure exercise with their clients. It is not a submission I can accept. The experience in the US shows that there are likely to be a multiplicity of relevant documents, and that they might well <u>not</u> be supportive of the Claimants' case. The economic literature and regulatory best practice all assume that empirical quantitative analysis must be benchmarked not only against the data used by the expert in question (which of course is the product of that expert's own choices) but <u>also</u> other evidence. Courts and regulatory authorities routinely observe that unguarded internal documents may be more informative than "*documents created as advocacy material*". For example the US Department of Justice (Antitrust Division) in its Horizontal Merger Guidelines (August 19th 2010, paragraph [2.2.1]) takes the firm view that in a counterfactual analysis (such as that being conducted in the present case) the <u>internal</u> documents of the companies concerned have greater probative value than "*advocacy*" documents created for the purposes of litigation or enforcement proceedings:

> "2.2.1 The Agencies typically obtain substantial information from the merging parties. This information can take the form of documents, testimony, or data, and can consist of descriptions of competitively relevant conditions or reflect actual business conduct and decisions. *Documents created in the normal course are more probative than documents created as advocacy materials in merger review.* Documents describing industry conditions can be informative regarding the operation of the market ... ."
>
> (Emphasis added)

626. I can see no reason why in legal logic or in common sense a Court should have to accept an evidential process which is markedly inferior to that which regulators applying internationally accepted best practice standards see as the norm.

627. I give one illustration which goes to the core of the Claimants' quantitative analysis. In April 2013 the CEO of Imperial stated in public that: *"As I'm looking at Asia Pacific, I should mention Australia, we've had the first six months of the plan pack*

environment in Australia. We've seen the market decline roughly 2% to 3%, so maybe not as bad as we might have anticipated". This is the considered view of a CEO about post-implementation Australia and it is a view that – presumably – such a CEO would not deliver lightly not least because it could be price sensitive. It refers, implicitly, to internal projections being worse than the 2-3% figures and suggests - as one would have thought was inevitable – that internal assessments of future sales in the light of standardised packaging had been undertaken. It also confirms the conclusions of the Defendant's experts who rely upon this 2-3% figure and whose own quantitative analysis generates figures of this order of magnitude. As I have said elsewhere the impact of standardised packaging in Australia simply must have involved the tobacco companies in predicting future sales. Their marketing men would have been failing in their elementary duties if they had not done this. If all of this *internal* analysis was held up and put side by side with *external* expert reports it would put them into context. If the external experts had been seised of all of the internal projections of their clients when they prepared their reports this would have forced them to address that internal material, to modify their own views or at least to explain in a credible way why the internal analysis was wrong or unreliable. And if that internal material corroborated the expert's conclusion that would enhance the reliability of those reports before the Court. In my judgment I am bound to be cautious of analysis created entirely by experts prepared in blissful ignorance of the clients' internal analysis and research.

(v) Broader considerations relevant to the margin of appreciation

628. I have set out at paragraphs [438] – [472] above a variety of considerations indicating that I should apply a relatively broad latitude to the evidence adduced by the Secretary of State. These factors provide yet further support for the *prima facie* conclusion that I arrived at.

629. These include: (a) the fact that the Regulations are public health measures where both the precautionary principle applies and where the scientific evidence is predictive and not fully mature or robust; (b) the fact that there exist scheduled reviews at points in time when it can be expected that the evidence will have developed and matured; (c) the fact that the decision maker was Parliament and that the process of promulgation of the Regulations was supervised by the EU Commission; (d) the fact that the adoption of standardised packaging measures is endorsed at the highest level of international consensus; and (e) the fact that this is an area of shared competence between the EU and the Member States in which the Member States must take a high level of protection of health as their starting point.

(16) The limits of judicial decision making

630. I wish at this stage to draw some threads together and make some observations about the process of evidence collection and presentation in cases such as the present. This case has, in my view, raised two issues of concern. The first is a constitutional issue and concerns the relationship between Courts and Government and the nature of the task now being imposed upon the Courts. The second is as to the mechanics of the exercise which the Courts are instructed to perform.

(i) The constitutional point

631. **The evolution of evidence over time:** This case raises a constitutional issue about the relationship between the Courts and legislatures. If the Court is required to take a decision on evidence that was not before the decision maker, which may include a legislature, then the extent to which judicial deference can apply is diluted since the Court is grappling with evidence that the decision maker never addressed itself to. Indeed on this basis a Court might strike down a measure whilst concluding simultaneously that at the time the impugned measure was adopted the legislature acted perfectly lawfully. And the longer the period of time between the initial decision and the Court proceedings and the greater the volume of new evidence the less logical it becomes to accord to the decision maker deference because of its status.

632. **Reconciling deference with the assessment of new evidence**: The approach that I have adopted in this judgment seeks to reconcile the need to review the new evidence and form my own judgment with the need to pay proper respect to the fact that I am assessing, in a judicial review, the legality of legislation promulgated by a democratically elected Parliament. To achieve an appropriate balance I have sought to apply the sorts of margin of appreciation factors that would apply to the decision maker, and which are consonant with the facts of this case, to the evidence before the Court. The Court thus adopts the mantle and garb of the decision maker and then, within the confines of the appropriate margin of appreciation, applies up to date evidence. The way in which relevant margin of appreciation factors apply might alter with the passage of time. I have for instance, as set out above, taken into account whether the precautionary principle *still* applies and whether the decision to adopt the Regulations *remains* predictive and whether the evidence *remains* insufficiently robust or mature, etc. These were all factors relevant to the original decision and I have re-tested them against the evidence as it exists as of the date of judgment and made the appropriate adjustments. In this way the Court complies with the instructions given to it by the Supreme Court and the Court of Justice in cases of this sort, yet respect the constitutional limits inherent in the fact that this is a judicial review of legislation.

(ii) The evidence point

633. **The issues in the present case**: This case has proven to be an acid test of how a Court can cope with complex technical evidence. I start with some very general observations. The evidence was voluminous and highly complex. Expert evidence is adduced in many different types of Court proceedings and, in the main, it is of such a nature that it is comprehensible to the normal Court. An example is medical evidence in clinical negligence trials; experience indicates that the issues in such cases invariably boil down to narrow disputes of fact which are capable of being understood and analysed by a Court. Most of the evidence tendered in this case, in contrast, is <u>not</u> the sort that would be easily digestible and readily understood by a Court. I form this view from the perspective of a judge with at least some background and knowledge of economic and econometric analysis. I note that the same point has been made by specialist regulators whose best practice guidelines emphasise that cases cannot be resolved at the level of high level discourse between experts (see paragraph [326] above). The evidence has to be comprehensible to non-experts. I am not however criticising the parties for choosing to serve empirical evidence of the sort in issue: it is appropriate evidence in the context of this case. My concern lies with ensuring that in

the future Courts confronted with the task of assessing complex evidence in a proportionality setting are able to perform that job with confidence. If Courts find themselves presented with an impossible task then the harsh reality may well be that a claimant risks failing in the challenge regardless of the merits. But if this were to happen it could represent a denial of justice and the provision of an effective remedy.

634. **The need for a process driven solution**: I set out below a process which in my judgment should be adopted in cases such as the present. In the light of my experience in this case there is a real risk that unless some process of the sort described below is used then the more complex and evidence based of proportionality challenges risk withering on the vine. The solution is process driven. The guiding principle must be that it is the primary responsibility of the parties to reduce to the absolute minimum the number and scope of evidential disputes and also to provide to the Court a road map setting out how the remaining disputes are to be resolved. In my view a process along the following lines was necessary in this case.

635. **Early mutual engagement of experts**: First, the parties should exchange experts' reports at the earliest possible stage and long before the hearing. At the outset of litigation there should be a detailed *inter partes* discussion as to how expert evidence is to be presented to and addressed by the Court. The parties should not await case management hearings before embarking upon this process.

636. **Identification of areas in dispute**: Second, the parties' experts should meet and identify the areas in dispute between them. They should then draw up a list which identifies both areas of agreement and areas of disagreement. This then needs to be appropriately recorded. The areas of agreement may be capable of being recorded in the form of agreed facts or materials (e.g. one side might admit the contents of a witness statement or all or part of the expert report of the other side).

637. **Identification of materiality of areas of dispute:** Thirdly, in relation to each area of disagreement the experts should then seek to agree which are material and which are immaterial to the outcome and why. This is critical since disputes which are not material should henceforward be discarded. Again this should be properly recorded so that the Court has a record which may be referred to in judgment. This exercise should also set out the respective views on the *extent* of the materiality of the dispute (given that there can and probably will be degrees of materiality).

638. **Identification and articulation of reasons for disagreement / listing of assumptions**: Fourth, in relation to the remaining material disputes the experts should set out *why* they disagree and their criticism of the other experts' opinion on that particular issue. If not already properly recorded in experts' reports any assumptions underpinning an expert's view should be clearly and concisely set out in terms which can be understood by a non-expert. In the present case a major difficulty for me has been in both identifying and then being able to test the assumptions which underlie a great deal of the expert evidence. If Courts are to be able to rule, effectively, upon complex economic evidence then it is very important that the assumptions which underpin models are laid bare. It will not suffice for assumptions to be concealed amidst or submerged below a welter of complex jargon or maths. Rarely, if ever, should a Court be asked to resolve a dispute based on maths. Such matters should be capable of expert resolution and agreement prior to a hearing.

639. **Identification of evidence relevant to outstanding disputes**: Fifth, in relation to each and every such remaining dispute the experts, perhaps at this stage assisted by the legal representatives, should identify and list all documents and/or pieces of evidence which are relevant to the dispute and its resolution.

640. **Articulation of a road map to resolving the dispute**: Sixth, the experts should set out their opinions on exactly *what* the Court has to decide in order to resolve the dispute and *how* this can be achieved. For example, if the dispute is about the validity of an identified assumption the parties should identify the corpus of evidence that is relevant to determining that particular point. If the dispute turns upon the construction of a document the parties should set out what part of the document is in dispute and why. If the dispute turns upon the inferences to be drawn from the pre-existing literature base then each relevant item of research should be identified and the precise issue isolated and the competing contentions recorded. It should be made plain what consequences would flow from a ruling by the Court on each issue, i.e. what each dispute goes to and how significant the answer is to the overall case.

641. **Creation of a proper record**: Seventh, the above process should be reduced to a single, composite, document or set of documents which should represent the entirety of the exercise the Court is then expected to conduct. This is not only important as a record of the process but it should also be important in enabling a limit to be set for the documentary material that is then placed before the Court.

642. **Compliance with the CPR**: Eight, the relevant experts must in this exercise comply fully with the wording and spirit of CPR 35. The Court must be confident that the experts are aware that their overriding and primary duty is to the Court and this awareness must feed, constructively, into the exercise of boiling down the expert evidence to manageable proportions. This is not adherence to mere formalities. The CPR requires, for instance, that experts set out in a balanced way material both for and against themselves (see paragraphs [316] – [319] above). The expert declaration is not a mere mantra; it should be viewed as a statement that the experts take seriously and truly adhere to.

643. **Case management / judicial supervision / disclosure**: Ninth, the Court may well need to exercise a close case management and supervisory role in relation to the entire exercise from an early stage. In a judicial review it should, ordinarily, be possible to reduce the disputes to a relatively modest number of issues to be decided. It will be evident from this judgment that I take the view, at least in a case such as this, that a disclosure exercise would need to have been undertaken as part of this process. The earlier the parties and the Court engage with this process the more likely it is that the disclosure exercise may be calibrated to the needs of the case in a proportionate manner.

644. **Cross-examination**: Cross-examination is not the norm in judicial reviews; but it can occur. If the boiling down process is effective there may be no need for cross-examination. But even if it is effective it may be proper to order cross-examination of experts within strictly confined limits. The Court might also consider alternative techniques such as "hot-tubbing" where the Court questions the experts who give evidence simultaneously, supplemented if appropriate by more traditional cross-examination.

645. **Appointment of experts / assessors to assist the Court**: If at the end result of the boiling down process there remains a large number of outstanding disputes the Court might seek an explanation as to why this is so and the Court might require the parties to use the services of an independent third party expert to assist in reducing the scope of the dispute yet further. This could be through a form of expert mediation as between the parties or by the preparation of a report from the third party expert for the assistance of the Court. A Court might need to give directions as to the costs of this exercise and make any orders for disclosure that are relevant. I reiterate that the purpose of this is (i) to compel the parties to reduce to the utmost minimum the number of actual disputes to be resolved by the Court; and (ii) to ensure that the Court is given maximum assistance. The use of assessors and external experts to assist a Court is rare but by no means unheard of. It is, for instance, a practice used in patent cases, even where the judges *are* specialised in and may possess, themselves, relevant scientific background: See by way of illustration the discussion of the practice of appointing assessors in the procedural judgment of Birss J in *Electromagnetic Geoservices ASA v Petroleum Geo-Services ASA et ors* [2016] EWHC 27 (Pat) at paragraphs [27] - [36]. The power to appoint assessors exists under Section 70(1) Senior Courts Act 1981, and, CPR 35.15. The assessor appointed under this procedure becomes a quasi-judicial official whose task it is to assist the Court. The assessor plays such part in the proceedings as the Court directs and this can include, *inter alia*, preparing a report for the Court on any matter at issue in the proceedings and attending the whole or any part of the trial to advise the Court. Provision is made for the communication to the parties of any report that the assessor prepares before the trial has begun. In *Electromagnetic Geoservices ASA* (ibid) Birss J ordered the appointment of a Marine CSEM (Controlled Source Electromagnetic) scientist to provide a non-controversial one-day introductory course to the judge in the use of a particular technology to locate marine oil deposits. It is clear that such assessors can be used imaginatively to provide whatever level of assistance is required by the Court. In a complex case, for instance, where the Court was not satisfied that the parties' initial efforts to reduce the technical issues to manageable proportions were sufficient the Court might obtain the assistance of an assessor in requiring the parties, through appropriate directions, to further boil down the issues; or an assessor might be useful in providing guidance and advice to the Court in how to resolve outstanding issues; or, as in *Electromagnetic Geoservices* ASA, an assessor might provide a general or introductory education to the judge. In the final judgment in *Electromagnetic Geoservices ASA* [2016] EWCA (Pat) 881 the judge, following the trial, explained how useful the teach-in process had been. He made the telling point that what mattered with experts was not just their actual opinions but also "… *the material on which those opinions are based and the reasons for them*" (ibid paragraph [7]). This short judgment is a useful explanation of how and why the use of third party assessors can save Court time and overall costs and lead to better justice.

646. In the present case, no process such as I have described above was conducted and I was left to read and absorb with scant assistance a vast amount of material on a wide range of expert issues including qualitative evidence of a psychological and medical nature; quantitative regression analyses; methodological critiques; economic commentary and opinion evidence on the mechanics of downtrading and price competition in the tobacco market; opinion evidence on the purpose and economics of trade marks; and expert evidence on the valuation of the Claimants' property rights,

etc. Having read it in detail I came to the conclusion that much of it was immaterial to the true issues in dispute in the case.

647. Further a great deal of the key quantitative evidence emerged late on, some indeed was served by the parties very shortly before the hearing. The key empirical evidence thus never went through any comprehensive process for boiling down the issues. An attempt was made as between Professor Chaloupka and Professor Mulligan to engage in a very limited task of this nature and it did, to some degree, bear fruit in that it focused attention on the alleged "hard edged" errors. However this arose late on, was not accompanied by any disclosure exercise, and covered only a small portion of the issues arising (for example it did not cover the qualitative evidence). It was too little and too late, but it did reflect the embryo of what a fully-fledged exercise might have become.

648. I accept that in the present case the proceedings were expedited and that accordingly the amount of time that the parties had to prepare was more limited than normal; and I also accept that evidence was emerging from Australia on a more or less constant basis and that the experts wished to take that emerging evidence into account. However, there was still time for a process of this sort to have been conducted at an early stage. Quite a few of the expert reports prepared for the case were served in May 2015 in relation to a December 2015 scheduled hearing.

(17) Conclusion

649. The qualitative and quantitative evidence submitted by the Secretary of State during the litigation establishes *prima facie* a proper basis for demonstrating the suitability and appropriateness of the Regulations. That conclusion is supported and reinforced by my analysis of the Claimants' evidence. The quantitative (econometric) evidence adduced by Professor Mulligan and Mr Dryden was sophisticated and thorough. It does not however serve to exclude the competing quantitative evidence relied upon by the Secretary of State. The Claimants' evidence was not benchmarked against potentially inconsistent internal documents from the Claimant tobacco companies, it had not been through any verification process (whether peer review, or regulatory evaluation, or a pre-hearing process such as that described above), and the assumptions which provided its bedrock were opaque. Furthermore, there are serious doubts as to whether the data which is relied upon is, as yet, sufficiently voluminous or longstanding to be robust and reliable. Ultimately, the disagreements between the experts were no more than reasonable experts disagreeing over the nuts and bolts of the regression analysis. There were no "hard edged" errors identified of a type which would lead a Court to conclude that the Secretary of State's quantitative evidence was so flawed that it should be discounted or ignored. My conclusion is further supported by various factors which indicate that a relatively broad margin of appreciation must be applied to Parliament even when viewed through the up to date evidential optic of the proceedings before this Court. For all of the above reasons, and on the basis of the most up to date evidence, I reject the Claimants' submission that the Regulations are disproportionate because the measures are not appropriate or suitable.

H. GROUND 4: THE REGULATIONS FAIL THE NECESSITY TEST OF PROPORTIONALITY BECAUSE OTHER EQUALLY EFFECTIVE BUT LESS RESTRICTIVE MEASURES EXIST WHICH HAVE BEEN IGNORED

(1) The issue

650. All of the Claimants submit that the aims of the Regulations could be achieved by other measures which are less restrictive and accordingly the second necessity limb of the proportionality test is not satisfied.

(2) Claimants' submissions

651. The Claimants submit that the Secretary of State has failed to prove that standardised packaging is proportionate because the evidence does not show that there are no equally effective but less restrictive alternatives. The Claimants impose upon the Secretary of State a high standard of proof – to prove the negative viz., that there are no alternatives that are equally effective but less restrictive. BAT demands precision: *"... if the defendant is to discount the alternatives presented by the Tobacco Claimants, it must be able to identify precisely the problem which plain packaging – but not the alternatives – addresses*.". It is for the tobacco companies to advance possible alternatives but then for the Member State to disprove them.

652. PMI contends that there is a less restrictive and more effective alternative policy available to the Government, namely taxation. The argument is advanced at a high level of analysis. It is contended that it is *obvious* that taxation is more effective. They rely upon the expert evidence of Professor Mulligan who argued that taxation was a tobacco control policy "*that obviously works*" and that even from the starting point of a high tax and price base, the excise tax increases that Australia put in place between 2010 and 2014 caused large and immediate reductions in prevalence and consumption. This is "*…all the Court needs to know to conclude that standardised packaging is unlawful: there is a less restrictive and more effective policy alternative available*".

653. They also submit that if authority were needed for the proposition the Opinion of the Advocate General and judgment of the Court of Justice in *Scotch Whisky* commend taxation as a legitimate less restrictive alternative in the context of public health measures than a minimum alcohol pricing regime.

654. The Claimants attack two arguments relied upon by the Secretary of State as flawed. These are, first, that standardised packaging and tax are different because the latter operates through a different mechanism to standardised packaging; and, secondly, that tax and standardised packaging are "*not mutually exclusive, they are complementary, and only together can they achieve the overriding objective of improving public health by continually reducing smoking*". The Claimants submit that it does not matter through which mechanism a tobacco control measure works, what matters is whether and to what extent the measure brings about a reduction in smoking. The Secretary of State's rejection of alternatives on the ground that they operate in a different way to standardised packaging or in a complementary manner illegitimately forecloses any proportionality review altogether. On the Defendant's approach, there could never be a less restrictive alternative.

655. The Claimants also attack the argument advanced by ASH that taxation is complementary to standardised packaging because it can offset any reduction in average prices that is brought about by downtrading caused by standardised packaging. Professor Mulligan says that the argument is illogical: if standardised packaging reduces the average price paid by consumers and taxation increases the average price paid by consumers, then one policy will offset the impact of the other. Although the combined policy may reduce smoking, taxation alone would have reduced it by more.

656. BAT adopts a wider ranging and more confrontational approach. It criticises the Government for referring to the "*promotional effect of tobacco packaging*" but complains that the Government does not "*contextualise*" its "*assertion*". BAT then says that there is clear evidence before the Court that existing awareness of the health risks posed by smoking is universal and that consumers are already well aware of the health warnings which appear on tobacco packaging. It describes the Government's arguments to the contrary as "*circular*" and "*casuistry*".

657. I have had some difficulty in assessing this ground of challenge. The Claimants initially pointed to a range of alternative control measures which it was said were all equally effective, but less restrictive. PMI in its written submission on behalf of the Claimants as a whole abandoned any reliance on measures other than tax. BAT, however, maintained the initial broad position and contended that in addition to tax numerous alternatives would be equally effective but less restrictive including increasing the minimum age at which people can buy tobacco, educational campaigns and improved health warnings. In relation to none of these submissions however has much if anything by way of supporting evidence been adduced.

658. To address these arguments I need first to set out the law and, then, to address the merits in the light of the relevant governing principles. As to the law the most important issues are: the burden and standard of proof and the sorts of evidential factors which a Court should take into consideration.

(3) The law

659. The standard of proof imposed on Member States is lower than that contended for by the Tobacco Claimants. In *Scotch Whisky* (ibid paragraph [55]) the Court of Justice stated that the Member States were not required to prove "*... positively that no other conceivable measures could enable the legitimate objective pursued to be attained under the same conditions*".

660. The Court cited with approval in this regard its prior judgment in Case C-110/05 *Commission v Italy* in which the Court addressed the standard of proof that Member States must meet when establishing before a Court that a measure said to amount to a less restrictive but equally adequate measure does not meet the stated objective. The case concerned a prohibition in Italy of the combination of mopeds, motorcycles, motor tricycles and quadricycles with towing trailers. It was contended by the Commission, in infraction proceedings, that less extreme measures would adequately safeguard public health. The Court rejected this contention:

> "66. In the present case, the Italian Republic contends, without being contradicted on this point by the Commission, that the

> circulation of a combination composed of a motorcycle and a trailer is a danger to road safety. Whilst it is true that it is for a Member State which invokes an imperative requirement as justification for the hindrance to free movement of goods to demonstrate that its rules are appropriate and necessary to attain the legitimate objective being pursued, that burden of proof cannot be so extensive as to require the Member State to prove, positively, that no other conceivable measure could enable that objective to be attained under the same conditions (see, by analogy, Case C-157/94 *Commission* v *Netherlands* [1997] ECR I-5699, paragraph 58).
>
> 67. Although it is possible, in the present case, to envisage that measures other than the prohibition laid down in Article 56 of the Highway Code could guarantee a certain level of road safety for the circulation of a combination composed of a motorcycle and a trailer, such as those mentioned in point 170 of the Advocate General's Opinion, the fact remains that Member States cannot be denied the possibility of attaining an objective such as road safety by the introduction of general and simple rules which will be easily understood and applied by drivers and easily managed and supervised by the competent authorities.
>
> 68. Moreover, it should be noted that neither the terms of the International Convention on Road Traffic nor those of the recitals in Directives 93/93 and 97/24, referred to by the Italian Republic, allow the presumption that road safety could be ensured at the same level as envisaged by the Italian Republic by a partial prohibition of the circulation of such a combination or by a road traffic authorisation issued subject to compliance with certain conditions.
>
> 69. In the light of those factors, it must be held that the prohibition on motorcycles towing trailers specially designed for them and lawfully produced and marketed in Member States other than the Italian Republic must be regarded as justified by reasons relating to the protection of road safety".

661. The mere fact that alternative measures could be *envisaged* which might be equally efficacious and less restrictive was thus not decisive. The Member State was entitled to rely upon measures which were general, simple, easily understood and readily managed and supervised. And of importance to the present case is the recognition that the policy adopted by Italy was one which was consistent with international conventions and applicable EU directives (cf. paragraph [68]).

662. The burden and standard of proof advanced by the Claimants as that to be applied is not a formulation accepted by the Court of Justice. Whilst it is correct that the Member States must satisfy the Court that the necessity test is met, and hence the burden of proof lies with the Member State, this does <u>not</u> mean that the State must prove a negative or disprove an envisioned less restrictive possibility posited by a

litigant who opposes the measure. In the absence of a sensible case advanced by a party challenging the State's decision the State can confine itself to explaining why in its view the measure it has adopted was necessary. I do not count mere assertion that some other measure is equivalent and less intrusive as sufficient.

663. I turn now to the submission that the judgment in *Scotch Whisky* establishes that fiscal adjustment is an equivalent and less restrictive alternative. In *Scotch Whisky* there were clear, and fact specific, reasons established by settled case law which explain why the Court of Justice doubted the necessity for Scotland to introduce a minimum price per unit of alcohol ("MPU"). This was because increases in duty are ultimately reflected in final retail prices and, as with any MPU, they therefore raise floor prices. Consequently, tax increases and MPU work through the same economic mechanism, i.e. retail prices. Yet tax is innately less restrictive than a MPU because when the floor price is increased by tax retailers still have a freedom in principle to set their own prices, but in contrast they lose this freedom when an MPU is imposed. As the Court put it tax increases are less restrictive of competition because they affect consumption *"... without impinging on free formation of prices"* (ibid paragraph [44] and see also paragraphs [21] and [25] and [46]). The right to set prices unfettered is a principle at the heart of the rules regulating all agricultural product markets under the relevant legislative framework. The well-established economic connection between fiscal adjustment and minimum prices thus made it easy and logical for the Court to compare them against each other.

664. This point - which at base is founded in simple economic logic - is far from new and reflects a position settled in a long line of case law. The Court in *Scotch Whisky* cited, for instance, the judgment in Case C-216/98 *Commission v Greece* [2000] ECR I-8934 at paragraphs [31] and [32]:

> "31. In this case it must be observed that the objective of protecting public health may be adequately attained by increased taxation of manufactured tobacco products, which would safeguard the principle of free formation of prices.
>
> 32. The ability of manufacturers and importers not to pass on increases in excise duty on their products is in any event limited by the extent of their profit margin, with the result that excise duty increases are sooner or later incorporated in retail selling prices".

665. In *Lumsdon* the Court (ibid paragraph [67]) stated that in applying the "*less restrictive alternative*" test it was necessary to have regard to all the circumstances bearing on the question whether a less restrictive measure could equally well have been used and that this would include (but necessarily be limited to) such matters as: the conditions prevailing in the national market; the circumstances which led to the adoption of the measure in question; and the reasons why less restrictive alternatives were rejected. The Supreme Court emphasised that a reviewing Court would be "*heavily reliant on the submissions of the parties for an explanation of the factual and policy context*".

(4) Analysis and conclusions

666. In my judgment, the Regulations are necessary. I do not accept the Claimants' submission. There are a series of different reasons why the argument does not succeed.

667. **Absence of a case as to the level of any tax increase**: In *Scotch Whisky* the Court of Justice made clear that Member States did not have to prove negatives and in *Commission v Italy* it was stated by the Court of Justice that simply because other measures could be "*envisaged*" was not enough to undermine the choice actually made by the Member State. In this case I have a real difficulty with the absence of quantitative or indeed any evidence as to the actual level of tax increase that the Claimants submit would be sufficient to achieve the objective of standardised packaging. At one level it stands to reason that if the Government wished to eliminate smoking it could do so by (say) increasing excise duties and other taxes by 10,000% or more. Virtually overnight all purchases of tobacco would cease. Of course the Government would then get no revenue from tobacco as sales evaporated. But as a blunt yet effective instrument of health policy tax works. As such tax could also eliminate the need for <u>any</u> other regulatory measure to be adopted, including standardised packaging and other advertising restrictions. The WHO would not need to recommend any additional measures because no one would be able to afford to smoke anyway. The tobacco companies would simply fold. The reality however is that tobacco control regimes operating within the EU and in the United Kingdom and elsewhere throughout the world all assume that Governments do <u>not</u> use tax as the sole mechanism to eliminate the health problem.

668. Of course a tax rise of a magnitude to prevent all further smoking is not what the tobacco companies want at all. They do not wish tax to be used to abolish *de facto* their business. And so the issue becomes one of degree. Should the alternative to advertising restrictions be that tax should increase by *x*% or *y*%? But the Claimants have not modelled the relative benefits of any particular measure of tax increase against the benefits of the new advertising restriction. The Claimants' argument amounts to mere assertion.

669. **Impact on illicit trades**: There is an obvious linkage between excise duty increases and the incentive for duty unpaid products to be imported. Elsewhere the Tobacco Claimants submit that standardised packaging would increase illicit trades. But they have conducted no material analysis or evidence (that they are prepared to place before the Court) of the impact on illicit trades of a significant further rise in excise duty and whether this would – on their case – generate an even greater problem.

670. **Complementarity as an integral part of the international consensus**: In the case of standardised packaging it is a core tenet of the FCTC that contracting states should use a range of different measures to attack tobacco supply and demand from all angles. Tobacco control policies should be "*comprehensive*". This is the position adopted by the Australian Government: See e.g. at paragraph [529] above. Indeed no WHO contracting state has adopted a tax only policy. In my judgment this is an important consideration in justifying the necessity of the Regulations. In *Scotch Whisky* the Court of Justice treated as relevant to the "appropriateness" limb of the proportionality test that the Scottish MPU was one part of a wider portfolio of measures designed overall to combat a recognised evil ("*the devastating effects of*

alcohol" – cf. paragraph [38]) . The Court referred, approvingly, to the fact that the minimum pricing proposal was one out of about 40 measures designed to combat alcoholism in a *"...consistent and systematic manner*" (ibid).

671. **Health inequalities/addiction**: One aspect of the justification for standardised packaging is the removal of health inequalities. This was an important issue addressed in the 2014 Impact Assessment at paragraphs [10] – [13]. Tobacco is already a highly taxed product; using tax as the sole or dominant method of control risks placing a disproportionate financial burden on the socially and financially disadvantaged. It hits them far harder in their pockets than it does more affluent consumers. Standardised packaging does not have this financial effect. And if the less affluent consumers are addicted then the increased costs are unavoidable which tends to exacerbate the health inequalities that standardised package restrictions seek to reduce or eliminate. Taxation further does little, or at least far less, to deter new uptake amongst the young, *as yet,* irregular smoker, who will not be spending as much on tobacco but promotion and branding restrictions are targeted at this cohort. Equally, increased taxation does nothing to change attitudes about smoking or to "denormalise" a product which for decades has been perceived as normal. The relative positions of standardised packaging and tax sit in contrast to *Scotch Whisky* where, as I have already explained, tax increases and minimum prices have long been recognised as working through the same retail price deterrent mechanism. Combining tax and advertising measures is in contrast a strategy which addresses supply and demand from different angles and perspectives.

672. **Consistency with international law**: In *Commission v Italy* it was a relevant consideration that the type of measure adopted by Italy was endorsed by an international convention and by EU legislation (ibid paragraph [68]) and neither operated upon the basis that other less restrictive measures would suffice. In the present case the FCTC specifically identifies advertising on packaging and product as causative of a health risk. There is no hint of a suggestion that the same suppressive effect as an advertising ban could or should be achieved through tax.

673. **Uncertainty of outcome**: In *Scotch Whisky* the Court accepted that when Courts reviewed the decisions of Member States against a test of proportionality *"... the possible existence of scientific uncertainty as to actual and specific effects on ... consumption"* was a factor that could be taken into account (ibid paragraph [57]), i.e. it was not a valid criticism to make that the state could not with precision quantify or pinpoint with certainty the expected effects or outputs of a measure. In this case the position set out in the 2014 Impact Assessment and in the evidence before the Court is that there is no specific quantity of effect which is hoped for. It is accepted that the benefit might be relatively modest in terms of numbers affected but, as the net monetised assessment shows, in the longer term the cumulative impact is very substantial. In any process of comparing and contrasting the effect of the Regulations as against a putative tax increase the uncertainty as to the exact effects is a relevant factor. If the precise effect of the Regulations is not quantifiable then it is impossible to modulate tax so as to achieve the same effect. All that could be done is to err on the side of caution and impose a tax increase which was of a magnitude which would safely exceed any possible effect of the Regulations but this risks being a blunt instrument and highlights why tax and advertising restrictions are part of a complementary suite of measure rather than substitutes for each other.

674. **Other proposed measures**: BAT floated (asserted) the possibility that other measures would suffice. No evidence has been adduced to support the contention. The two posited (increased education and improved health warnings) are already part of the overall package of measures and they do not address the specific objective of the advertising restrictions. An enhanced educational message might reinforce the increased saliency of the health warning brought about by the introduction of standardised packaging but it does not replace it. Equally increased health warnings are said to be rendered more efficacious by the advertising restrictions and so supplement them but do not substitute for them. The two suggested solutions work in tandem with standardised packaging but not in substitution. At all events the submissions are mere assertion and do not impose upon the state a burden of proof to disprove them.

675. **No analysis of relative restrictiveness**: In *Scotch Whisky* the Court of Justice clarified that when assessing necessity a Court should compare the nature and the scale of the impact of the impugned measure on the public interest recognised at EU level. In *Scotch Whisky* that meant assessing the impact of the MPU on "*free movement of goods*" (ibid cf. paragraph [58]). There it was possible to calculate with precision what the MPU would be for a given drink by reference to a stipulated statutory formula (ibid paragraph [7]) and it was accordingly possible also to determine accurately what the actual impact upon the freedom to set prices would otherwise be. In the present case the core objection of the Tobacco Claimants is not as to the free movement of goods but as to the impact upon their property rights and their ability to use those rights to maximise their profits. In this light it is hard to see how a tax which reduces the profits of the tobacco companies is more or less restrictive than advertising restrictions which achieve the same end.

676. **Margin of appreciation**: All of the above individual factors must be seen in the context of the margin of appreciation. In the field of public health Member States have latitude in choosing the "*degree of protection*" and "*level*" they wish to "*assure*" and the "*way in which that protection is to be achieved*" (*Scotch Whisky* ibid paragraph [35]; Case C-262/02 *Commission v France* [2004] ECR I-6597, at paragraph [24]; Joined Cases C-171/07 and C-172/07 *Apothekerkammer des Saarlandes v Saarland* [2009] ECR I-04171 at paragraph [19]). In Case C-170/04 *Rosengren v Riksaklagaren* [2007] ECR I–4107 the Court of Justice reflected this in applying a test whereby a Court should ask whether the measure adopted went: "*manifestly beyond what is necessary for the objective sought, which is to protect younger persons from the harmful effects of alcohol consumption*" (ibid paragraphs [51]). The Supreme Court in *Lumsdon*, at paragraphs [64]-[66], cited *Rosengren* with approval. All of this strongly suggests that Member States possess a wide margin of appreciation in relation to the necessity test and this consideration applies also to proceedings before a Court.

677. In *Scotch Whisky* the Court of Justice did not clearly articulate how the margin of appreciation translated into an actual test but wrapped everything up in a reasonableness test. At paragraph [49] in relation to the necessity test the Court stated:

> "49. It is however for the referring court, which alone has available to it all the matters of fact and law pertaining to the circumstances of the main proceedings, *to determine whether a measure other than that provided for by the national legislation*

> *at issue in the main proceedings, such as increased taxation on alcoholic drinks, is capable of protecting human life and health as effectively as that legislation, while being less restrictive of trade in those products within the European Union*".
>
> (Emphasis added)

Then, at paragraph [56], the Court used a slightly different formulation in relation to both the appropriateness and the necessity components of the proportionality test:

> "56. In that context, it is for the national court called on to review the legality of the national legislation concerned to determine the relevance of the evidence adduced by the competent national authorities in order to determine whether that legislation is compatible with the principle of proportionality. *On the basis of that evidence, that court must, in particular, examine objectively whether it may reasonably be concluded from the evidence submitted by the Member State concerned that the means chosen are appropriate for the attainment of the objectives pursued and whether it is possible to attain those objectives by measures that are less restrictive of the free movement of goods*".
>
> (Emphasis added)

678. The heart of the ruling of the Court of Justice in *Scotch Whisky* was thus an objective reasonableness test. Quite how, if at all, this differs from the test formulated in *Rosengren* and approved of in *Lumsdon* is unclear. In order to err on the side of caution (since on one view it might imply a stricter test than that identified in *Lumsdon* and *Rosengren),* I have applied the objective reasonableness test in *Scotch Whisky.*

679. For all of these reasons I do not accept this ground of challenge. In my judgment, objectively, Parliament acted reasonably in concluding that there was no equally effective less restrictive measure which met the aims and objectives of standardised packaging and that conclusion still holds true in these proceedings.

I. GROUND 5: PROPORTIONALITY *STRICTU SENSU*: THE REGULATIONS FAIL TO STRIKE A FAIR BALANCE BETWEEN THE COMPETING INTERESTS

(1) The issue: Proportionality *strictu sensu* (fair balance)

680. As set out above (see paragraph [429]) there is some debate as to whether the proportionality test in EU law incorporates as an ingredient an overall balancing of the rights and interests of the various parties, here the State invoking public health and the tobacco industry invoking private rights to property. The Secretary of State submitted that this limb of the proportionality test did not arise. The Claimants submit to the contrary that it does. As already observed the Supreme Court in *Lumsdon* merely observed that sometimes the Court of Justice recognises the existence of this limb of the proportionality test but that in other cases it does not, and that there is no clear articulation in the case law which explains the difference in

approach. The issue is in this case academic because I propose to address the issue regardless of the debate. Nonetheless, had it been critical I would have held that the proportionality *strictu sensu* limb *is* relevant in this case. In my judgment this is because the basic fundamental right said by the Claimants to be trespassed upon by the Regulations is the right to property under A1P1 of the ECHR and the equivalent in the EU under the Fundamental Charter and, according to the Fundamental Charter, there is intended to be coincidence of application between the ECHR and the Charter. It is not in dispute that such a balancing test does arise under the ECHR (see for instance *Vékony* discussed at paragraphs [753] – [770] below) and hence in an EU case where the Charter is at stake or where the ECHR is prayed in aid as a general principle of EU law, it would be inconsistent to refrain from similarly applying this component of the proportionality test. To do otherwise would be to create the risk that a Court would apply two different tests when deciding whether the same fundamental right was breached, even though the tests under EU law and the ECHR were intended to be the same. I draw support from the fact that in *Philip Morris* (ibid) Advocate General Kokott applied this limb of the proportionality test to the TPD as did the Court of Justice (see paragraphs [271] – [272] above).

681. I also take the view that where the EU "proportionality *strictu sensu*" limb applies it will have the same effect as the ECHR "*fair balance*" test. I can detect no material difference between the factors taken into account under the ECHR *fair balance* test and the considerations taken into account by the Court of Justice in cases where it applies the "proportionality *strictu sensu*" test, and this seems to have been the approach of the Advocate General and Court of Justice in *Philip Morris*. Again, and certainly in a case involving the ECHR and/or Fundamental Charter rights, it would be inconsistent for the tests to operate in a substantively different manner.

(2) The colliding rights

682. I must therefore balance the interests of the Claimants with those invoked by the State. So far as the latter is concerned the protection of public health is recognised in law as one of the highest of all public interests that can be prayed in aid: See paragraphs [438] – [447] above. And the unchallenged facts about the specific adverse health consequences of tobacco consumption place the suppression of tobacco usage towards the top end of the public health category. Put shortly, the public interest weighs heavily in the scales.

683. To be set against this are the rights of the tobacco manufacturers in their trade marks and other property rights to use those marks to promote the consumption of tobacco. The bottom line interest of the tobacco companies in the right to promote their property is "*profit*". The benefit to shareholders is at the expense of the public purse. The two interests collide in the most irreconcilable of ways.

684. The Claimants, albeit faintly, contended that their interest in the principle of the free movement of goods within the EU was also in play. But there was no analysis of the extent of this interest. The fact that the tobacco manufacturers already use national trade marks and develop national brands means that parallel importers already have to address the consequences of differences in trade marks across the EU. In some respects the introduction of absolutely standard rules might even make repackaging easier for parallel importers. At all events this was not an interest which the

manufacturers pressed hard and for good reason. In so far as it is in fact relied upon it is easily outweighed by the powerful public health interests in issue.

(3) The monetised net balance

685. By its nature an Impact Assessment is designed to monetise the various competing interests to enable a netting-off of the pros and cons in financial terms to occur. Official guidance is provided by HM Treasury in the form of the "Green Book"[28], which is a "best practice" guide for government departments and executive agencies. It demands a proportionate approach to the measuring of costs and benefits. Similar guidance is given in the BIS "Better Regulation Framework Manual"[29]. The limitations of any such exercise are set out in these documents and are reflected in the 2014 Impact Assessment. Nonetheless the assessment conducted in the present case was that over the relevant time period the benefits of introducing standardised packaging were £30 billion and the costs were £5.2 billion leaving a net benefit of circa £25 billion.

686. In the 2014 Impact Assessment the Defendant valued the costs to the Claimants: See at paragraphs [115ff]. The net impact on manufacturers was estimated: *"...as a one off decline in the ability of manufacturers of premium tobacco products to generate future economic benefits from the visual branding in which they have already invested*". The assessment then went on to quantify the reduced profits attributable to the *"...reduction in branding due to increased downtrading and due to smokers who smoke premium / mid priced brand quitting*".

687. The 2014 Impact Assessment assumes a degree of downtrading and assessed the discounted (NPV) loss of profits to manufacturers, wholesaler and retailers.[30] It concluded:

- that the discounted loss of profits over 10 years to tobacco companies UK shareholders from downtrading is circa £21million: See paragraph [121];
- The loss attributable to quitters is estimated at £14 million over 10 years (£140 in total to all shareholders): See paragraph [123];
- The loss in profit attributable to retailers is £90 million over 10 years: See paragraph [124];
- The loss attributable to quitters incurred by retailers is estimated at £61 million over 10 years: See paragraph [125];
- Further losses due to reductions in tobacco sales is estimated at £180 million over 10 years for manufacturers and for retailers £92 million over 10 years: See paragraph [126].

688. The assessment stated that many of these losses would be offset over time by profits made elsewhere due to normal shifts in investment opportunity: See paragraph [116]. Accordingly the long term net loss would be materially smaller than the above total.

[28] HM Treasury (2011) "The Green Book: Appraisal and Evaluation in Central Government (November 2014 edition).
[29] The Department of Business, Industry and Skills (2015) "Better Regulation Framework Manual".
[30] The accounting basis for the NPV calculation is set out in paragraph [121ff] of the 2014 Impact assessment.

(4) The Claimants' case on loss of value.

689. In a fair balance assessment the value of the loss said to be sustained by the Claimants is relevant. In their written submissions the Claimants relied upon, *inter alia*, the expert report of Mr Anson who considered that the losses of the tobacco companies were likely to run into "*billions of pounds*". A further expert, Mr Bezant, expressed the view that the loss of brand value to PMI (which holds c. 8% of the market share for RMC[25]) alone was between £340m and £515m. In oral argument figures measured in "*billions*" were said to be at stake.

690. I set out my view on these valuations below. However I note that in their final written submissions on behalf of all the Claimants on this issue JTI stated "*The marks have not been valued*" and they (more or less) disavowed reliance upon Mr Anson and Mr Bezant. I am not surprised.

(i) Anson

691. Variously in this ligation the tobacco companies have asserted that the Regulations will cause "*billions*" in losses. No internal documentation was however produced to substantiate this claim. Instead, BAT produced an expert report by Mr Weston Anson (August 2014) entitled "Preliminary Analysis of the UK Department of Health 2012 and 2014 Impact Assessment of Standardised Packaging for Tobacco Products". The conclusions of Mr Anson were relied upon by Mr Martin Silva, Head of Marketing for the UK and Ireland for BAT, in his Witness Statement (21st May 2015) prepared for this litigation. Mr Silva stated, on the basis of this report, that the Regulations would lead to an actual loss in intellectual property value to UK tobacco companies which would be "*…measured in the billions of Pounds Sterling*". The "*billions*" figure was then used by a number of other parties during their oral and written submissions.

692. Notwithstanding that the expert report was tendered for the purpose of this litigation, it has not been updated since 2014 and it is not accompanied by a Statement of Truth and nor does it declare that it is compliant with the CPR. I could have rejected it as inadmissible but I propose instead to take it at face value.

693. The myriad limitations of the Report are evident from the Report itself. The documents considered by Mr Anson are listed in Appendix B and it numbers 9 documents. Two of these comprise the 2012 and 2014 Impact Assessments; there are two annual reports; there are two references to literature (from 1996 and 2005) on the measurement of brand equity; and there are a number of documents relating to the acquisition by Reynolds American Inc. of Lorillard in July 2014. Mr Anson does not analyse any internal documents of his client. Mr Anson sets out four methodologies relevant to the valuation of brands but concedes that his conclusion amounts to a "*…preliminary view of the limited materials made available to date*". The Report is short and a significant portion is devoted to a description of the expert's qualifications. In relation to valuation methodologies he states:

> "When valuing intellectual properties, it is essential to consider each of the different valuation methodologies, in the light of the

[25] According to evidence submitted by Mr Inkster on behalf of PMI, which I accept for these purposes.

> information available and the specific circumstances, in order to determine the best method for ascertaining value. The methodologies commonly used to determine the value of intellectual properties are: the Cost Approach, the Income Approach, the Market Approach, and a hybrid methodology known as the Relief from Royalty Approach".

His conclusion is that the Cost Approach is one of the most useful and he accepts that in order to conduct such an analysis one would need data on such matters as: legal fees, application/registration and other fees; development costs; production costs; historic marketing and advertising costs; and historic promotion costs. With such data one can then extract "*...a conservative minimum value for the assets*" but not an indication of the economic benefit derived from ownership. The Cost Approach would be based upon the costs that "*...each tobacco company has individually invested*". The second approach that he advocates is the Relief from Royalty Approach. This involves an analysis of royalty rates paid under comparable licence agreements. It also establishes income levels generated through the use of assets. He concludes that the two methodologies he has identified are the most appropriate in the present situation. He notes the potential significance of a further method, the Income Approach and, as with the other methodologies, he recognises that this requires "*relevant and verifiable data*".

694. Mr Anson does not, however, apply <u>any</u> of these approaches.

695. Instead, he sets out a brief summary of four transactions that he has been able to analyse from public sources. None are remotely relevant or comparable to the valuation of the brands in issue in the light of the Regulations. None are related to the UK trade marks or other property rights in issue in this litigation. All the comparators used are from a different period of time. None take into account the fact that the tobacco companies do not assert or contend that the TPD is in breach of A1P1 or gives rise to any claim for compensation and therefore must stand as a relevant benchmark for the assessment of any post-TPD diminution of value.

696. I now summarise, briefly, the transactions upon which Mr Anson relies to arrive at his conclusion of lost value. The first was the acquisition by Reynolds American Inc. in July 2014 of Lorillard for $27.4 billion. He accepts that at the time of writing no detailed purchase price allocation was available but he felt able to draw conclusions regarding the value of the goodwill and intangible assets by analysing the target's latest quarterly financial results. There is no analysis of why a transaction in 2014 which does not relate to the UK property rights and which pre-dates the TPD is relevant. The second transaction considered is much older and concerned the acquisition in February 2008 by BAT of Tekel, the Turkish State-owned tobacco company for $1.72 billion. He observes, from published accounts, that the value of intangible assets acquired and goodwill comprised 89% of the purchase price. Again how or why this is relevant is not explained. The third transaction identified was the acquisition by Lorillard in October 2013 of SKYCIG® the target was a UK based electronic cigarette business. Mr Anson observes that from published documents Lorillard disclosed that 74% of the purchase price was paid to acquire trade marks. This, conceivably, might have been closer to home but the analysis is so sparse as to provide no sensible basis for proper inferences to be drawn. The final transaction identified was the acquisition by Imperial Tobacco Group Plc in July 2014 of a

portfolio of US cigarette brands from Reynolds American Inc. for $7.1 billion. From public documents he infers that 88.7% of the purchase price was attributable to goodwill and intangible assets. Once again why or how the acquisition of US property rights is relevant to the UK market is not explained.

697. It will be seen that the analysis conducted is of a small number of international transactions with no or no obvious or material relevance to the UK market. Whilst they establish the (in my view) obvious conclusion that intellectual property rights may have significant value, they provide very little if anything at all which would enable anyone to identify what the incremental loss of value was to any particular tobacco company from the introduction of the Regulations either at all or following on from the implementation of the TPD. It is, in my view, impossible to find any support for the conclusion of Mr Anson or Mr Silva and repeated in submissions by the parties that the actual loss of brand value could be measured in "billions" of pounds sterling or anything remotely like that.

698. In the context of the above I am satisfied, because it is common sense, that the Claimant tobacco companies will have conducted some analysis, internally, of the economic and financial implications for each of them of the introduction of the Regulations. None of that analysis is before the Court or has been (apparently) seen by the experts instructed by the tobacco companies. It would have been open to any of the Claimants to instruct an expert to review, in detail, the actual putative loss by reference to any one or more of the methodologies favoured by Mr Anson as applied to the UK property rights in issue set against the backdrop of the introduction of the TPD and the Regulations, but this has not been done. I reject Mr Anson's conclusions.

(ii) Bezant

699. The Claimants also relied upon an expert report by Mr Bezant. Notwithstanding that I have doubts and reservations about a number of aspects of the analysis in this Report this was nonetheless a piece of work of an altogether higher quality. The Report was concise, well written, and transparent as to the assumptions relied upon.

700. Mr Bezant concluded that the Regulations would cause a loss to PMI of between £340m and £515 in NPV terms. He set out clearly the assumptions that he relied upon. He concluded that these were conservative; and this is where I disagree. I take the view that some of the assumptions were extremely (heroically) favourable to PMI. Nonetheless, the premises upon which he expressed his opinion were clearly and succinctly articulated.

701. He accepted that modelling intangible assets and the impact that government regulation would have was often a complex exercise and that reasonable valuers could reach different conclusion.

702. He implicitly rejected the approach adopted by Mr Anson. In relation to comparables he stated that there were no closely analogous transactions for comparison which involved UK-only premium cigarettes brands in circumstances analogous to the Regulations. He noted the recent $25 billion Reynolds/Lorillard transaction (upon which Mr Anson relied) where a substantial portion of the consideration was attributed to trade mark value and goodwill but he accepted that this was not "*directly analogous*", albeit that it indicated the high values that could be attributed to rights.

703. I do not need to dwell long upon this analysis.

704. First, I rely upon this report to support my conclusion that Mr Anson's report is unsustainable. Mr Anson's conclusion, widely recycled by the tobacco companies, that the loss caused by the Regulations would be "billions" is completely untenable and unverified. As Mr Bezant quite properly records there are no relevant comparables with which to work.

705. Second, Mr Bezant sets out his key assumptions in paragraph 2.11 of his Report. When modelling losses into the future he has however nowhere taken into account that the mandatory advertising and promotional rules and restrictions in the TPD come into effect at the same time as the Regulations (May 2016). The TPD measures will substantially curtail the ability of the tobacco companies to use their trade marks and seek quite deliberately to undermine their attractive effects by *(inter alia*) increased health warning saliency and imposing prohibitions upon certain types of advertising and promotion. Indeed, the Claimants have argued as an independent ground of challenge that the Secretary of State erred in failing to take into account the substantial effect of the TPD (see Section O, Ground 11) when concluding that the Regulations would be effective. The premise behind that ground is that the TPD is very restrictive and likely to be effective in curtailing tobacco company advertising and promotional efforts. The TPD will therefore by its very nature make the Claimants' trade marks less valuable in the United Kingdom. The loss that is attributable to the Regulations can thus *only* be that which is incremental over and above that caused by the TPD. The instructions given to Mr Bezant are set out in his report. He was not however asked to model loss taking into account this *novus actus interveniens*. For this reason it is highly probable that the loss he identifies as attributable to the Regulations is very substantially overstated.

706. Third, even if Mr Bezant's analysis were correct it would still mean that the cost/benefit analysis contained in the 2014 Impact Assessment came squarely down on the side of favouring the public over the private interest, such is the vast gulf between the costs imposed upon the state and the loss of value to the tobacco companies. Mr Bezant assumes that the loss must be assessed in perpetuity (and therefore well after the ten year period used in the 2014 Impact Assessment (Report paragraph [3.22 ff])). It is clear from his more detailed calculations that if he were wrong in this one assumption it would make a very substantial difference indeed to his overall calculation. I am very doubtful that it is proper to use perpetuity as the relevant timeframe. However, even <u>if</u> it were correct to do so if the 2014 Impact Assessment had (equally) sought to model the costs to the state in perpetuity this would have made the net cost/benefit analysis even more compelling against the tobacco companies.

(5) Non-monetised rights and values

707. The 2014 Impact Assessment provides a monetised measure of overall public versus private net costs and benefit and this, at least in this case, is one relevant way to consider the issue <u>but</u> it is not the only way. Mr Eadie QC, for the Secretary of State, submitted, in my view correctly and importantly, that the proportionality assessment was not in a case such as this a purely financial exercise and had to take into account other social and moral objectives and imperatives. He submitted that there were relevant policies the proportionality of which could not be sensibly quantified in

monetary terms. In the present case, he submitted, there were important or moral imperatives relating to quality of life which included preventing children and youths taking up smoking, the extra years of life that a person would acquire from quitting and the reduced pain and increased quality of life that people would gain from avoiding smoking related disease. So for example the 2014 Impact Assessment estimated, on a discounted basis, that the Regulations would generate health benefits equivalent to saving "0.49m life years", i.e. 490,000 years (see ibid paragraph [20], set out in Section C(14) above).

708. It would in my view be wrong to ignore these significant non-monetary factors which must also be placed on the scales. Since the Claimants' interest is essentially a money interest it can be said, with confidence, that the balance lies heavily in favour of the state. But had it been more finely balanced I would have attributed significant weight to these non-monetised considerations.

709. The 2014 Impact Assessment also examined a range of additional socio-moral factors such as: cleaner streets, consumer surplus, avoidance of second hand related health problems, etc.

710. The Defendant also points out that in striking a fair balance Parliament did not impose the new rules on cigars or pipe tobacco since these were not used by children and that substantial time had been given to the tobacco industry to adjust and thereby "old" non-compliant stock could be sold. Branding is still allowed in the wholesale market and on corporate letterheads etc.

(6) Conclusion

711. In my judgment the application of an overall proportionality / "fair balance" test leads, overwhelmingly, to the conclusion that the Regulations are justified and proportionate in the public interest.

J. GROUND 6: NON-EXPROPRIATION OF PROPERTY WITHOUT COMPENSATION - ARTICLE 1 OF THE FIRST PROTOCOL OF THE ECHR ("A1P1")

(1) The issue

712. The Claimants submit that the State has unlawfully expropriated their property rights without offering to pay compensation. The Claimants' case can be summarised in the following way:

- First, the Claimants will be prohibited from affixing any of their non-word trade marks to either the packaging or the tobacco products themselves.
- Second, the Claimants will be prohibited from affixing their word trade marks, except for a brand name and a variant that may only be presented to smokers in a standardised way which has never previously been used and with which consumers will be entirely unfamiliar.
- Third, the Regulations will deprive brands of their reputation and distinctive nature. Packs that are currently diverse will be made to look and feel essentially the same as indeed is the object of the Regulations.

- Fourth, given the nature of the requisite property, the substance and value of which is dependent on use, this will in essence destroy the Claimants' rights and such a destruction amounts to a *de facto* deprivation and goes beyond a mere control of use.
- Fifth, regardless of whether this is "deprivation" or mere control of use the interference with the property right is so extreme as to trigger the obligation to pay compensation.
- Sixth, the obligation is to pay compensation for the loss of value reasonably related to the value of those rights.

713. There are three legal bases upon which these submissions are mounted: (i) A1P1; (ii) Article 17 of the Fundamental Charter; and (iii) the common law. In this section of the judgment I consider only A1P1.

(2) Text of A1P1

714. The relevant provision under the ECHR is Article 1 of Protocol No. 1 which provides:

> "Every natural or legal person is entitled to the peaceful enjoyment of his possessions. No one shall be deprived of his possessions except in the public interest and subject to the conditions provided for by law and by the general principles of international law.
>
> The preceding provisions shall not, however, in any way impair the right of a State to enforce such laws as it deems necessary to control the use of property in accordance with the general interest or to secure the payment of taxes or other contributions or penalties".

715. In the present case the issues for determination are: (i) whether the Regulations relate to "property" or "possessions": (ii) whether there has been a deprivation or control of use of that property by virtue of the operation of the Regulation; and (iii) whether there is a duty to pay compensation.

(3) Intellectual property and goodwill as "possessions"?

(i) Intellectual property rights

716. There is no material dispute between the parties: It is accepted that in principle intellectual property is capable of amounting to "property" for the purposes of A1P1. The Claimants submit that the following amounts to property for the purposes of A1P1: (i) the relevant domestic and international trade marks; (ii) other intellectual property rights such as design rights; and (iii) goodwill attaching to the IP rights. In their written submissions and in the evidence the Claimants set out, in considerable detail, the details of the property rights they assert amount to property for the purposes of A1P1. The Court has adopted an approach to the classification of a right as a possession or property which is based upon substance and not form. In *Oneryildiz v Turkey* (2005) 41 EHRR 20 paragraph [124] the Court stated:

> "The Court reiterates that the concept of "possessions" in the first part of [A1P1] has an autonomous meaning which is not limited to ownership of physical goods and is independent from the formal classification in domestic law: the issue that needs to be examined is whether the circumstances of the case, considered as a whole, may be regarded as having conferred on the applicant title to a substantive interest protected by that provision … Accordingly, as well as physical goods, certain rights and interests constituting assets may also be regarded as "property rights", and thus as "possessions" for the purposes of this provision …".

717. A similar expression of principle was made in *Depalle v France* (2012) 54 EHRR 17 paragraph [68]. The Claimants point out that in the trade mark context the Courts have considered whether a company's legal position "*gave rise to interests of a proprietary nature*": a test which the Grand Chamber in *Anheuser-Busch Inc v Portugal* (2007) 45 EHRR 36 ("*Anheuser-Busch*") held was satisfied even by the filing of an application for the registration of a trade mark (paragraph [78]). What matters is whether the "*bundle of financial rights and interests*" has, or is capable of having, a "*substantial financial value"* (ibid paragraph [76]). The Court has held that A1P1 "*is applicable to intellectual property as such"* (*Anheuser-Busch*, paragraph [72]). In this context support for this proposition is also found in Article 17(2) of the Fundamental Charter which states in terms that "*Intellectual property shall be protected".* Not surprisingly the Court of Justice has held that "*intellectual property rights such as copyright*" are property to which the protections of Article 17 extends. The Explanations to the Fundamental Charter highlight that "*the guarantees laid down in paragraph 1"*, which include that there shall be no deprivation without compensation, *"shall apply as appropriate to intellectual property"*, including trade marks. Given that Article 17 is intended to reflect A1P1 then it is of some additional value in assisting in construing A1P1.

(ii) Goodwill as "possessions"?

718. The Claimants submit that their claim for loss of goodwill attaching to trade marks relates to *present* possessions and in principle is protectable under A1P1. The issue between the parties is whether goodwill is to be categorised as alleged losses relating only to <u>future</u> expected income, or, reflects the <u>present</u> value of the assets or property rights in question.

719. Authority distinguishes between income and the value of present assets. The law was recently considered by the Court of Appeal in *Breyer Group Plc v Department of Energy & Climate Change* [2015] EWCA Civ 408. The Court confirmed that a "possession" within the meaning of A1P1 did not include a right to acquire possessions and a mere prospective loss of future income did not amount to a "possession". The Court of Appeal held that domestic case law, and that of the Court, could be summarised by way of the following propositions. First, loss of future income is not a possession protected by A1P1. Second, loss of marketable goodwill may be a possession protected by A1P1. Third, a number of factors may point towards the loss being goodwill rather than the capacity to earn future profits including marketability and whether the accounts and arrangements of the Claimant were organised in such a way as to allow for future cashflows to be capitalised. Fourth,

goodwill may be a possession if it has been built up in the past and has a present day value as distinct from something which is only referable to events which may or may not happen in the future. Fifth, and in consequence of the earlier propositions, if there is interference which causes a loss of marketable goodwill at the time of the interference, and if that can then be capitalised, it is *prima facie* protected by A1P1 (ibid paragraph [23]).

720. In *Breyer* the Court also stated that although the distinction between goodwill and future income was fundamental to the Strasbourg jurisprudence the distinction was not always easy to apply and the Court had not addressed the attendant difficulties (ibid paragraph [43]). Marketable goodwill is a possession notwithstanding that its present value reflects a capacity to earn future profits. There is thus no easy, or in every case necessarily logical, clear divide between goodwill and future income. As the Court of Appeal stated in *Breyer*:

> "The important distinction is between the present day value of future income (which is not treated by the [Court] as part of good will and a possession) and the present day value of a business which reflects the capacity to earn profits in the future (which may be part of good will and a possession)".

721. The Court also accepted that goodwill was not susceptible to precise definition (ibid paragraph [44]). The Court did, however, derive assistance from the classic formulation of Lord Macnaghten who (in a somewhat different context) stated in *Commissioners of Inland Revenue v Muller & Co. Margarine Limited* [1901] AC 217 at page [223]:

> "It is the benefit and advantage of the good name, reputation, and connection of a business. It is the attractive force which brings in custom. It is the one thing which distinguishes an old-established business from a new business at its first start. The good will of a business must emanate from a particular centre or source. However widely extended or diffused its influence may be, good will is worth nothing unless it has power of attraction sufficient to bring customers home to the source from which it emanates. Good will is composed of a variety of elements. It differs in its composition in different trades and in different businesses in the same trade…The good will of a business is one whole, and in a case like this it must be dealt with as such".

722. This long-established articulation finds echoes at the Strasbourg level in the judgment of the Court in *Van Marle v The Netherlands* (1986) 8 EHRR 483. That case concerned a complaint by accountants that their applications for registration as accountants had been unfairly refused by the State. They contended that their right to practice as accountants fell within A1P1. The Court accepted their submissions:

> "41. The Court agrees with the Commission that the right relied upon by the Applicants may be likened to the right of property embodied in [A1P1]: by dint of their own work, the Applicants had built up a clientele; this had in many respects the nature of

> a private right and constituted an asset and, hence, a possession in the meaning of the first sentence of [A1P1]. This provision was accordingly applicable in the present case.
>
> 42. The refusal to register the Applicants as certified accountants radically affected the conditions of their professional activities and the scope of those activities was reduced. Their income fell, as did the value of their clientele and more generally, their business. Consequently, there was interference with their right to the peaceful enjoyment of their possessions".

723. In *Breyer* the Court of Appeal also endorsed the statement of the Court in *Ian Edgar (Liverpool) Limited* (2000) Application No 37683/97, where the Applicant was engaged in the business of the distribution of firearms and complained that a prohibition upon handguns imposed by legislation amounted to an interference with the peaceful enjoyment of its possessions or alternatively a deprivation of its possessions without compensation. In analysing the submission that the loss included goodwill the Court examined whether the Claim was one for future revenues by considering the "*substance*" of the claim:

> "The Court notes that the Commission has in the past held that good will may be an element in the valuation of a professional practice but the future income itself is only a "possession" once it has been earned, or an enforceable claim to it exists…The Court considers that the same must apply in the case of a business engaged in commerce. In the present case, the Applicant refers to the value of its business based upon the profits generated by the business as "good will". The Court considers that the Applicant is complaining in substance of the loss of future income in addition to loss of good will and a diminution in value of the company's assets. It concludes that the element of the complaint which is based upon the diminution in value of the business assessed by reference to future income, and which amounts in effect to a claim for loss of future income, falls outside the scope of [A1P1]".

724. The above formulation from *Ian Edgar* was approved of by the Court in *Denimark Limited v UK* (2000) 30 EHRR CD 44. These principles were applied by the Court of Appeal in *R (Malik) v Waltham Forest NHS PCT* [2007] EWCA Civ 265.

725. The Claimants in this case contend that the goodwill in their possession represents a present rather than a future value.

726. First, they contend that the present case concerns the present value of what has been built up and the goodwill arises from the existing reputation of the goods. Second, they contend that their intellectual property portfolios have been built up for over 100 years and elements of "get-up" had become part of the brand identity through long standing use. Third, the Claimants contend that the argument of the Secretary of State that no goodwill attaches to graphic or composite trade marks alone ignores the case law making clear that there is goodwill attaching to non-word trade marks or "get-up"

even if a word mark is also used (see for example *Reckitt & Colman Products Limited v Borden Inc. (No. 3)* [1990] 1 WLR 491). Individual elements of intellectual property right portfolios are marketable and Sections 24(1) and 24(6) of the 1994 Trade Marks Act acknowledged that goodwill is a marketable asset. They submit that graphical marks may be highly distinctive and may also be individually and separately marketable. Fourth, the Claimants rely upon Case C-398/13P *Inuit Tapiriit Kanatami & Others v Commission* which is to the effect that Article 17 of the Fundamental Charter includes within its rights asset values which create "*... under the legal system, an established legal position enabling the holder to exercise those rights autonomously and for his benefit*" (ibid paragraph [60]).

727. The Secretary of State rejects the above analysis. He starts by submitting that goodwill in common law is a negative concept, like other intellectual property rights. Passing off gives rise to what is essentially a negative right to prevent third party traders from misrepresenting their goods as that of the proprietor of the goodwill. The means by which the misrepresentation may occur might involve the use of same or similar marks or indicia such as get-up but that is not necessarily the case. The Secretary of State submits that this does not equate to a positive right to use those marks or other indicia in the face of other laws that may prevent or restrict such use. The common law rule against the assignment "in gross" of the goodwill attached to another unregistered mark continues to be recognised and goodwill thus has no value independently capable of assignment: see *Iliffe News & Media v HMRC* [2014] FSR 6.

728. In terms of substance the Secretary of State in any event denies that the Regulations interfere with the Claimants' marketable goodwill. The alleged losses relate only to future expected income which cannot amount to a possession. On the facts as asserted by the Claimants the goodwill attaches to their businesses in general or at best particular brands rather than attaching to any individual device marks or equivalent. Customers already loyal to a particular brand of tobacco product would not realistically desert that brand upon the basis of a change in package design provided that the brand to which they owed allegiance remained distinguishable from others in practice, which they will do in accordance with Regulation 13. There is no marketable goodwill attaching to the graphic marks as used upon packaging since they are not, in any realistic commercial sense, marketable independently of the brand or capable of valid assignment independently of the business as a whole. It is pointed out that many of the graphic or composite marks relied upon by the Tobacco Claimants already incorporate within them their word trade marks for the brand concerned and they could not even be used as a matter of law by a third party if sold without the continuing consent of the brand word mark owner. Even where graphic marks used on packaging do not actually incorporate a brand word mark their association in the public mind with the brand renders them in practice not marketable independently of the brand.

729. The Secretary of State thus submits, in summary, that the Regulations do not interfere with the Claimants' goodwill as properly defined and that any wider definition of goodwill will in fact relate to the acquisition of potential new customers and was thus, properly analysed, a claim for expected future income.

(iii) Analysis: Conclusion on goodwill

730. It is indisputable that trade marks and other standard intellectual property rights amount to possessions. Certain types of goodwill are capable of being possessions. A difficulty in the present case is that the Claimants have not particularised their claim for goodwill upon the basis of their individual positions nor, in particular, analysed the goodwill said to be attached to individual marks. The claims were advanced at a high level of generality and there is no supporting documentation or disclosure or evidence to buttress these claims.

731. If, contrary to my principal conclusions under this Ground, the Claimants were entitled to recover compensation for the expropriation or control of use of their property rights then this is an aspect of the case which would require far greater particularisation before any quantification of compensation could be arrived at. For present purposes I would only observe that the manner in which the Claimants have advanced their case "*in substance*" appears to relate more to future income stream than to present value. However, it is not necessary for me to arrive at a definitive conclusion on this issue given that I have rejected, for other reasons, the Claimants' claim under A1P1.

(4) Expropriation or control of use?

(i) The distinction between expropriation and control of use: Claimants' submissions

732. A1P1 differentiates between expropriation of a right, and control of use of the right. The classification of a measure as expropriating or, in the alternative, controlling a property right, according to case law, leads mainly to a distinction as to the strictness of (i) the operation of the proportionality principle and (ii) the duty to compensate. The law applies more strictly (and favourably to the right holder) in the case of an expropriation/deprivation than in the case of a simple control of use. The Claimants' submissions on this can be summarised in the following way.

733. First, the distinction between expropriation and control is not rigid or fixed. On the facts of this case the interference amounts in substance, even if not in form, to a deprivation: See e.g. *Smith Kline & French Laboratories Ltd v Netherlands* (App. No. 12633/87, 4 October 1990) in relation to patents; *Balan v Moldova* (App No. 19247/03 29 January 2008) [2009] ECHR 6, paragraph [34] in relation to copyright.

734. Second, a *de facto* deprivation may arise even if legal title to the possession is retained by the proprietor. In *Papamichalopoulos v Greece* (1993) 16 EHRR 440 under Greek law the claimants were still formally the owners of land which had been occupied by the Navy (paragraph [41]), but they "*were unable to make use of their property or to sell, bequeath, mortgage or make a gift of it*" (paragraph [43]). This loss of the ability to dispose of the land amounted to a *de facto* expropriation (paragraph [45]); and see also to similar effect *Vasilescu v Romania* [1999] 28 EHRR 241 ("*Vasilescu*"), paragraph [53]).

735. Third, to determine whether such a *de facto* expropriation has occurred, the Court considers whether there is "*meaningful use*" left of the property in the context of the measure in question: see e.g. *Pine Valley Developments v Ireland* (1992) 14 EHRR

319 ("*Pine Valley*"), in which there was no expropriation of property when planning permission had been revoked in relation to land which "*could have been farmed or leased"*, and which was not "*rendered worthless*" (paragraph [56]).

736. In the text below I consider three different issues: First, the legal classification of trade marks; second, the economic value of trade marks; and thirdly, the guidance derived from case law.

(ii) The nature of trade marks: A negative right to exclude third parties or a positive right to use?

737. An important issue in this context is how to define a trade mark. The Regulations substantially curtail the tobacco companies' ability to use, commercially, their trade marks and they submit that, as such, the *real-world* substance of the marks is destroyed. The Secretary of State, however, argues from a much narrower and purist perspective that trade marks are defined in law as negative rights, i.e. by their ability to prevent third party use, but that right does not extend to an inherent right on the proprietor to use the mark itself. On the contrary, it is said that the law addresses use only through sanctions on non-use (through the risk of revocation). There is thus an obligation to use to avoid revocation but not a positive right to use, and certainly not a right that can be said to be untrammelled. The way in which trade marks are classified is thus said to be relevant to the A1P1 question – Is a restriction on use an expropriation or curtailment of anything that can be said to be a trade mark right? I turn now to set out the competing submissions.

738. Mr Martin Howe QC, for the Secretary of State, submitted that it was evident from the terms of TRIPS (cf. Article 16), from the TMD (cf. Article 10 of the recast TMD) and from the CTMR (cf. Article 9) as well as from domestic law (Section 9ff Trade Marks Act 1994) that the essence or substance of a trade mark was its negative right i.e. the right to prevent third parties from using the mark and it did not extend to a right of use (see Section D(3) above in relation to TRIPS). As such, since the Regulations merely limited the use of trade marks and (through Regulation 13) did not strip from the Claimants the legal right to prevent or exclude and, on the contrary, preserved registrations from the risk of revocation through non-use there was no deprivation and any curtailment of the ability to *use* the trade marks was not a limitation or restriction on a right which was relevant to the essence of the property right. He accepted that TRIPS permitted contracting states to define the rights attaching to trade marks by use but that in the EU and in the United Kingdom this had not happened.

739. He referred to judgments of the High Court and Court of Appeal in which the right had been defined by reference to its exclusionary characteristics: See for example the observations of Arnold J in *Pinterest Inc v Premium Interest Ltd* [2015] FSR 27, a case under the CTMR where, following a review of the authorities, Arnold J concluded at paragraph [36] (and especially at sub-paragraph (a) below):

> "36. In my judgment it is *acte clair* that registration of a Community Trade mark: (a) *confers no positive right to use that mark*; and (b) does not provide a defence to a claim for passing off or unfair competition. So far as Point (a) is concerned, it is trite law that intellectual property rights are

> negative rights to exclude others. A Community Trade mark is no different in this respect. This proposition is not undermined by showing that courts sometimes refer loosely to the trade mark proprietor having the "right to use" the mark, particularly when one bears in mind that one way in which the owner of a trade mark (or other intellectual property right) may use it is by licensing it. Still less is it undermined by anything in art.9 of the Regulation or art.17 of the Charter".
>
> (Emphasis added)

740. The same point applies to the other rights in issue. The design rights have exclusionary properties by virtue of Article 19 Council Regulation (EC) 6/2002 of 12 December 2001 on Community Designs; the patent rights have exclusionary properties by virtue of The Patents Act 1977; and the copyrights have equivalent such properties (e.g. *Ashdown v Telegraph Group Ltd* [2002] Ch 149, §30 (Lord Phillips MR)).

741. The Secretary of State's core submission was put in this way:

> "No interference with property rights
>
> 85. The Tobacco Claimants rely upon their property rights in registered trade marks relating to graphics and text used on their tobacco products. Imperial and BAT also rely on various copyrights, patents, design rights and goodwill. They claim that the Regulations deprive them of these "valuable and commercially significant intellectual property rights".
>
> 86. None of these rights, however, are interfered with by the Regulations. The Claimants' argument to the contrary ignores the nature of the intellectual property rights in question. They are purely negative rights, from the outset subject to inherent limitations. They are rights to exclude others from performing certain restricted acts but confer no legal right on the proprietor of the trade mark (or other right) to perform the acts himself. In short, no intellectual property right confers a right to use, only a right to prevent others from using.
>
> 87. In particular, the acquisition of registered trade marks and other intellectual property rights does not grant the holder immunity from future regulation of the wider commercial and regulatory context within which those rights exist and operate. Being subject to government regulation regarding the conditions of sale and marketing of tobacco products is simply part of doing business in that industry – the acquisition and ownership of specific trade marks does not change that underlying burden and the relevant rights were never intended to do so.

> 88. This inherent limitation of the Claimants' underlying rights resonates under A1P1 as much as under Article 17 and the common law. Even though the term "possession" in A1P1 is an autonomous Convention concept, there still needs to be a "substantive interest" capable of being protected under A1P1. The substantive interest the Claimants' are trying to protect here is their ability to market and sell tobacco products unencumbered by legitimate regulation. Yet, this is not an interest (or a legitimate expectation) that the underlying rights the Claimants rely on ever bestowed on them and thus not one that is protected by A1P1".

742. The Claimants' submissions on this point were advanced by Mr David Anderson QC. He submitted that the Defendant's position was artificially narrow and that it was an error to focus upon what, in technical or classificatory terms, might be understood to be the "essence" or "substance" of a trade mark since the real value of a trade mark for the purposes of A1P1 resided in its *commercial* exploitation i.e. its use, and that a trade mark was an economic hollow shell if it could not be so used. The relevant law in issue under A1P1 is, he submitted, based on substance and not form and in substance the effect of the Regulations is that the Claimants' rights are rendered meaningless. In so far as *any* distinction could be drawn between the various rights in issue (which the Claimants did not accept) then under the terms of the Regulations the symbol or figurative marks could no longer be used at all either on packaging or on the tobacco products themselves, whereas the name trade marks could at least be used albeit only in a highly circumscribed manner. Each individual trade mark had to be analysed separately since each was a discrete "property" in law. It was not therefore permissible to look at the trade marks in the round i.e. as a single composite bundle of rights.

743. Mr Anderson QC also relied upon the observations of the High Court of Australia in *JTI International SA v Commonwealth of Australia* [2012] HCA 43 where, even though the Court rejected the appeal of the tobacco companies on legal grounds (see paragraph [49] above) it nonetheless accepted their submission that the effect of the Australian standardised packaging measures was to denude the trade marks of their real substance. The Court found that property rights had been adversely affected: "*rendered useless for all practical purposes*", according to Heydon J, at 216); and on the basis that "*rights to exclude others from using property have no substance at all if use of the property is prohibited*" (according to French CJ, 37); and that "*each property right conferred included a right of use by the owner*" (according to Heydon J at 216); and/or that the owners' proprietary rights included "*the right to turn the property to valuable account by licence or assignment*" (Crennan J at page [264]. See also Gummow J at page [137], Hayne and Bell JJ at page [163] and Kiefel J at page [347]).

(iii) The test is substance not classification

744. The law relevant to this issue does (as Mr Anderson QC submitted) focus upon substance not formalistic legal rights (cf. e.g. *Oneryildiz v Turkey* (ibid, set out at paragraph [716] above) – the test is not one of *"classification"*). It follows that in delineating the property rights in issue a Court is not confined to the narrow and legalistic task of identifying and "classifying" what the bare minimum legal *essence*

of the right is[31]. And as to practical, real world, substance it is clear, and was not in fact disputed by the Secretary of State, that the economic value of a trade mark lay in its use as well as its ability to exclude. In particular, the commercial value of a trade mark lay in its ability to forge links of recognition or identity and reputation in the mind of consumers. The Claimants adduced a substantial body of evidence on this which included evidence of international transactions where trade marks had accounted for a significant portion of the consideration paid. There is no need to set this evidence out. I accept the thrust of it.

(iv) Word and figurative/symbol trade marks: The reality

745. However, even when one adopts a substance over form analysis it is not, in my judgment, correct to say that the substance of the rights has been wholly destroyed. I do accept that the rights have been significantly and even substantially diminished but this is not the same thing as saying that they have been destroyed or eradicated. On the contrary the rights retain important functions. Regulation 13 explicitly protects against revocation for non-use and preserves the rights attached to registration and hence the right to prevent others from using the trade marks in an unauthorised manner. This is not, as was submitted, an illusory or fictitious exercise; on the contrary the Regulations permit tobacco companies to both place their name and the brand name on the packaging. As such the trade marks still serve their core function as an identifier of origin. The practical effect can be ascertained by considering the position of each manufacturer in the absence of the residual rights conferred by the Regulation. In such a world manufacturers could neither identify themselves nor their brand. They would sell an undifferentiated commoditised product. The end-conclusion in the Regulations is something of a compromise though one which is not at all favourable to the tobacco companies. The Regulations cannot therefore be said to destroy or deprive the trade marks of their essential function but they do nonetheless significantly diminish the value of the rights.

746. I turn now to the point made by the tobacco companies that a clear distinction has to be drawn between the name trade marks (which may still be used, albeit in reduced form) and the symbol or figurative marks (which cannot be used on packaging or product at all under the Regulations, though may be used in non-retail contexts). The tobacco companies point out that, in principle, figurative trade marks can be very powerful (the Nike Swoosh was one illustration given). They submit therefore that independent and important property rights have, on any view, had their very essence stripped from them and that, whatever might be the position in relation to the word marks, the analysis of the non-word marks is far more extreme: these are clear cut cases of *de facto* expropriation of rights.

747. In my judgment, in the real world where substance and not form matters, the Claimants' submission is far too stark and extreme. In reality in this market the word and figurative marks are used in conjunction with each other to convey a collective message to consumers. In this case in the context of A1P1 it is necessary to consider the use of the property rights in the round and collectively.

[31] This is not to say that there are no occasions when a much more precise legalistic exercise in delineation of the formal right is not called for. Where, as part of a legal analysis, it is necessary to be exact about what the essence of a right is then this sort of enquiry may well be called for: See for example in relation to Ground 7, Section K, below.

748. To analyse this submission it is necessary to consider the regulatory environment which has existed in the past; and which will exist in the future when the TPD comes into force. This goes to two points: (a) that in the past figurative or symbol trade marks have not played any major function as standalone identifiers or creators of reputation in the same way that (say) the Nike Swoosh has; and (b), that quite irrespective of the effect of the Regulations in the future the scope for such rights in the light of the TPD would in any event be even more limited.

749. First, the evidence submitted to the Court is that in practice the trade marks used by the Claimants work in conjunction with each other. It is the portfolio effect that matters i.e. the combined effect of the manufacturers' name, the brand name, and any colours and figurative marks or symbols. I do not accept that there is any trade mark that has the standalone characteristics of (say) the Nike Swoosh. This is, in my view, for obvious reasons. Tobacco manufacturers have not, for some years, been able lawfully to advertise in the United Kingdom their tobacco products upon billboards or on the sides of buses or in newspapers or on the television or on clothing in the same way that the seller of running shoes or cameras or computer games can. There has accordingly been no real or material scope for a sign or symbol to develop an ability which is independent from the name mark to act as an identifier of source which can inure to the benefit of the reputation of the proprietor. On the contrary over the past decade and more non-word marks have been compelled to play a supporting role to the name trade marks. This is simply because the tobacco companies cannot do anything else. The physical space available for <u>any</u> type of advertising has become so limited that <u>all</u> branding, of whatever type, is forced to work cheek by jowl with each other. In essence whilst I accept that in theory the non-word trade marks are independent property rights when, as the Claimants urge is essential, one focuses upon substance and not form then the true picture emerges of these trade marks playing their commercial role as supplements or complements operating in conjunction with the other word marks.

750. The second point relates to the impact that the introduction of the TPD would exert <u>in the future</u> upon the scope for symbol or figurative marks to develop independent value, quite irrespective of the restrictive effect of the Regulations. If the Regulations were not introduced then because the TPD would <u>further</u> limit substantially the physical space for any sort of advertising or promotion then the potential for non-word trade marks to develop independent commercial potency would in any event quite irrespective of the Regulations be even more circumscribed than at present. The most obvious limitation which the TPD will impose is the requirement that health warnings take up 65% of both main sides of the package. Any advertising or promotion that remains allowed post-TPD must be squeezed and crowded into an increasingly small space. This means that on the front and back of a pack only a small space is left for *any* sort of advertising at all. And in that small space it is highly improbable (and no tobacco company suggested otherwise) that the manufacturer would seek to develop an independent, free-standing, non-word trade mark.

751. What does this lead to? First, the Regulations preserve the right of registration and, hence, the strict legal right to prevent use by third parties. That right is by no means illusory in relation to word trade marks, which the evidence indicates are in this context the more important commercial marks. Secondly, as to those marks that will

no longer be able to be used whilst it is true that in law they are separate properties in substance they form an integral part of the overall bundle of property rights that have been affected by the Regulations.

752. The conclusion that I have arrived at is supported by the expert opinion evidence of Professor Kevin Keller on behalf of PMI and relied upon by all Claimants. He produced a report dated 20th May 2015. He provides the standard CPR 35 expert declaration. The report was entitled "Branding and the Standardised packaging of Tobacco Products Regulations 2015". This was an interesting report very little of which was challenged by the Secretary of State. It provided, from a proprietor's perspective, a broad overview of: the nature and role of branding; the commercial effects that branding changes can exert on consumer behaviour; the role of branding in the United Kingdom cigarette market; and, the impact on branding of the introduction of the Regulations. It was an important theme of Professor Keller that branding could be very effective and could and did impact upon consumer behaviour, though he concentrated his analysis upon how this effect was directed at differentiating between competing brands. A further important point was that the impact upon consumers was essentially brought about by the cumulative effect of the totality of branding elements used by a proprietor. In paragraphs [30ff] of his report Professor Keller described the critical importance of the combined effects of brands and logos. He explained how firms "*mix and match*" brand elements to maximise brand "*equity*" and that it was the "*entire set of brand elements [that] makes up the brand identity*". He observed:

> "31. The combined effect of brand elements is far greater than the sum of the individual parts. Perceptually, the various brand elements of a successful brand will combine to create a "gestalt" effect: consumers develop an impression of a brand's identity through the collective contribution of the brand elements"

753. In paragraph [33] he said: "*The combined effect of brand elements is critical to the success of a branded product*". As such Professor Keller endorses the conclusion that I have arrived at which is that whilst it is true that each trade mark is in legal terms an independent property it is nonetheless the cumulative effect of the rights that matters when the issue is examined (as the Claimants submit it should be under A1P1) from the perspective of real life substance and not form.

(5) Case law: *Vékony v Hungary* [2015] ECHR 5 (13th January 2015)

754. I turn now to the case law. I start with a judgment of the Court on the issue of tobacco control: *Vékony v Hungary* (13th January 2015). I deal with this separately and in detail because it concerns tobacco and the FCTC and it provides guidance on a number of key issues and in particular the distinction between expropriation and restrictions on use, and, the right to compensation. In their written submission the Claimants argued that the case proved their case. I disagree. The judgment repays careful consideration.

755. **Facts**: I start with the facts. In 1994 the Applicant's family operated a grocery which sold alcohol and tobacco products. On average the turnover of tobacco represented about one third of total turnover. Tobacco products were sold pursuant to an excise

licence which was, at least initially, in the name of the Applicant's mother. The Applicant himself obtained a shop-keeping licence in 1999 and in 2005 he was registered in his own capacity as a trader of excise goods. On the 11th September 2012 Parliament enacted a law on the Repression of Smoking of the Youth and on Tobacco Retail. The Act was published on the 24th September 2012 and was subsequently amended on a number of occasions with the final version being enacted on the 6th June 2013 and coming into force on the 1st July 2013. Prior to the Act excise products, including tobacco, were sold through approximately 42,000 retail outlets. However, pursuant to the Act tobacco retail was to become a state monopoly exercised through a state owned company. Tobacco retailers would become licensed through a concession tender. This was advertised on the 15th December 2012. Tenderers could apply for concessions to operate up to five retail outlets. Those applying for these new concessions were required to produce business plans reflecting, *inter alia*, the new government policy to limit to the greatest possible degree the access of minors to tobacco products. This was to be achieved notably by prohibiting those under the age of 18 going into such shops. Under the new licences tobacco retail could take place only in shops with separate entrances, with dark shades in the shop window preventing tobacco products being visible and with only a limited selection of other goods on sale. As already recorded the tenders were advertised on the 15th December 2012 and the expiry date for applications was the 22nd February 2013. There were no incumbency benefits or privileges conferred upon those retailers who had, hitherto, been engaged in tobacco retail. The decision about the grant of concessions was to be taken by the new statutory monopoly. In total approximately 6,800 licences were granted across the country.

756. The Applicant applied for a concession on the 4th February 2013. This was for a licence to cover the existing retail operation. The Applicant subsequently amended the application upon the basis of forthcoming new rules on the 20th February 2013. The application was succinct and, according to the Government of Hungary, "*in no way developed*" in particular it did not contain an appropriate business plan which had been part of the formal criteria for tenders. The Applicant submitted however that no information had been made available to tenderers about the assessment process and that the paucity of available information explained the conciseness of the application.

757. On 23rd April 2013 the Applicant was informed that he had been unsuccessful in his tender for a new concession. The rejection decision contained no reasons. Nor was there any indication of the Applicant's score on the tender adjudication score sheet. The rejection decision was not susceptible to any legal challenge. The consequences of the negative decision were that the Applicant's business was obliged to terminate the business of tobacco by the statutory deadline of the 14th July 2013. Tobacco wholesalers were under an obligation to re-purchase any outstanding stocks from terminated dealers.

758. The net effect of the termination of the Application's licence was that the entire family enterprise was no longer profitable and it was wound up. Under the relevant law no compensation was available for former holders of tobacco retail licences who, by not having been awarded a concession, lost part of their livelihood.

759. The Applicant complained that both others in a comparable situation to himself and also those who were non-comparable (i.e. retailers who had never engaged in tobacco sales in the past), had been granted concessions. The Applicant objected that the

difference in treatment could not be explained by any circumstance "*other than political adherence*". The Constitutional Court in Hungary declared the Applicant's complaints admissible but dismissed the motions upon their merits. The Court noted that the legislature had adopted the legislation to eliminate underage smoking and for this reason had restricted the accessibility of the right to conduct the retail of tobacco products. The Court observed that this measure was in accordance with the obligations of Hungary pursuant to the WHO FCTC (see at paragraph [13]).

760. **Parties' submissions**: I turn now to the parties' submissions to the Court. The Court summarised the submissions of the parties in the following way. So far as the Applicant was concerned the economic interests connected with the business and reflected in the prior licence represented a "possession" for the purpose A1P1 and its withdrawal by operation of law was an interference with the Applicant's rights pursuant to that Protocol. Further, the lawfulness of this interference was exacerbated by the "*hasty adoption*" of the law in question, its amendments during the course of the tender adjudication procedure, and the absence of a transparent procedure or a legal remedy. The Applicant did not question that the "purported aim", namely to combat underage smoking and protect the health of the population in general, was capable of amounting to a legitimate objective. The Applicant contended that "*... in reality, the measure rather aimed to monopolise tobacco retail and re-distribute the market shares, which could not be accepted as a legitimate aim, even in the face of the State's wide margin of appreciation in this field*" (paragraph [27]). The Applicant questioned further the adequacy of the means chosen pointing to the fact that if the acquisition of tobacco products was made more difficult this would have an effect which benefitted the black market. Finally, it was submitted that no fair balance had been struck between the Applicant's interest and that of the community in that by losing the Applicant's principal source of livelihood without compensation the Applicant had been forced to bare an "*excessive individual burden*".

761. Hungary submitted that the Applicant's application for a concession had been overly succinct and had lacked elaboration and contained no relevant business plan. The Applicant had achieved a very low score in the adjudication process. The Applicant had no right to complain about not acquiring a new concession since he had no right to "*acquire*" such a property (paragraph [28]). Hungary rejected the suggestion that the Applicant had any legitimate expectation to obtain a new concession; all he could legitimately expect was an appropriate transition period to adjust to the new situation. In this regard Hungary submitted that there were adequate transitional arrangements. The new legislative measures were no more than a control on the use of property; the Applicant had not been deprived of his business. Only the scope of activities available to him had been curtailed. Under the new regime grocery stores could no longer sell tobacco and, accordingly, his previous licence had simply become obsolete and its loss could not be seen as a deprivation of property. He suffered no actual damage apart from losing the entitlement for the future. The measure in question had sought to reduce the number of sales points for tobacco retail in order to combat underage smoking and improve society's health. Other states of the Council of Europe had introduced similar measures and a creation of a state monopoly to achieve these objectives fell within the state's wide margin of appreciation in this field. Finally the Government contended that the Applicant had not suffered an excessive individual burden because only the scope of his business had been reduced and such a control of "use of property" did not entail an automatic obligation on the part of the State to

provide compensation. Hungary cited *J A Pye (Oxford) Ltd et ors v United Kingdom* (Case 44302/02) (2007) paragraph [79].

762. **Judgment of the Court**: I turn now to the judgment of the Court. The Court ruled that, upon the facts, there had been a breach of A1P1. First, the Court accepted that the public health object or purpose behind the interference (the revocation of the licence) was lawful in the light of the FCTC and in accordance with the public interest and it rejected the submission of the Applicant that the measure was adopted to introduce a state monopoly over the tobacco retail market and redistribute market shares. However, even upon the assumption that the interference was *prima facie* lawful, the surrounding circumstances disclosed a violation of the Applicant's rights under A1P1 (see paragraph [31]).

763. For the reasons set out in paragraphs [32]-[36] of the judgment the system adopted by Hungary in order to pursue this, *ex hypothesi*, lawful objective imposed an excessive and unreasonable burden upon the Applicant and was thereby disproportionate. According to consistent case law even legitimate measures of interference must strike a "*fair balance*" between the demands of the general interests of the community and the requirement of the protection of the individual's fundamental rights. The Court stated that "*the search for this balance*" was reflected in the structure of A1P1 as a whole and it, accordingly, was also a constituent part of the second paragraph thereof: "*There must be a reasonable relationship of proportionality between the means employed and the aim sought to be realised… A proper balance between the general interest and the individual's rights will not be found if the person concerned has had to bear an individual and excessive burden…*".

764. The Court accepted (paragraphs [33] and [35]) that the competent authorities enjoyed a "*wide margin of appreciation*" which extended to: (i) the need for the legislation; (ii) its aims; and (iii) its effects. The Court stated that these should be accepted unless it was "*manifestly unreasonable and imposed an excessive burden on the person concerned*" (ibid [33] citing *James* (ibid) at paragraphs [46] and [50]).

765. **Factors relevant to disproportionality / lack of a "fair balance"**: On the facts, and notwithstanding the broad margin of appreciation, an excessive and disproportionate burden had been placed upon the Applicant. It is possible to identify five reasons for the Court's conclusions:

i) **Consequences for Applicant**: The loss of the licence reduced the Applicant's business by approximately one third of its turnover which, in due course, led to the Applicant's business being wound up. This amounted to 'serious economic consequences' and amounted to a 'severe measure' in all the circumstances (ibid paragraph [33]).

ii) **Absence of proper transitional protection**: The Applicant was accorded an insufficient transitional period within which to adjust. Only 10 months had elapsed between the enactment of the impugned law and the deadline for terminating the Applicant's tobacco retail operation. From the point in time when the Applicant was informed that he had been refused a licence less than three months remained before he was required to cease retail operations. In the context of the business benefiting from a licence for approximately 20 years

these transitional periods could '*…hardly be regarded as sufficient'* (ibid paragraph [34]).

iii) **Absence of protection against arbitrary, discriminatory or disproportionately harsh consequences**: Within the confines of the second paragraph of A1P1 authorities must follow a '*genuine and consistent policy regarding licensing*'. Here there were insufficient safeguards against arbitrary conduct by the decision maker and there was a lack of a reasonable opportunity for the Applicant to put his case to the responsible authority or by way of subsequent challenge before the Courts (ibid paragraph [34]). The procedure adopted for the determination of licences appears to have been '*devoid of elementary transparency and of any possibility of legal remedies*'. Any interference with the peaceful enjoyment of possessions had to be accompanied by procedural guarantees affording to the individual or entity concerned a reasonable opportunity to present its case to the responsible authority for the purpose of effectively challenging the measure interfering with the rights guaranteed by A1P1 (ibid).

iv) **Manner of introduction of impugned law**: In addition the impugned law was introduced with '*remarkable hastiness*' and even then with '*constant changes*' (ibid paragraph [35]). The very short period provided to licence holders to make adequate arrangements to respond to the impending change to their source of livelihood was also not alleviated by any positive measures on behalf of the State, for example the adoption of a scheme of reasonable compensation.

v) **Arbitrariness of the rules themselves**: Finally, the criteria for selection were not such as to '*offer a realistic prospect*' for the Applicant to obtain a concession and were '*verging on arbitrariness*' (ibid paragraph [36]). In this particular connection the Court identified five features: (a) the fact that the long duration of the previous licence had been disregarded; (b) that there was no possibility under the new scheme for a former licence holder to continue tobacco retail under the new arrangements; (c) that the new concession system contemplated the grant of five concessions to a single tenderer which had the effect of diminishing the possibility of an incumbent licence holder of small size obtaining a licence; (d) the absence of transparent rules in relation to the awarding of concessions; and (e), the omission from concession grant system of any incumbent trader's privileges, such as limiting the scope of the first round of tenderer to such persons.

766. **The obligation to pay compensation**: For the above reasons the Court concluded that the new system violated A1P1. The Court then proceeded to decide whether compensation was due. The Court noted (ibid paragraph [39]) that the Applicant's claimed €10,000 as the Applicant's "*global estimate*" of lost business. The Court observed:

> "41. Without speculating on the profit which the Applicant would have achieved if the violation of the Convention had not occurred, the Court observes that he suffered a reasonable loss of business. Therefore considers it appropriate to order lump sum in compensation for the loss of future earnings. In

> addition, the Court considers that the violation it has found of Article 1 of Protocol No 1 in the instant case must have caused the Applicant prolonged uncertainty in the conduct of its business and feelings of helplessness and frustration, entailing some non-peculiarly damage".

In these circumstances the Court considered that it was reasonable on the basis of equity to award the Applicant an overall sum of EUR 15,000 covering all heads of damage.

767. **Implications for present case**: The Claimants submit in their written submissions that this judgment establishes beyond doubt that there are no exceptional circumstances in the present case which would justify the decision not to compensate the Claimants for the interference with their rights. They accept that the Court accepted that the removal of the tobacconist's licence served a legitimate purpose, but notwithstanding, they point out that because the Court held the rules did not strike a "fair balance": "*It must follow that the aim of the Regulations is not so exceptional, or unique, as to rebut the presumption that the Claimant should be compensated for the deprivation of their valuable property*".

768. *Vékony* does not in fact provide the compelling answer that the Claimants suggest it provides. There are three main points to make. First, *Vékony* was not a case where the challenge was to the system as a whole, upon the basis that it was, at a macro level, ineffective. The Applicant did not submit that the curtailment of the number of retail outlets and the imposition of marketing restrictions would not be effective to achieve the stated health objective and as such this was not a belt and braces attack on the legislation. On the contrary this was a "micro" challenge only to the internal modalities of the system in circumstances where the Applicant accepted that the overall object of the measures was lawful and legitimate. Put another way the success or failure of the Applicant's case did not involve the Court in having to evaluate the strength of the objective advanced for the legislation by the State and the appropriateness of the measures in achieving those goals. Instead the Court took into account the long prior period during which the particular Applicant had retailed tobacco, and, the catastrophic impact on the Applicant's overall business caused by the loss of the licence. As such the judgment is not even necessarily a precedent for any other disappointed applicants for a licence under the same system. Second, the Court treated the total withdraw of the right to sell tobacco as a curtailment of a use right, not an expropriation. This was even though the curtailment led to the applicant not only losing the right to retail tobacco but, moreover, to the collapse of his ability to trade in all goods and services. Yet this still fell within the second part of A1P1 which, in turn, imposed a higher evidential threshold upon an applicant seeking compensation. Third, the Court held that in principle the state possessed a "*wide margin of appreciation*" (paragraph [35]) to withhold any form of compensation and in deciding whether the applicant had "*to bear an individual and excessive burden*" (paragraph [32]). It is not entirely clear from the judgment whether the Court accepted the submission of the State of Hungary that an Applicant had to show that the State's conduct was "*manifestly unreasonable and imposed an excessive burden*" (judgment paragraph [33]). Nonetheless, the Court explicitly accepted that the State enjoyed a "*wide margin of appreciation*" (paragraph [35]). It may be that the endorsement of a wide margin of appreciation was no more than the juridical converse of a test of

manifest unreasonableness. In any event the litmus test, or proxy, employed by the Court was to answer the question whether the burden imposed was "*individual*" and "*excessive*": In answering this question it is important to recognise that these are twin ingredients (i) individuality and (ii) nature and extent of burden (was it "excessive"?). In this regard the Court relied upon the judgment in *Rosenzweig and Bonded Warehouse Ltd v Poland* [2005] ECHR 5520 (28th July 2005) at paragraph [48]. In *Rosenzweig* the Court relied upon *James* (ibid) at paragraph [50]:

> "50. This, however, does not settle the issue, not only must the measure depriving a person of his property pursue, on the facts as well as in principle, a legitimate aim 'in the public interest', but there must also be a reasonable relationship of proportionality between the means employed and the aims sought to be realised… This latter requirement was expressed in other terms in the Sporrong and Lonnorth judgment by the notion of 'fair balance' that must be struck between the demands of the general interest of the community and the requirements of the protections of the individual fundamental rights… The requisite balance will not be found if the person concerned has had to bare 'an individual and excessive burden'… Although the Court was speaking in that judgment in the context of the general rule of peaceful enjoyment of property enunciated in the first sentence of the first paragraph, it pointed out that 'the search for this balance is… reflected in the structure of Article 1(P1-1)' as a whole… It was the Applicant's contention that the leasehold reform legislation does not satisfy these conditions. In their submission, even assuming there to be a social injustice, the means chosen to cure it were so inappropriate or disproportionate as to take the Legislature's decision outside the margin of appreciation. The Court considers that a measure must be both appropriate for achieving its aim and not disproportionate thereto. Whether this was so on the facts will be examined below when dealing with the Applicant's various arguments".

769. The Court in *Vékony* also cited *Tre Traktörer AB v Sweden* (7th July 1989) at paragraph [55] for the proposition that it was the second paragraph of A1P1 (use curtailment) that applied, and not the first. In that case the Court had to decide under which part of A1P1 a state measure revoking an alcohol retail licence fell. The Court stated:

> "55. Severe though it may have been, the interference at issue did not fall within the ambit of the second sentence of the first paragraph. The applicant company, although it could no longer operate Le Cardinal as a restaurant business, kept some economic interests represented by the leasing of the premises and the property assets contained therein, which it finally sold in June 1984 (see paragraph 23 above). There was accordingly no deprivation of property in terms of Article 1 of the Protocol (P1-1). The Court finds, however, that the withdrawal of

> TTA's licence to serve alcoholic beverages in Le Cardinal constituted a measure of control of the use of property, which falls to be considered under the second paragraph of Article 1 of the Protocol (P1-1)".

770. These authorities show that if the applicant retains title to the right in issue this is a strong indication that there is no expropriation and equally the severity of the economic consequences is not a factor which is especially relevant to the distinction between expropriation and control. It also suggests that even if what is left of a right following the state interference is limited or vestigial or non-existent that may still be sufficient to render the interference a control of use and not a expropriation.

(6) Case law: A review of other authorities

771. A large number of other cases were cited in the case. I summarise some of the main strands arising out of the case law. The authorities are consistent with *Vékony*. They address: (i) the distinction between expropriation and control of use; and (ii) the test in each case for compensation.

772. In *AGOSI v UK* (1987) 9 EHRR 1 the seizure and forfeiture of smuggled gold coins for the enforcement of domestic legislation making the importation of Krügerrand illegal was held to constitute a control of use and this included in relation to property which was wholly forfeit. In paragraphs [48] – [51] the Court stated:

> "48. Article 1 (P1-1) in substance guarantees the right of property (see the Marckx judgment of 13 June 1979, Series A no. 31, pp. 27-28, para. 63). It comprises "three distinct rules": the first rule, set out in the first sentence of the first paragraph, is of a general nature and enunciates the principle of the peaceful enjoyment of property; the second rule, contained in the second sentence of the first paragraph, covers deprivation of possessions and subjects it to certain conditions; the third rule, stated in the second paragraph, recognises that the Contracting States are entitled, amongst other things, to control the use of property in accordance with the general interest (see, inter alia, the Sporrong and Lönnroth judgment of 23 September 1982, Series A no. 52, p. 24, para. 61). However, the three rules are not "distinct" in the sense of being unconnected: the second and third rules are concerned with particular instances of interference with the right to peaceful enjoyment of property and should therefore be construed in the light of the general principle enunciated in the first rule (see the Lithgow and Others judgment of 8 July 1986, Series A no. 102, p. 46, para. 106).
>
> 49. The forfeiture of the smuggled Kruegerrands amounted to an interference with the applicant company's right to peaceful enjoyment of their possessions as protected by the first sentence of Article 1 (P1-1). This point has not been in dispute.

> 50. The Court must first determine whether the material provision in the present case is the second sentence of the first paragraph or the second paragraph.
>
> 51. The prohibition on the importation of gold coins into the United Kingdom clearly constituted a control of the use of property. The seizure and forfeiture of the Kruegerrands were measures taken for the enforcement of that prohibition. It is true that the High Court based its decision to declare the Kruegerrands forfeited on sub-paragraph (f) of section 44 of the 1952 Act, holding that they had been goods concealed in a manner appearing to be intended to deceive an officer. However, the Commissioners' counterclaim for forfeiture also relied on, inter alia, sub-paragraph (b) of the same section, which provided for the forfeiture of goods imported in contravention of an importation prohibition (see paragraphs 26 and 33 above). It does not appear material in this context that the High Court chose to rely on one of these sub-paragraphs rather than the other. The forfeiture of the coins did, of course, involve a deprivation of property, but in the circumstances the deprivation formed a constituent element of the procedure for the control of the use in the United Kingdom of gold coins such as Kruegerrands. It is therefore the second paragraph of Article 1 (P1-1) which is applicable in the present case (see, mutatis mutandis, the *Handyside* judgment of 7 December 1976, Series A no. 24, p. 30, para. 63)".

773. In *Air Canada v UK* (1995) 20 EHRR 150 the Applicant's plane was seized and returned only after the payment of a compulsory fee. The Court held that there was a "*deprivation of possessions*" (paragraph [31]) but it did not involve a transfer of ownership (paragraph [32]) and, most critically, it was a measure in the public interest in furtherance of drug control (paragraph [34]). And therefore "*as such*" (paragraph [34]) it amounted to a control of the use of property:

> "31. The applicant considered that it had been deprived of its aircraft albeit for a temporary period and, subsequently, as a permanent measure, of the £50,000 that it was required to pay as a condition for the return of its property. There had thus been a deprivation of possessions.
>
> 32. For the Government, with whom the Commission agreed, this was not a case involving a deprivation of property since no transfer of ownership of the applicant's aircraft had taken place. The seizure and demand for payment were to be seen as part of the system for the control of the use of an aircraft which had been employed for the import of prohibited drugs.
>
> 33. The Court is of the same view. It observes, in the first place, that the seizure of the aircraft amounted to a temporary restriction on its use and did not involve a transfer of ownership, and, in the second place, that the decision of the

> Court of Appeal to condemn the property as forfeited did not have the effect of depriving Air Canada of ownership since the sum required for the release of the aircraft had been paid (see paragraph 15 above).
>
> 34. In addition, it is clear from the scheme of the legislation that the release of the aircraft subject to the payment of a sum of money was, in effect, a measure taken in furtherance of a policy of seeking to prevent carriers from bringing, inter alia, prohibited drugs into the United Kingdom. As such, it amounted to a control of the use of property. It is therefore the second paragraph of Article 1 (P1-1) which is applicable in the present case (see, mutatis mutandis, the above-mentioned AGOSI judgment, p. 17, para. 51)".

774. In *Pinnacle Meat Processors Company v UK* (1999) 27 EHRR CD217 the Court was concerned with State measures adopted in the wake of the BSE crisis. The effect of the measures adopted had the effect of making unlawful the cattle deboning businesses of the nine applicants. Six in consequence went out of business. Despite this, the regulation was considered a control of use rather than a *de facto* expropriation.

775. In *Andrews v UK* (App. No. 37657/97, 26 September 2000) the Court was concerned with firearms control legislation banning the sale of certain guns. This was considered to be a control of use rather than a deprivation in respect of the Applicant's business of selling these guns (to the extent that it amounted to interference at all).

776. In *J.A. Pye (Oxford) Ltd and J.A. Pye (Oxford) Land Ltd v. the United Kingdom* (30th August 2007) [2007] ECHR 5559 the Court reviewed earlier case law, including *AGOSI* and *Air Canada,* and made clear that the simple fact that an applicant lost ownership of a possession did not mean, necessarily, that this was anything other than a control of use. The critical consideration (cf. paragraph [66]) was whether the regulatory measure in dispute was intended to pursue a legitimate public interest objective:

> "64. The Court has, on a number of occasions, considered cases in which a loss of ownership of possessions was not categorised as a "deprivation" within the meaning of the second sentence of the first paragraph of Article 1 of Protocol No. 1. In the cases of *AGOSI* and *Air Canada*, the forfeiture of the applicant companies' possessions was considered to amount to a control of use of gold coins and a control of the use of aircraft which had been employed for the import of prohibited drugs, respectively (*AGOSI v. the United Kingdom*, referred to above, § 51; *Air Canada v. the United Kingdom*, judgment of 5 May 1995, Series A no. 316 A, § 34; see also *C.M. v. France* (dec.), no. 28078/95, ECHR 2001 VII). The applicant company in the case of *Gasus* had sold a concrete-mixer to a third party subject to a retention of title clause. The tax authorities' seizure of the concrete-mixer was considered as an exercise of the State's

> right to "secure the payment of taxes", although the tax debts were not those of the applicant company (*Gasus Dosier-und Fördertechnik GmbH v. the Netherlands*, judgment of 23 February 1995, Series A no. 306 B, § 59). The Court declined, in the case of *Beyeler*, to determine whether the interference with the applicant's property rights constituted a "deprivation of possessions", as it sufficed to examine the situation complained of in the light of the general rule in the first sentence of the first paragraph of Article 1 (*Beyeler v. Italy*, referred to above, § 106).
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> 65. The applicant companies did not lose their land because of a legislative provision which permitted the State to transfer ownership in particular circumstances (as in the cases of *AGOSI*, *Air Canada*, *Gasus*), or because of a social policy of transfer of ownership (as in the case of *James)*, but rather as the result of the operation of the generally applicable rules on limitation periods for actions for recovery of land. Those rules provided that at the end of the limitation period, the paper owner's title to unregistered land was extinguished (section 17 of the 1980 Act). In the case of registered land, the position was amended to take into account the fact that until the register was rectified, the former owner continued to appear as registered proprietor. Thus in the present case, section 75(1) of the 1925 Act provided that on expiry of the limitation period the title was not extinguished, but the registered proprietor was deemed to hold the land in trust for the adverse possessor.
>
> 66. The statutory provisions which resulted in the applicant companies' loss of beneficial ownership were thus not intended to deprive paper owners of their ownership, but rather to regulate questions of title in a system in which, historically, 12 years' adverse possession was sufficient to extinguish the former owner's right to re-enter or to recover possession, and the new title depended on the principle that unchallenged lengthy possession gave a title. The provisions of the 1925 and 1980 Acts which were applied to the applicant companies were part of the general land law, and were concerned to regulate, amongst other things, limitation periods in the context of the use and ownership of land as between individuals. The applicant companies were therefore affected, not by a "deprivation of possessions" within the meaning of the second sentence of the first paragraph of Article 1, but rather by a "control of use" of land within the meaning of the second paragraph of the provision".

777. In *Jahn v. Germany* ECHR 2005-VI (Applications nos. 46720/99, 72203/01 and 72552/01) following German reunification the applicants alleged that the obligation imposed on them to reassign their property without compensation had infringed their right to the peaceful enjoyment of their possessions, contrary to A1P1. The case was

first heard by a Chamber which held that there was a violation of A1P1 and that compensation was payable; the Grand Chamber disagreed:

> "109. The Court notes that it has in the past already been required to rule on whether an intervention by the legislature with a view to reforming the economic sector for reasons of social justice (see *James and Others*, cited above, examined under the second sentence of the first paragraph of Article 1, and concerning the reform of the British system of long leasehold tenure), or to correct the flaws in an earlier law in the public interest (see *National & Provincial Building Society, Leeds Permanent Building Society and Yorkshire Building Society v. the United Kingdom*, judgment of 23 October 1997, *Reports of Judgments and Decisions* 1997-VII, examined under the second paragraph of Article 1, and concerning retrospective tax legislation) respected the "fair balance" between the relevant interests in the light of Article 1 of Protocol No. 1.
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> 110. Admittedly, there are certain similarities between the instant case and the aforementioned cases in that in 1992 the German legislature had sought to correct the flaws in the Modrow Law for reasons of social justice. It differs from the case of *James and Others v. the United Kingdom*, in particular, however, as the second Property Rights Amendment Act does not provide for any compensation whatsoever for the applicants.
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> 111. As the Court has stated above (see paragraph 94), a total lack of compensation can be considered justifiable under Article 1 of Protocol No. 1 only in exceptional circumstances.
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> 112. It must therefore examine, in the light of the unique context of German reunification, whether the special circumstances of the case can be regarded as exceptional circumstances justifying the lack of any compensation.
>
> 113. In that connection the Court reiterates that the State has a wide margin of appreciation when passing laws in the context of a change of political and economic regime (see, *inter alia*, *Kopecký v. Slovakia* [GC], no. 44912/98, § 35, ECHR 2004-IX, and *Zvolský and Zvolská*, cited above, §§ 67-68 and 72). It has also reiterated this point regarding the enactment of laws in the unique context of German reunification (see, most recently, *von Maltzan and Others v. Germany* (dec.) [GC], nos. 71916/01, 71917/01 and 10260/02, §§ 77 and 111-12, ECHR 2005).
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> 114. In its judgment of 22 January 2004 the Chamber found that, in order to comply with the principle of proportionality, the German legislature "could not deprive the applicants of their property for the benefit of the State without making provision for them to be adequately compensated" (see § 91).

The Chamber concluded that "even if the circumstances pertaining to German reunification ha[d] to be regarded as exceptional, the lack of any compensation for the State's taking of the applicants' property upset, to the applicants' detriment, the fair balance which ha[d] to be struck between the protection of property and the requirements of the general interest" (see § 93).

115. The Court does not share the Chamber's opinion on that point however.

116. Three factors seem to it to be decisive in that connection:

(i) firstly, the circumstances of the enactment of the Modrow Law, which was passed by a parliament that had not been democratically elected, during a transitional period between two regimes that was inevitably marked by upheavals and uncertainties. In those conditions, even if the applicants had acquired a formal property title, they could not be sure that their legal position would be maintained, particularly as in the absence of any reference to heirs in the Modrow Law, the position of those among them who were not farming the land themselves and were not members of an agricultural cooperative remained precarious even after that Law had come into force;

(ii) secondly, the fairly short period of time that elapsed between German reunification becoming effective and the enactment of the second Property Rights Amendment Act. Having regard to the huge task facing the German legislature when dealing with, among other things, all the complex issues relating to property rights during the transition to a democratic, market-economy regime, including those relating to the liquidation of the land reform, the German legislature can be deemed to have intervened within a reasonable time to correct the – in its view unjust – effects of the Modrow Law. It cannot be criticised for having failed to realise the full effect of this Law on the very day on which German reunification took effect;

(iii) thirdly, the reasons for the second Property Rights Amendment Act. In that connection the FRG parliament cannot be deemed to have been unreasonable in considering that it had a duty to correct the effects of the Modrow Law for reasons of social justice so that the acquisition of full ownership by the heirs of land acquired under the land reform did not depend on the action or non-action of the GDR authorities at the time (see paragraphs 103-104 above). Likewise, the balancing exercise between the relevant interests carried out by the Federal Constitutional Court, particularly in its leading decision of 6 October 2000, in examining the compatibility of that

> amending Law with the Basic Law, does not appear to have been arbitrary (see paragraphs 41-42 above). Given the "windfall" from which the applicants undeniably benefited as a result of the Modrow Law under the rules applicable in the GDR to the heirs to land acquired under the land reform, the fact that this was done without paying any compensation was not disproportionate (see, *mutatis mutandis, National & Provincial Building Society,* cited above, §§ 80-83). It should also be noted in that connection that the second Property Rights Amendment Act did not benefit the State only, but in some cases also provided for the redistribution of land to farmers (see paragraphs 67-69 above).
>
> 117. Having regard to all the foregoing considerations and taking account, in particular, of the uncertainty of the legal position of heirs and the grounds of social justice relied on by the German authorities, the Court concludes that in the unique context of German reunification, the lack of any compensation does not upset the "fair balance" which has to be struck between the protection of property and the requirements of the general interest.
>
> There has therefore been no violation of Article 1 of Protocol No. 1".

778. In *Friend v United Kingdom (Countryside Alliance)* (2010) EHRR SE6 (24th November 2009) the Court applied *Jahn v Germany* and held that the margin of appreciation accorded to the decision maker was a broad one and that two particular considerations played a part in the overall assessment. These were the status of the decision maker and the nature and extent of the degree of scrutiny undertaken by the decision maker. These factors would be weighed in the scales against the (*in casu* severe) financial impact on those whose business had been interfered with:

> "56. The Court recalls that in *Jahn and Others v. Germany* [GC], nos. 46720/99, 72203/01 and 72552/01, § 91, it stated that "the margin of appreciation available to the legislature in implementing social and economic policies should be a wide one [and the Court] will respect the legislature's judgment as to what is 'in the public interest' unless that judgment is manifestly without reasonable foundation" (see also *J.A. Pye (Oxford) Ltd and J.A. Pye (Oxford) Land Ltd v. the United Kingdom* [GC], no. 44302/02, § 71, ECHR 2007 ...). It also observes that the 2004 Act was preceded by extensive public debate, including the hearings conducted by the Burns Committee. It was enacted by the House of Commons after equally extensive debate in Parliament where various proposals were considered before an outright ban was accepted. In those circumstances, the Court is unable to accept that the House of Commons was not entitled to legislate as it did or that the refusal of the Burns Report to draw any conclusions as to the suffering of animals during hunting substantially undermined the reasons for the 2004 Act. The

judgment that it was in the public interest to ban hunting was, as Lord Hope observed in context of the proportionality of the hunting ban in Scotland, pre-eminently one for the House of Commons to make.

57. For the lack of compensation in the 2004 Act, the Court accepts that a ban on an activity which is introduced by legislation will inevitably have an adverse financial impact on those whose businesses or jobs are dependent on the prohibited activity (see, *mutatis mutandis*, *C.E.M. Firearms Limited and others v. the United Kingdom* (dec.), nos. 37674/97 and 37677/97, 26 September 2000). Nevertheless, the domestic authorities must enjoy a wide margin of appreciation in determining the types of loss resulting from the measure for which compensation will be made. As stated in *C.E.M. Firearms Limited* "the legislature's judgment in this connection will in principle be respected unless it is manifestly arbitrary or unreasonable". This applies, *a fortiori*, to cases where the interference concerns control of the use of property under the second paragraph of Article 1 rather than deprivation of possessions under the first paragraph of the Article. There is normally an inherent right to compensation in respect of the latter but not the former (see *Banér v. Sweden*, no. 11763/85, Commission decision of 9 March 1989; *J.A. Pye (Oxford) Ltd*, cited above, § 79). The Court does not find the absence of compensation in the 2004 Act to be arbitrary or unreasonable. Nor does it find that, in reaching the judgment it did, the United Kingdom upset the fair balance between the demands of the general interest and the requirements of the protection of the applicants' property rights by imposing on the applicants an individual and excessive burden. Indeed, the Court of Appeal's finding that hunts have continued to gather since the passage of the Act, albeit without live quarry, appears to confirm the decision of the House of Commons not to offer compensation to those affected by the ban.

58. Finally, the domestic courts have given the greatest possible scrutiny to the applicants' complaints under the Convention and especially those complaints brought under Article 1 of Protocol No. 1. The Court also notes that the High Court, the Court of Appeal and the House of Lords (as well as, for the 2002 Act in Scotland, the Inner and Outer Houses of the Court of Session in *Adams*) were each unanimous in finding that the ban was proportionate for the purpose of Article 1 of Protocol No. 1. Serious reasons would be required for this Court to depart from the clear findings of those courts. From the applicant's submissions, it can discern no such reasons; accordingly, and for the above reasons, this part of the complaint must also be rejected as being manifestly ill-founded pursuant to Article 35 §§ 3 and 4 of the Convention".

779. In *OAO Neftyanaya Kompaniya Yukos v Russia* (2012) 54 EHRR 19 the Court was concerned with an allegation that the Russian State had through wholly artificial and contrived means, deprived the applicant of its property. It was alleged that the state action amounted to unlawful deprivation. The Court summarised the interference in the following way:

> "555. The Court notes that between December 2003 and January 2005 the domestic authorities subjected the applicant company to a number of measures in connection with its alleged failure to pay the correct amount of tax for the years 2000-2003. In particular, as a result of the Tax Assessment proceedings the applicant company was found guilty of repeated tax fraud and was ordered to pay an overall sum of at least RUB 572 billion (around EUR 16 billion) in outstanding taxes, default interest and penalties. In the enforcement proceedings, simultaneously conducted, the applicant company was ordered to pay an additional 7% enforcement fee on the overall amount of the debt: its assets were attached and seized, whilst 76.79 percent of shares in its main production unit, OAO Yuganskneftegaz, were sold in satisfaction on the mentioned liability.
>
> 556. The Court notes that the parties did not dispute that these measures, whether taken alone or together, constituted an interference with the applicant company's property rights as guaranteed by Article 1 of Protocol No. 1. The Court further notes that the company complained about the measures separately and that it also complained about the Government's intentions in connection with those measures. In this latter respect, the applicant company argued that, in bringing the relevant proceedings, the authorities had sought to destroy the company and expropriate its assets. The Court has now to satisfy itself that each instance of such interference met the requirement of lawfulness, pursued a legitimate aim and was proportionate to the aim pursued".

780. Notwithstanding the extreme effect upon the company the Court considered that the facts reflected a control of use:

> "557. Having regard to the circumstances of the case and the nature of the applicant company's complaints, the Court finds that the complaints concerning the separate decisions and measures in the context of the proceedings against the applicant company fall to be examined under the third rule of Article 1 of Protocol No. 1, taken in conjunction, where appropriate, with other Convention provisions relied on by the applicant company".

781. The Court held also that the proper way in which to analyse the various individual acts of interference was not in isolation but by reference to their substance as a whole since each act was part of an overall strategy with a common and ultimate goal of

forcing the company to meet its tax liabilities. Accordingly the appropriate analysis was "*as one continuous event*":

> "645. Turning to the substance of the applicant company's complaints, the Court notes that in April 2004, simultaneously with the Tax Assessment proceedings, the domestic authorities initiated enforcement proceedings aimed at securing their tax claims and later recovering the sums awarded by the courts as a result of the examination of these claims. They attached the company's assets located in Russia and later partly froze the company's domestic bank accounts and seized the shares of the applicant company's Russian subsidiaries. On 20 July 2004 it was decided to auction off the company's principal production subsidiary OAO Yuganskneftegaz, in satisfaction of the company's tax liability, which at the time amounted to RUB 106.182 billion (some EUR 3.005 billion). As a result of the proceedings with regard to the Tax Assessments 2001 and 2002, the company's debt to the tax authorities further increased and by the time the auction of OAO Yuganskneftegaz took place in December 2004 the company already owed the tax authorities some RUB 431.259 billion (some EUR 11.061 billion). In addition to the payments resulting from the Tax Assessments 2000-2003, the company was also required to pay the bailiffs a 7% enforcement fee on the overall amount of the debt.
>
> 646. The Court notes that the authorities used a variety of measures in connection with the enforcement of the debt, such as the attachment and freezing orders, the seizure orders, the orders to pay enforcement fees and the compulsory auction procedure. *Though each of these measures could be seen as a separate instance of interference with the applicant company's rights under Article 1 of Protocol No. 1, their common and ultimate goal was to force the company to meet its tax liabilities. Accordingly, the appropriate way to analyse this part of the application is to examine the enforcement proceedings in their entirety as one continuous event.* The Court further notes that the enforcement measures in question fall to be analysed under the third rule of Article 1 of Protocol No. 1, which allows the member States to control the use of property in accordance with the general interest, by enforcing "such laws as [they] deem necessary to secure the payment of taxes or other contributions or penalties". It follows that the Court's task is to determine whether the State authorities complied with the Convention requirement of lawfulness and, if so, whether they struck a fair balance between the legitimate state interest in enforcing the tax debt in question and the protection of the applicant company's rights set forth in Article 1 of Protocol No. 1".

(Emphasis added)

782. Mr Anderson QC also cited a line of authorities concerned with unlawful demolition of properties by state authorities where the Court had held that the demolition amounted to "deprivation" (i.e. expropriation) within the second sentence of the first paragraph of A1P1 and where compensation was ordered to be paid: See for example *NA v Turkey* (Application NO 37451/97) (11th October 2005; and, *Yildirir v Turkey* (Application No 21482/03) (24th February 2010). These cases turn on unusual facts and do not in my view advance the analysis much. In *NA v Turkey* the applicants obtained a licence in good faith to construct a hotel having paid the requisite fees; 12 months later the Treasury revoked the licence and ordered the demolition of the hotel. This was upheld by the domestic Courts. The Court in Strasbourg held that the demolition order was justified in the public interest (to remedy the fact that a permit had earlier been given to construct the hotel on a public beach). The Court nonetheless held that there was a violation of A1P1 and ordered full compensation. The reasoning is very short and conclusionary. But the facts rather speak for themselves: the applicants should never have been granted a permit in the first place to build on a public beach but, having been granted a licence, they were entitled to compensation because, in effect, of the (lawful) change of position. The present case is not comparable; there has been no change of position such as occurred in *NA v Turkey* which could lead a Court to conclude that wasted expenditure should be compensated for. In *Yildirir v Turkey* the applicant purchased a property relying upon entries in the Land Register. There was however no entry in that public document recording that the property had in fact been illegally constructed. Subsequently the applicant was ordered to demolish the property for what the Court accepted were valid public health reasons. Domestic law stipulated that the State was liable for any damage caused by incorrect entries in the land registry. Yet no compensation was paid. The Court in Strasbourg held on the facts that compensation was due. Again this is a case very much on its own facts. It provides little guidance of relevance to the present case.

(7) Summary of main principles

783. The main principles coming out of the case law of relevance to the present case can be summarised as follows:

i) A1P1 covers both expropriation of property by the State and control of the use of property belonging to third parties.

ii) Property may be lawfully expropriated or its use controlled if it serves a legitimate public interest and is proportionate (in the sense of striking a fair balance between the relevant interests). Member States enjoy a wide margin of appreciation in determining the need for the measure, its aims and its effects. The status of the decision maker is important with particular weight being attributed to democratically elected legislatures.

iii) The two most important criteria for differentiating between an expropriation and a control of use are (a) whether the measure pursues a legitimate objective and (b) whether title transfers to the State. If the measure serves a legitimate end and title does not transfer to the State then, invariably, the measure is classified as control of use and not expropriation.

iv) Where an otherwise legitimate measure is categorised as an expropriation, full compensation is payable save in "exceptional" circumstances.

v) Where an otherwise legitimate measure is categorised as a control of use, compensation is payable where applying the test of "fair balance" it is right to do so.

vi) In determining whether applying a fair balance test, compensation is payable for a control of use the most important criteria are: the importance of the public interest being served in relation to the nature and importance of the private property interest being intruded upon; the economic consequences for the applicant; the existence of transitional protection; the reasonableness of the process by which the rules were introduced.

vii) In analysing fair balance the facts are examined for their substance to see whether, for instance, they amount to a single event or one continuous state of affairs.

viii) An order to pay compensation may be partial.

(8) Conclusion on expropriation v control of use

784. In my judgment the Regulations amount to a control of use, not an expropriation of property. This conclusion applies to the Claimants' trade marks when viewed collectively (see paragraphs [745] – [753] above); but I would have arrived at the same conclusion even if I had treated word and non-word trade marks discretely.

785. First, the trade marks (of whatever description) remain unequivocally the property of the Claimants; the state has not expropriated or taken away the rights for itself or to be handed to some third party. Regulation 13 makes this explicitly clear. Registration rights are preserved. In substance the Regulations impose substantial restrictions on the freedom of the tobacco companies to use their property rights, and in particular their trade marks. However, the restrictions are far from being total and the Claimants remain entitled to market themselves though the affixing of a brand name and their own manufacturer's name. Self-evidently this is not optimal use of the trade marks for the Claimants; but it also far from the situation that would prevail if the Claimants were not entitled to use any identifying marks at all and were forced to sell their cigarettes and tobacco products as a homogenous unidentified commodity.

786. Second, when measured against the function attributed to trade marks in EU law they (and especially the word marks) can still perform this role both in terms of a right to prevent unauthorised use and, more broadly, as an identifier of origin. Once again they do not do so in the way the Claimants would wish but they have not lost those core functions altogether and they remain important attributes.

787. Third, the curtailment of the use of the trade marks does not result in the Claimants being unable to conduct their business.

788. Fourth, the interference was unequivocally in the public interest and there is no challenge to the legitimacy of the objective pursued by Parliament in promulgating the Regulations.

(9) Is there a duty to pay compensation?

789. I turn now to the question whether there is a duty on the Defendant to institute a scheme of compensation for the Claimants.

790. It is necessary to consider this from two different perspectives: First, assuming that this is a case of control of use; and secondly assuming that this is a case of expropriation. It is necessary to consider the alternatives because of the Claimants' argument that (a) the Regulations *de facto* expropriated all the trade marks (whether word or non-word) but (b) even if word marks were not expropriated the non-word marks were (see paragraph [742] above).

(i) Compensation: Control of use

791. The test is the "fair balance" test. This has according to the case law two components which focus upon the impact upon the individual and the excessiveness of the burden imposed. It is clear from *Vékony* and the other authorities cited that the Court must examine all of the surrounding circumstances concentrating upon substance and not form. It is also clear that it is necessary to measure the importance or weight of the public interest being pursued.

792. I have set out my analysis on fair balance under Ground 5 (Section I) in relation to the third main proportionality challenge. There is no need to repeat the conclusions that I have already arrived at. I rely upon those matters for the conclusion that there is no duty on the State to compensate the tobacco companies for any losses that they might suffer.

793. In the text below I limit myself to additional observations.

794. The Claimants seek compensation for the loss of the ability to promote a product that is internationally recognised as pernicious and which leads to a health "epidemic". It is as such unlike any other case in which the Courts have granted compensation. Comparing the present case with the facts of *Vékony* highlights why the present case is not one where compensation is payable. First, there is no risk of the present Claimants being put out of business which was the fate which befell the Applicant in *Vékony* as a direct causal consequence of the impugned measure. Second, there is no criticism of the transitional arrangements being introduced by the Defendant. The Claimants thus acknowledge that, assuming that the Regulations are lawful, they will have plenty of time within which to adapt their commercial conduct. Third, there has been (without prejudice to the outcome of the challenges launched by BAT to the consultation process) a lengthy consultation process which the Claimants were fully entitled to participate in. Fourth, there is a full right of judicial review to the Courts. Fifth, the Regulations themselves are not arbitrary in the sense being used in *Vékony*. They apply without exception to all manufacturers and sellers so that there is no single class of comparable traders from amongst whom winners and losers must be chosen (here there are only losers – but that is the nature of the beast). The case is thus quite unlike the facts of *Vékony* where a legitimate ground of objection was that small retailers with existing businesses were materially discriminated against vis-à-vis other retailers by the very structure of the rules.

795. The Claimants could not identify a case where compensation had been paid for the suppression or control of a private activity that pursued an end or objective recognised as a public vice. The decided cases where compensation has been ordered invariably concern the expropriation of real property or a licence which was in the past (in the hands of the former owner) and would in the future (in the hands of the expropriating State or replacement licensee) be put to a good and legitimate use. Or they concerned the shares in, or assets of, a trading body that served a legitimate commercial end and which the State wished to take into state ownership, by way of nationalisation, to run in the public interest. The Secretary of State cited two authorities from the Court of Justice which were, loosely, on point in that they were cases where there was an interference of a profound nature with a property right to an agricultural product which if permitted to be in free circulation would be likely to spread disease. In such cases the Court of Justice made clear that compensation was not payable: see Joined cases C-20/00 and C-64/00 *Booker Aquaculture Ltd v The Scottish Ministers* [2003] ECR I-7411. There the Community legislature laid down animal health and preventive measures which Member States were required to take to prevent and to eliminate certain fish diseases in their territory. This included the destruction of diseased fish. No right of compensation was provided for even though there was a power to compensate in some circumstances. The Court of Justice had to determine whether, in the absence of compensation for affected farmers the relevant directive was compatible with the fundamental right to property. The Court of Justice held that it was since the requirement to slaughter the fish was part of a Community policy adopted in the public interest:

> "78. Directive 93/53 therefore seeks to contribute to the completion of the internal market in aquaculture animals and products and forms part of a regime intended to introduce minimum Community measures for the control of certain fish diseases. Accordingly, the measures which that directive imposes are in conformity with objectives of general interest pursued by the Community.
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> 79. As to whether, taking into account the objective sought and in the absence of compensation, the restrictions on the right to property resulting from those measures constitute a disproportionate and intolerable interference impairing the very substance of the right to property, it must be observed that those measures are urgent and are intended to guarantee that effective action is implemented as soon as the presence of a disease is confirmed and to eliminate any risk of the spread or survival of the pathogen.
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> 80. Further, the measures referred to do not deprive farm owners of the use of their fish farms, but enable them to continue to carry on their activities there.
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> 81. In effect, the immediate destruction and slaughter of all the fish enable owners to restock the affected farms as soon as possible".

796. In addition the Court of Justice took account of the fact that the diseased fish had, in any event no intrinsic value and that the slaughter of diseased fish was an ever present, systemic, risk accepted by the industry. For all of these reasons the measures were not disproportionate (ibid paragraph [86]). This authority was cited and applied with approval by the Court subsequently in Case C-65/13 *Erekcsanadi Mezgazasagi* (22nd May 2014) at paragraph [48].

797. The property rights in the present case are the antithesis of the property rights which have been in issue in prior decided case. The property rights in the present cases directly serve the promotion of a trade which is profoundly adverse to the public interest, and acknowledged by all concerned to be so because of the harm the products cause to health. Under the FCTC (see paragraphs [157] above) they are "*lethal*". The "*spread of the tobacco epidemic is a global problem with serious consequences for public health*" (Recital 3). The preamble to the FCTC states: that "… *scientific evidence has unequivocally established that tobacco consumption and exposure to tobacco smoke cause death, disease and disability, and that there is a time lag between the exposure to smoking and the other uses of tobacco products and the onset of tobacco-related diseases*" (Recital 5). The product promoted by the trade mark is "*highly engineered so as to create and maintain dependence…*" (Recital 6).

798. The Regulations bear the same characteristics as other regulatory measures designed to further the public interest which, in so doing, impose burdens and costs on the regulated community. Public policy evolves. Political thinking evolves. No individual or company can have an expectation that if it produces and supplies a product that is, or becomes recognised as, contrary to the public interest that it will be entitled to continue to produce and sell that product, or that if the State comes to prescribe or curtail the product in issue that it will be entitled to compensation. There can be no sensible argument based upon a reasonable or legitimate expectation (which might well be the best explanation for the demolitions cases before the Court in Strasbourg – see paragraph [782] above). Manufacturers have been well aware for some years that across the world States have been obliged under international law to prohibit marketing and that this necessarily would bite down hard upon the use of trade marks. Markets are complex and the freedom to trade which is the hallmark of most world economies is almost inevitably accompanied by regulation which is the essential *quid pro quo* of the liberty. The law is awash with examples of the introduction of unwelcome regulation which causes equally unwelcome costs and burdens for traders. The use of asbestos for construction was commonplace but is now acknowledged to be dangerous and building rules and regulations prohibit its use. When these were introduced manufacturers were not compensated for ceasing production even though expensive plant and equipment might have been stripped of its value as a result. When thalidomide no longer came to be viewed as a wonder drug and instead became a pariah medicine the manufacturer did not receive compensation for the wasted research and investment or the trade marks used to promote the product (and on the contrary became subject to a slew of civil claims).

799. In short, applying a fair balance test no compensation is payable.

(ii) Compensation: "Exceptional circumstances"

800. I now analyse the case on the assumption that I am wrong in my conclusion that this is a control of use case and instead it must be analysed as a case of expropriation

(whether in relation to all the trade marks or other non-word rights). The Claimants submit that there are no "exceptional circumstances" arising in the present case which could justify the Court in refusing compensation. Mr David Anderson QC, in particular in his final oral address on this issue for the Claimants, set out in a beguiling and bold submission (which I have nonetheless felt able to resist despite its oratorical lure) an exposition of why tobacco was not exceptional and why the current of analysis that ran though the Secretary of State's analysis was "*utterly false*". His submission was entitled "*The Myth of Tobacco Exceptionalism*". His argument went along the following lines. Tobacco products are sold lawfully throughout the world. Tobacco trade marks are not in a special position which can be seen from the fact that trade marks may be registered in respect of a long list of controversial products such as (in no particular order): uranium, plutonium, polonium, arsenic, cyanides, cocaine, opium, strychnine, steroids, narcotics, traps for wild animals, bayonets, military drones, rocket launchers, tear gas weapons, ivory, whalebone, and love dolls. Nothing about tobacco or their trade marks justifies "*bending the normal legal rules – whether as regards the right to compensation, participation in the internal market or the principles of administrative fairness and equality of arms*". Tobacco companies are not inherently dishonest, untrustworthy or liable to browbeat expert witnesses and their evidence merits precisely the same dispassionate and unprejudiced weighting as that of any other person, whether at the consultation stage or in the course of litigation.

801. Notwithstanding the force of the advocacy I cannot accept the submission that tobacco is not exceptional. Mr Anderson QC is of course right that the tobacco companies sell a lawful product and that they are, like other litigants, entitled to fair and dispassionate treatment both during consultative processes and in Court proceedings. The only question is whether on the facts of this case and applying ordinary principles they are entitled to compensation. In my view they are not.

802. The reason why there is no breach of A1P1 if compensation is not paid is due to (a) the undeniable and all pervasive harm caused by the product; (b) the fact that the trade marks are used *causally* to further that harm by promoting the product to consumers; and (c) the fact that they thereby impose on the State clear up and remedial costs of a staggeringly large scale.

803. Whether that can also be said of the other controversial products cited by the Claimants is unknown but seems very doubtful. It is by no means obvious that the use of the trade marks and brands associated with those products has the same characteristics as advertising for tobacco: for example, military drones and uranium are not sold to consumers; and love dolls (I surmise) are but not to minors and they do not cause profound public health harm and concomitant costs, etc. But in any event even *if* the State decided to impose equivalent restrictions on the use of trade marks connected to those products the proportionality of such a restriction would have to be assessed separately according to its own merits and no easy comparisons can properly be made.

804. The Court in *Vékony* is not compelling authority, as the Claimants initially contended, for the proposition that in the present case the deprivation was so extreme that it amounted to *de facto* expropriation and must inexorably lead to compensation. The Claimants in their written submissions stated:

> "The ECtHR's recent *Vékony* decision establishes beyond doubt that there are no exceptional circumstances in the present case. The Court accepted that the removal of a tobacconist's licence served the purpose of combating underage smoking, which was an aim "*in accordance with the general interest"* (para 31). It was also prepared to assume that the measure was lawful. However, despite the measure only being categorised as a control on use (and thus not requiring "*exceptional circumstances"* to be justified), it was held to be disproportionate. It must follow that the aim of the Regulations is not so exceptional, or unique, as to rebut the presumption that the Claimants should be compensated for the deprivation of their valuable property".

805. For the reasons set out above on the contrary, not only does *Vékony* not support this conclusion but it actually provides a framework of analysis which points to the opposite conclusion.

806. In my judgment the Claimants' submissions place the bar of exceptionality far too high. I agree that the test is one of exceptionality. Though in *Vistins* (see below) the Court (ibid at paragraph [112]) seemed to use the test of exceptionality as the benchmark for circumstances when zero compensation would be paid; the Court did not say that it would be exceptional to pay less than 100%. At all events in the present case Parliament has made no provision at all for compensation so the exceptionality test applies. In this regard I have no doubt that the facts of the decided cases cited by the Claimants are exceptional. But I disagree with the proposition that nothing short of facts which are comparable to these cases will suffice. The phrase "*exceptional*" can convey a multiplicity of meanings. At one level a situation is exceptional if it does no more than depart from a norm; it is an exception thereto. But the scope of the exception may still be quite substantial. On the other hand both in general parlance and in judicial pronouncements use of the phrase "exceptional" is sometimes intended to convey the sense of a limited derogation from the norm, or even a very limited derogation with exceptional meaning rare or very rare. The question therefore is how exceptional is exceptional?

807. To answer this question the phrase must be understood in its context. It involves first of all an assessment of the importance of the basic rule: Is it the sort of rule from which derogations should *in principle* only rarely be tolerated in the sort of democratic society that is contemplated by the ECHR? When put into this context it seems plain that the right to the peaceful enjoyment of property rights is a very basic rule of a civilised society and it would follow that derogations should be exceptional in the sense that they should be rare. The sanctity of property rights and the correlative right of individuals to be free from arbitrary, capricious or corrupt expropriations is a mark of a fully developed society. This is the view taken by commentators and reflected in case law. But even this does not give much practical guidance as to the scope of even a limited exception. The Claimants' Rubicon lies in cases of post-civil war or revolution reconciliation and repair. Nothing less than this sort of scenario will suffice to be "exceptional".

808. In my judgment the divide lies further back. In this case the trade marks are being used to promote what is universally recognised as an ill and a drain on society's

resources. The Secretary of State encapsulated the nub of the issue when he stated that the present case was exceptional because: "*There is no other widely used consumer product in the world which kills half of its long term users prematurely*". The 2014 Impact Assessment sets out compelling evidence for the conclusion that the Regulations will generate a vast net benefit for the State because it will reduce the negative costs smoking imposes on the State. It is hard to avoid the conclusion that the suppression of rights which promote a health epidemic and impose huge costs on the taxpayer is precisely the sort of circumstance where exceptionality does apply.

809. A recent statement of principle by the Grand Chamber of the Court is found in *Vistiņš and Perepjolkins v. Latvia Vistins* (*Application no. 71243/01)* (22nd October 2012) ("*Vistins*"). I have set out the relevant parts of the judgment below. This was a case that unequivocally concerned an expropriation of rights (see paragraph [94]): *"In the present case, it is not in dispute that there has been a "deprivation of possessions" within the meaning of the second sentence of Article 1 of Protocol No. 1*". From this Judgment the following propositions emerge. First, any assessment under A1P1 requires an analysis of both sides of the public interest equation i.e. the nature and strength of the public interest pursued by the state which is said to warrant the interference with the private property right but also the nature and strength of the private rights being interfered with. Second, the State enjoys a wide margin of appreciation with regard both to choosing the means of enforcement and to ascertaining whether the consequences of enforcement are justified in the general interest for the purpose of achieving the object of the law in question. Third, the existence of a wide margin of appreciation does not absolve a Court from determining whether the requisite balance was maintained in a manner consonant with the applicants' right to the peaceful enjoyment of their possessions. Fourth, where there is an expropriation the State should set up a procedure which makes an overall assessment of the consequences of the expropriation, undertake a valuation of the expropriated property in line with normal market values, determine who the persons to be paid compensation are, and provide award of an amount of compensation in line with the value of the expropriated property. Fifth, there is however no absolute rule that compensation is payable; it will "*normally*" be payable and the occasions when total or full compensation are not payable will be "*exceptional*". The duty to pay is not a binary all or nothing; there may be cases where the public interest leads to the result that less than full compensation is payable. Cases where less than full value may be payable include interferences for purposes relating to "*economic reform or measures designed to achieve greater social justice*", or laws of expropriation which are "*enacted in the context of a change of political and economic regime*".

810. These propositions can be found in the following text from paragraphs [108ff]:

> "108. Even if it has taken place "subject to the conditions provided for by law" - implying the absence of arbitrariness - and in the public interest, an interference with the right to the peaceful enjoyment of possessions must always strike a "fair balance" between the demands of the general interest of the community and the requirements of the protection of the individual's fundamental rights. In particular, there must be a reasonable relationship of proportionality between the means employed and the aim sought to be realised by any measure

depriving a person of his possessions (see *Scordino*, cited above, § 93).

109. In determining whether this requirement is met, the Court recognises that the State enjoys a wide margin of appreciation with regard both to choosing the means of enforcement and to ascertaining whether the consequences of enforcement are justified in the general interest for the purpose of achieving the object of the law in question (see *Chassagnou and Others v. France* [GC], nos. 25088/94, 28331/95 and 28443/95, § 75, ECHR 1999-III, and *Herrmann v. Germany*[GC], no. 9300/07, § 74, 26 June 2012). Nevertheless, the Court cannot abdicate its power of review and must therefore determine whether the requisite balance was maintained in a manner consonant with the applicants' right to the peaceful enjoyment of their possessions, within the meaning of the first sentence of Article 1 of Protocol No. 1 (see *Jahn and Others*, cited above, § 93).

110. Compensation terms under the relevant legislation are material to the assessment whether the contested measure respects the requisite fair balance and, notably, whether it imposes a disproportionate burden on the applicants. The Court has already held that the taking of property without payment of an amount reasonably related to its value would normally constitute a disproportionate interference. In many cases of lawful expropriation, such as a distinct taking of land for road construction or other "public interest" purposes, only full compensation may be regarded as reasonably related to the value of the property (see *Former King of Greece and Others v. Greece* [GC] (just satisfaction), no. 25701/94, § 78, 28 November 2002; see also, *mutatis mutandis*, *Papachelas v. Greece* [GC], no. 31423/96, § 48, ECHR 1999-II; and *Efstathiou and Michailidis & Co. Motel Amerika v. Greece*, no. 55794/00, § 26, ECHR 2003-IX). On this point, the Court cannot equate a lawful expropriation, complying with domestic law requirements, with a constructive expropriation that seeks to confirm a factual situation arising from unlawful acts committed by the authorities (see *Guiso-Gallisay v. Italy* (just satisfaction) [GC], no. 58858/00, §§ 94-95, 22 December 2009).

111. Moreover, the Court reiterates that, where an individual's property has been expropriated, there should be a procedure ensuring an overall assessment of the consequences of the expropriation, including the award of an amount of compensation in line with the value of the expropriated property, the determination of the persons entitled to compensation and the settlement of any other issues relating to the expropriation (see *Efstathiou and Michailidis & Co. Motel Amerika*, cited above, § 29). As to the amount of the

compensation, it must normally be calculated based on the value of the property at the date on which ownership thereof was lost. Any other approach could open the door to a degree of uncertainty or even arbitrariness (see *Guiso-Gallisay* (just satisfaction) [GC], cited above, § 103).

112. However, Article 1 of Protocol No. 1 does not guarantee a right to full compensation in all circumstances (see *Broniowski*, cited above, § 182). Admittedly, a total lack of compensation can be considered justifiable only in exceptional circumstances (see *Former King of Greece and Others* (merits), cited above, § 89). Legitimate objectives of "public interest", such as pursued in measures of economic reform or measures designed to achieve greater social justice, may call for less than reimbursement of the full market value (see *James and Others*, cited above, § 54); in such cases, the compensation does not necessarily have to reflect the full value of the property in question.

113. This principle applies all the more forcefully when laws are enacted in the context of a change of political and economic regime, especially during the initial transition period, which is necessarily marked by upheavals and uncertainties; in such cases the State has a particularly wide margin of appreciation (see, among other authorities, *Kopecký v. Slovakia* [GC], no. 44912/98, § 35, ECHR 2004-IX; *Jahn and Others*, cited above, § 116 (a); and *Suljagić v. Bosnia and Herzegovina*, no. 27912/02, § 42, 3 November 2009). Thus, for example, the Court has held that less than full compensation may also be necessary *a fortiori* where property is taken for the purposes of "such fundamental changes of a country's constitutional system as the transition from a monarchy to a republic" (*see Former King of Greece and Others* (merits), cited above, § 87). The Court reaffirmed that principle in *Broniowski* (cited above, § 182), in the context of a property restitution and compensation policy, specifying that a scheme to regulate property, being "wide-reaching but controversial ... with significant economic impact for the country as a whole", could involve decisions restricting compensation for the taking or restitution of property to a level below its market value. The Court has also reiterated these principles regarding the enactment of laws in "the exceptional context of German reunification" (see *Maltzan and Others v. Germany* (dec.) [GC], nos. 71916/01, 71917/01 and 10260/02, §§ 77 and 111-112, ECHR 2005-V, and *Jahn and Others*, cited above).

114. Lastly, in order to assess the conformity of the State's conduct with the requirements of Article 1 of Protocol No. 1, the Court must conduct an overall examination of the various interests in issue, having regard to the fact that the Convention

> is intended to guarantee rights that are "practical and effective", not theoretical or illusory. It must go beneath appearances and look into the reality of the situation at issue, taking account of all the relevant circumstances, including the conduct of the parties to the proceedings, the means employed by the State and the implementation of those means. Where an issue in the general interest is at stake, it is incumbent on the public authorities to act in good time, and in an appropriate and consistent manner (see *Fener Rum Erkek Lisesi Vakfi v. Turkey*, no. 34478/97, § 46, 9 January 2007, and *Bistrović v. Croatia*, no. 25774/05, § 35, 31 May 2007)".

811. There are no cases where compensation has been paid for the curtailment of an activity which is unequivocally contrary to the public interest. In my judgment the facts of the case are exceptional such that even if this were a case of absolute expropriation no compensation would be payable.

812. For the avoidance of doubt my conclusion is that no compensation should be payable and this covers even an obligation to pay partial compensation. I simply cannot see a justification for compensation at any level.

U. GROUND 7: ARTICLE 17 OF THE CHARTER OF FUNDAMENTAL RIGHTS

(1) The issue

813. The Claimants rely also upon Article 17 of the Charter which, they submit, provides a greater degree of protection than A1P1, such that even if their claim under the ECHR fails they say they succeed under the Fundamental Charter. It is submitted that under the Charter there is no right, at all, for a Member State to "impair" the substance of a property right such as a trade mark. They submit however that the Regulations do just that – impair the substance of the property rights - and they submit that, in such circumstances, the Regulations are *per se* unlawful and this conclusion arises, even if they otherwise meet all of the conditions of the proportionality test. This Ground raises an important point about the scope and effect of the Fundamental Charter and its relationship with the ECHR.

(2) Article 17: The text

814. Article 17 provides:

> "Article 17
>
> Right to property
>
> 1. Everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions. No one may be deprived of his or her possessions, except in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation being paid in good time for their loss. The use of property may be regulated by law in so far as is necessary for the general interest.

2. Intellectual property shall be protected".

815. Article 17 is underscored by Article 47(1) on the right to an effective remedy: "*Everyone whose rights and freedoms guaranteed by the law of the Union are violated has the right to an effective remedy before a tribunal in compliance with the conditions laid down in this Article*". It will be seen that Article 17 is not in exactly the same language as A1P1 ECHR. Nonetheless, like A1P1, it is a qualified right. Property can be expropriated in the public interest and use may be regulated by law if necessary in the general interest.

(3) The explanations

816. The official "Explanations" relating to the Fundamental Charter provide a commentary on the Charter and have interpretative value. They also make clear that property rights are far from being unqualified and nothing in Article 17 shall "impair" the rights of Member States to limit those rights in the public interest:

> "These explanations were originally prepared under the authority of the Praesidium of the Convention which drafted the Charter of Fundamental Rights of the European Union. They have been updated under the responsibility of the Praesidium of the European Convention, in the light of the drafting adjustments made to the text of the Charter by that Convention (notably to Articles 51 and 52) and of further developments of Union law. Although they do not as such have the status of law, they are a valuable tool of interpretation intended to clarify the provisions of the Charter".

817. They explain that the legislative intent behind Article 17 was "*based upon*" A1P1: The text on Article 17 provides:

> "*Explanation on Article 17 — Right to property*
>
> This Article is based on Article 1 of the Protocol to the ECHR:
>
> 'Every natural or legal person is entitled to the peaceful enjoyment of his possessions. No one shall be deprived of his possessions except in the public interest and subject to the conditions provided for by law and by the general principles of international law.
>
> The preceding provisions shall not, however, in any way impair the right of a State to enforce such laws as it deems necessary to control the use of property in accordance with the general interest or to secure the payment of taxes or other contributions or penalties.
>
> This is a fundamental right common to all national constitutions. It has been recognised on numerous occasions by the case-law of the Court of Justice, initially in the Hauer judgment (13 December 1979, [1979] ECR 3727). The wording

> has been updated but, in accordance with Article 52(3), the meaning and scope of the right are the same as those of the right guaranteed by the ECHR and the limitations may not exceed those provided for there.
>
> Protection of intellectual property, one aspect of the right of property, is explicitly mentioned in paragraph 2 because of its growing importance and Community secondary legislation. Intellectual property covers not only literary and artistic property but also inter alia patent and trade mark rights and associated rights. The guarantees laid down in paragraph 1 shall apply as appropriate to intellectual property".

(4) Article 52

818. Notwithstanding that the Explanation indicates that A1P1 and Article 17 are of consistent scope and effect (a point made also by the Court of Justice in *Philip Morris* in relation to the ECHR and Article 11 of the Fundamental Charter: ibid paragraph [147]) and may be subject to limitations imposed in the public interest, the Claimants submit that Article 52 of the Charter means that Article 17 is in law of broader compass than A1P1. This is because of two components of Article 52. First, the reference to any limitations upon a right having to respect the "essence" of the right in Article 52(1) and, secondly, Article 52(3) last sentence which contemplates that the protection in the Fundamental Charter may go beyond that in the ECHR:

> "Article 52
>
> Scope of guaranteed rights
>
> 1. Any limitation on the exercise of the rights and freedoms recognised by this Charter must be provided for by law *and respect the essence of those rights and freedoms*. Subject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others.
>
> 2. Rights recognised by this Charter which are based on the Community Treaties or the Treaty on European Union shall be exercised under the conditions and within the limits defined by those Treaties.
>
> 3. In so far as this Charter contains rights which correspond to rights guaranteed by the Convention for the Protection of Human Rights and Fundamental Freedoms, the meaning and scope of those rights shall be the same as those laid down by the said Convention. *This provision shall not prevent Union law providing more extensive protection*".
>
> (Emphasis added)

(5) Analysis of Articles 17 and 52

819. The Claimants thus submitted that pursuant to Article 52 (and in particular (i) the references to the essence of rights being respected and (ii) the reference to EU law providing for more extensive protection than under the ECHR) any limitation on the exercise of the rights and freedoms recognised by the Charter (including but not limited to the right to property in Article 17) must satisfy certain conditions before it is lawful. These conditions are: (a) that the measure must be provided for by law; (b) that it must respect the essence of the right; and (c) that it must respect the principle of proportionality and be necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others. It was submitted that (b) was an entirely separate and free standing condition to (c) (proportionality). It followed that a measure failing to respect the essence of a recognised right would be unlawful quite *irrespective* of any issue of proportionality. In other words no legislation can interfere with a fundamental right to the extent that it impairs its substance *even if* that interference would otherwise be proportionate.

820. The practical upshot of this submission was that even if the Regulations were proportionate, because they impaired the essence of the trade marks they were still in breach of Article 17, which provided for a greater degree of protection than A1P1.

821. In support the Claimants cited a series of cases where it was submitted that the Court had made this clear. In particular they cited: (a) Joined Cases C-293/12 and C-594/12 *Digital Rights Ireland* (8th April 2014) at paragraph [38] – [40] ("*Digital Rights Ireland*"); and (b) Case C-362/14 *Maximillian Schrems v Data Protection Commissioner joined party Digital Rights Ireland Ltd* (6 October 2015) ("*Schrems*"), where the Court of Justice in relation to the right for the state to have access to private data held:

> "92 Furthermore and above all, protection of the fundamental right to respect for private life at EU level requires derogations and limitations in relation to the protection of personal data to apply only in so far as is strictly necessary (judgment in *Digital Rights Ireland and Others*, C-293/12 and C-594/12, EU:C:2014:238, paragraph 52 and the case-law cited).
>
> 93 Legislation is not limited to what is strictly necessary where it authorises, on a generalised basis, storage of all the personal data of all the persons whose data has been transferred from the European Union to the United States without any differentiation, limitation or exception being made in the light of the objective pursued and without an objective criterion being laid down by which to determine the limits of the access of the public authorities to the data, and of its subsequent use, for purposes which are specific, strictly restricted and capable of justifying the interference which both access to that data and its use entail (see, to this effect, concerning Directive 2006/24/EC of the European Parliament and of the Council of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic

> communications services or of public communications networks and amending Directive 2002/58/EC (OJ 2006 L 105, p. 54), judgment in *Digital Rights Ireland and Others*, C-293/12 and C-594/12, EU:C:2014:238, paragraphs 57 to 61).
>
> 94 In particular, legislation permitting the public authorities to have access on a generalised basis to the content of electronic communications must be regarded as compromising the essence of the fundamental right to respect for private life, as guaranteed by Article 7 of the Charter (see, to this effect, judgment in *Digital Rights Ireland and Others*, C-293/12 and C-594/12, EU:C:2014:238, paragraph 39).
>
> 95 Likewise, legislation not providing for any possibility for an individual to pursue legal remedies in order to have access to personal data relating to him, or to obtain the rectification or erasure of such data, does not respect the essence of the fundamental right to effective judicial protection, as enshrined in Article 47 of the Charter. The first paragraph of Article 47 of the Charter requires everyone whose rights and freedoms guaranteed by the law of the European Union are violated to have the right to an effective remedy before a tribunal in compliance with the conditions laid down in that article. The very existence of effective judicial review designed to ensure compliance with provisions of EU law is inherent in the existence of the rule of law (see, to this effect, judgments in *Les Verts* v *Parliament*, 294/83, EU:C:1986:166, paragraph 23; *Johnston*, 222/84, EU:C:1986:206, paragraphs 18 and 19; *Heylens and Others*, 222/86, EU:C:1987:442, paragraph 14; and *UGT-Rioja and Others*, C-428/06 to C-434/06, EU:C:2008:488, paragraph 80)."

822. They also cited the judgment of the General Court in Case T-187/11 *Trabelsi* (28 May 2013) at paragraphs [77] – [81]:

> "**The conditions on which a limitation on the exercise of the right to property may be accepted**
>
> 77 Article 52(1) of the Charter on Fundamental Rights provides, first, that '[an]y limitation on the exercise of the rights and freedoms recognised by [the Charter on Fundamental Rights] must be provided for by law and respect the essence of those rights and freedoms', and, second, that '[s]ubject to the principle of proportionality, limitations may be made only if they are necessary and genuinely meet objectives of general interest recognised by the [European] Union or the need to protect the rights and freedoms of others.'
>
> 78 It follows from that article that, to be held to comply with EU law, a limitation on the exercise of the right to property must, in any event, satisfy three conditions.

> 79 First, the limitation must be 'provided for by law' (see, to that effect, Case C-407/08 P *Knauf Gips* v *Commission* [2010] ECR I-6375, paragraph 91). In other words, the measure in question must have a legal basis.
>
> 80 Secondly, the limitation must refer to an objective of public interest, recognised as such by the European Union. Included in those objectives are those pursued in the context of the Common Foreign and Security Policy ('CFSP'), and referred to in Article 21(2)(b) and (d) TEU, namely to support democracy, the rule of law and human rights as well as sustainable development of developing countries with the essential objective of eradicating poverty.
>
> 81 Thirdly, the limitation may not be excessive. First, it must be necessary and proportional to the aim sought (see, to that effect, Case C-84/95 *Bosphorus* [1996] ECR I-3953, point 26; *Kadi and Al Barakaat International Foundation* v *Council and Commission*, paragraph 75 above, paragraphs 355 and 360). Second, the 'essential content', that is, the substance, of the right or freedom at issue must not be impaired (see, to that effect, *Nold* v *Commission*, paragraph 75 above, paragraph 14, and *Kadi and Al Barakaat International Foundation* v *Council and Commission*, paragraph 75 above, paragraph 355)."

823. The Claimants further cited Case C-491/01 *R (SSH) ex parte British American Tobacco* [2002] ECR I- 11550 ("*BAT*") at paragraphs [149] – [150]. The Court of Justice stated:

> "149. As regards the validity of the Directive in respect of the right to property, the Court has consistently held that, while that right forms part of the general principles of Community law, it is not an absolute right and must be viewed in relation to its social function. Consequently, its exercise may be restricted, provided that those restrictions in fact correspond to objectives of general interest pursued by the Community *and do not constitute a disproportionate and intolerable interference, impairing the very substance of the rights guaranteed* (see, in particular, Case 265/87 *Schräder* [1989] ECR 2237, paragraph 15; Case C-280/93 *Germany* v *Council* [1994] ECR I-4973, paragraph 78, and Case C-293/97 *Standley and Others* [1999] ECR I-2603, paragraph 54).
>
> 150. As paragraphs 131 and 132 above make clear, the only effect produced by Article 5 of the Directive is to restrict the right of manufacturers of tobacco products to use the space on some sides of cigarette packets or unit packets of tobacco products to show their trade marks, without prejudicing the substance of their trade mark rights, the purpose being to ensure a high level of health protection when the obstacles created by national laws on labelling are eliminated. *In the light*

> *of this analysis, Article 5 constitutes a proportionate restriction on the use of the right to property compatible with the protection afforded that right by Community law*."
>
> (Emphasis added)

824. The Claimants submit that it is clear that the Court in *BAT* would have found the prohibition in the Regulations on the graphic marks to undermine the essence or substance of the trade mark right, and accordingly to be unlawful. They submit that as the Advocate General stated (at paragraph [A266]): "*... it is only if normal usage is no longer possible as a result of provisions of public law that a situation can arise in which the substance of the right is affected by reason of those provisions*". They contend that the Court of Justice adopted that analysis at paragraph [150] of the judgment, finding that the restriction of trade marks to 50% of the pack did not prejudice the substance of the right because the trade marks could still be used on the packs. In simple terms, they argue, that the present case falls on the other side of the line established by the Court in *BAT*.

825. I have serious doubts about this analysis and especially the extreme interpretation given to the concept of respecting the essence of the right by the Claimants. Their argument assumes two propositions, neither of which in my view makes legal sense. First, it assumes that each and every fundamental right in the Charter (which is intended to mirror the ECHR) has an absolute and untouchable limit, even when it does not have such a limit in the ECHR. Secondly, it assumes that if on the application of the proportionality test the result is that a measure is proportionate, i.e. (a) suitable relative to its legitimate objective (b) necessary in the sense of being the least intrusive measure and (c) fair in the sense of striking a fair balance between competing interests, that it is still unlawful because the essence of the Claimants' interest (that has already been fairly balanced and found wanting) is impaired. Such a result is legal nonsense.

826. If the Claimants' analysis were correct then when two fundamental rights conflicted they would in principle become irreconcilable because one could never trump or take precedence over the other, even though it is trite that some fundamental rights are more important than and therefore outweigh others and this is true under the ECHR and the Fundamental Charter. Indeed the Court of Justice said as much in *Philip Morris* (ibid paragraph [156]).

827. Indeed, the Claimants' argument advanced in the light of the judgment in Philip Morris was that it confirmed their submission that if the Regulations affected the essence of the property right: "*...then they are unlawful per se and no proportionality analysis falls to be conducted*". This *per se* absolutist approach was said to be consistent with the ruling in *Philip Morris*. This cannot be right. If it were correct then in relation to a weak Charter right such as the Article 16 right to conduct a business, no government could ever prohibit a commercial activity (and thereby impair the substance of the Article 16 right) because, for instance, it caused catastrophic environmental damage or caused death or serious physical injury to consumers or workers. Equally it cannot be right because the protection of health is *also* a fundamental right and, on the Claimants' analysis, that right cannot be impaired either. Yet it is on the Claimant's analysis - by the use by the tobacco companies of their property rights which on the Claimants' analysis cannot be impaired.

828. Support for my conclusion is found in *Philip Morris* and in *Pillbox*. I have addressed these authorities in Section E under Ground 1 above at paragraph [270]. In *Pillbox* the Court of Justice held that Articles 16 and 17 of the Fundamental Charter fed into the proportionality analysis. In *Philip Morris* in the context of proportionality, the Court considered expressly what happens when two fundamental rights collided. In that case the tobacco companies argued that they had a right under Article 11 of the Fundamental Charter (on freedom of expression and information) which they said trumped all other considerations. The Court of Justice rejected this contention holding that the public health interest and right (under Article 35 of the Charter, inter alia – see paragraph [153]) outweighed the Claimants' asserted interests. The Court so held whilst simultaneously recognising that the Claimants' rights were interfered with (see ibid paragraph [148]). Yet, when the Court came to consider whether the "essence" of the Article 11 right had been impaired it cursorily dismissed the argument saying that they had not even been "*affected*". The Court's explanation (in paragraph [151]) is that the prohibition of "*certain elements and features*" did not affect the essence of the Article 11 freedom but merely controlled them in a clearly defined way. The Court did not explain how the Article 11 right could be interfered with but at the same time not even affected. And the Court did not (because it did not arise on the facts) go on and consider what happens in the paradigm test case where in order to protect a fundamental right of the very highest importance it is necessary to extinguish altogether a weaker fundamental right. Nonetheless, the message is clear: A fundamental right is not impaired or even affected just because another public interest right trumps it. This paradigm is by no means remote because the Court in *Philip Morris* has upheld provisions of the TPD which prohibit outright certain products and thus has implicitly endorsed the absolute primacy of the right to health over the right of persons to conduct business (Article 16) or to express themselves or to provide information in relation to that business (Article 11). Out of all of this it is, in my view, evident that the Court will not readily conclude that the essence of a fundamental right is impaired or affected or not respected where it is in competition with a strong public health ground and this extends even to those instances where one fundamental right is forced wholly to give way to a superior fundamental right.

829. In my view the extent to which a fundamental right may be intruded upon is logically an integral part of the proportionality test which (and certainly in relation to fundamental rights) includes the proportionality *strictu sensu* or "fair balance" limb and which, as a major part of that assessment, requires the Court to weigh up the competing public and private interests. It is here that the reconciliation between competing fundamental interests occurs. This relative weighing exercise takes account of how important each such right *actually is* and in this regard it is obvious and well established in case law that not all of the rights have equal weight (as the Supreme Court made clear in *Lumsdon* and has been endorsed in *Philip Morris*). The right to property is undoubtedly an important right but it is very far from being unqualified. Indeed the ECHR case law on A1P1 makes it clear beyond peradventure that exceptionally a private property right may be wholly expropriated by the State (in the sense that title is stripped from the original proprietor and transferred to the state) and no compensation payable at all: see e.g. case law set out at paragraphs [800ff] above. In such cases the substance or essence of the private right is utterly destroyed yet done so perfectly lawfully and proportionately and without even triggering an obligation to pay compensation. Of course it is because of this case law that the Claimants submit that EU law circumvents the problem and goes further than the

ECHR and creates a system of inviolable rights; but the Claimants have not explained how, on their argument, conflicting fundamental rights are reconciled or how or why EU law would take this illogical and counter-intuitive position.

830. In this regard I also disagree with the Claimants' analysis of the case law. The Advocate General in *BAT* did not say that the "*normal*" (cf. paragraph [823] above) use of a trade mark includes causing profound harm to public health. And the Court of Justice, for its part, did not say that it was *proportionate* or *tolerable* to use a trade mark to impair public health (cf. judgment paragraph [149]). Indeed the Court of Justice appeared to treat the impairment test as part of the proportionality test (ibid paragraphs [149] and [150]). This is also the way that the Court of Justice analysed the issue in *Pillbox* (see paragraph [270] above). In *Trabelsi* (ibid) the General Court (whose rulings are in any event subject to those of the Court of Justice) was not addressing facts which were remotely similar to those in issue in the present case nor was it actually addressing an argument about the scope of the proportionality test and whether, as part of the analysis there was a "fair balance" or proportionality *strictu sensu* assessment to be struck. In *Digital Rights Ireland* and in *Schrems* the Court of Justice held that the invasion of privacy, *as a matter of fact*, went too far and was not justified and for that reason the measure was not "necessary", i.e. it decided the case on an entirely separate basis. This is a far cry from a conclusion that a measure which negatives a particular use of a trade mark for otherwise good and proportionate health reasons is equally a step too far. In short in my judgment the question of whether a right is impaired is an integral part of the overall proportionality analysis and none of the case law relied upon suggests otherwise.

831. However, because the issue is not free from doubt and the terminology used by the Court of Justice has lacked conceptual precision, I propose to short circuit the debate and take the Claimants' argument at face value and decide this case upon the assumption (which I therefore rely upon *only* for the purpose of testing the Claimants' conclusion) that the Regulations would violate the Charter *if* they impaired the essence of the trade marks in question, quite irrespective of any issue of proportionality. This then focuses attention upon the critical questions: (a) what is meant by the essence of the right; and (b) do the Regulations fail to "*respect the essence of [the] rights and freedoms"* comprised of the Claimants' trade marks and other property rights?

832. In my judgment the answer to this in the present case is clear and is in the negative. First, in working out what the essence of a right is it is necessary to go back to the source legal text which defined the specific property right in issue. In the present case this is TRIPS. At this level of analysis it is necessary to be precise about the "essence" of the right. This is defined narrowly in TRIPS as a negative right to exclude. But even if it were defined more broadly to include use rights there is no conceivable basis in TRIPS for saying that the "*essence*" of a trade mark includes a right to *use* that property right to facilitate a lethal health epidemic. I have already set out in this judgment: (i) the relevant international and EU legislative context which in a multiplicity of places recognises that the use of trade marks can be curtailed according to the public interest, including public health interests; and (ii) that the limits on use are also laid down in the case law of the Court of Justice which makes it clear that a trade mark or other intellectual property right cannot be used to thwart the broader objectives of the Treaties, which includes *par excellence* the protection of

public health to a high degree: See the analysis of TRIPS in Section D(3) pages [176] – [186] above and the analysis of relevant EU law on trade marks at Sections D(4) and D(5). Nothing in international or EU law provides therefore that certain types of use of a trade mark cannot be *wholly* prohibited. Put another way the "essence" of a right is, itself, defined and limited in international and EU law by reference to superior rights and obligations.

833. An illustration of this point from the field of copyright where the Court of Justice limited the specific subject matter or essence of an intellectual property right by reference to an overarching public policy consideration is Joined Cases C-403/08 and C-429/08 *Football Association Premier League Limited & Others v QC Leisure & Others*; *Murphy v Media Protection Services Limited* (4th October 2011). There the Court of Justice was concerned, *inter alia*, with the interpretation of the Information Society Directive (Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society) and in particular it was required, *inter alia*, to determine the circumstances in which derogations from the principle of free movement could be allowed because they were necessary for the purpose of safeguarding rights which constituted the specific subject matter of copyright. The Court acknowledged that the specific subject matter of copyright included ensuring for the proprietor protection of the right to exploit commercially the marketing or the making available of the protected work by the grant of licences in return for payment of remuneration (ibid, paragraph [107]). This was based upon Recital 10 of the Copyright Directive which states:

> "(10) If authors or performers are to continue their creative and artistic work, they have to receive an appropriate reward for the use of their work, as must producers in order to be able to finance this work. The investment required to produce products such as phonograms, films or multimedia products, and services such as "on-demand" services, is considerable. Adequate legal protection of intellectual property rights is necessary in order to guarantee the availability of such a reward and provide the opportunity for satisfactory returns on this investment".

834. Accordingly the Court recognised that the directive conferred certain usage rights on the owner. However, the Court then imposed a limit on the use right and the ability of the right holder to maximise revenue by reference to a benchmark of "*reasonable remuneration*":

> "106. In this regard, it should be pointed out that derogations from the principle of free movement can be allowed only to the extent to which they are justified for the purpose of safeguarding the rights which constitute the specific subject-matter of the intellectual property concerned (see, to this effect, Case C-115/02 *Rioglass and Transremar* [2003] ECR I-12705, paragraph 23 and the case-law cited).
>
> 107. It is clear from settled case-law that the specific subject-matter of the intellectual property is intended in particular to

> ensure for the right holders concerned protection of the right to exploit commercially the marketing or the making available of the protected subject-matter, by the grant of licences in return for payment of remuneration (see, to this effect, *Musik-Vertrieb membran and K-tel International*, paragraph 12, and Joined Cases C-92/92 and C-326/92 *Phil Collins and Others* [1993] ECR I-5145, paragraph 20).
>
> 108. However, the specific subject-matter of the intellectual property does not guarantee the rightholders concerned the opportunity to demand the highest possible remuneration. Consistently within the specific subject-matter, they are ensured – as Recital 10 in the preamble to the Copyright Directive and Recital 5 in the preamble to the Related Rights Directive envisage – only appropriate remuneration for each use of the protected subject-matter.
>
> 109. In order to be appropriate, such remuneration must be reasonable in relation to the economic value of the service provided. In particular it must be reasonable in relation to the actual or potential number of persons who enjoy or wish to enjoy the service…".

835. The judgment is informative in that even where the right was held to include a use right its essential function or substance or essence was still defined and limited by reference to overarching public policy. The Court ruled that the right to maximise revenue which was set out in broad terms in the directive could not, without more, be assumed to be part of the specific subject-matter or essence of copyright.

836. As to *Digital Rights Ireland* (ibid) and *Schrems* (ibid), upon which heavy reliance was placed, these judgments are very far removed from the facts of the present case and the gravamen (*ratio*) of the judgments in any event concerned the necessity limb of the proportionality test. As is quite clear from the judgments the Court of Justice accepted as an important consideration the need for Member States to collect personal and private data for security reasons but the Court also recognised that there was a competing right in privacy. The essential objection of the Court was the very broad untrammelled extent of the rights of Member States to intrude into the rights of "*practically the entire European population*" (*Schrems* paragraph [58]). More specifically the Court was critical of the virtually unlimited discretion which the measure conferred upon the security forces of Member States and the almost wholly absent inclusion of *any* curbs or limits whatever on the powers conferred. It was for this reason that the legislation destroyed the essence of the right to privacy, because it was *unnecessary* in the proportionality setting. The Regulations in dispute in the present case could hardly be further along the spectrum of legal certainty to the other end. They are focused very specifically upon a narrowly defined class of persons and they set out with considerable precision and clarity precisely what can and cannot be done with the trade marks.

837. At base this point boils down to the correctness of the Claimants' proposition that the essence or substance of their trade marks allows them to facilitate a health epidemic (which is the necessary factual premise upon which the proposition must be based)

and that since they are prevented from using their property rights to do this by the Regulations those measures are unlawful, even if they are otherwise proportionate. In my judgment this is an unsustainable proposition. Nothing in international or EU law could or would tolerate this proposition; it runs counter to almost every sensible notion of how and why fundamental rights are to be defined and it assumes that the tobacco companies' shareholders have a greater hold on fundamental rights than do (say) the 600 children a day who start smoking in the United Kingdom and whose long term health prospects and life expectancy are threatened by the Claimants' product and who can also assert a (fundamental) right to protection of their health. In short and even assuming that nothing can impair the essence of a fundamental right, the very concept of "*the essence*" is flexible and it responds to and is governed by overriding public interest considerations. In the present case the fact that the Regulations intrude upon trade mark usage is simply a reflection of the fact that the *essence* of the rights yields to and is defined by superior health interests; the essence of the right is not impaired or disrespected as a result.

838. Finally, I propose to analyse the position which arises taking the Claimants' argument at face value. This means that if the right to property is impaired then the Regulations are unlawful under Article 17 of the Fundamental Charter even though: (a) the terms of Article 17 expressly make the right to property subject to overriding public interest considerations; (b) the curtailment of the right to use the trade marks and other property rights in the Regulations is (*ex hypothesi*) appropriate and necessary and reflects a fair balance between all competing fundamental rights (i.e. is proportionate); (c) the Regulations are designed to prevent those property rights from facilitating a health epidemic; and (d) the fundamental right to health in the EU treaties and in Article 35 of the Fundamental Charter is thwarted. Treating all of these considerations as irrelevant the question then is whether in actual fact the essence of the property rights is impaired by the Regulations. As to this the answer is "no". This is because: Regulation 13 preserves rights of registration (see paragraph [249] above) and thereby the negative right to exclude which, in formalistic terms, represents the nucleus or very essence of a trade mark under TRIPS; the property rights are not expropriated and title remains at all times with the proprietors; the word marks may be used as identifiers together with the use of the manufacturer's name and there are various other residual uses to which all of the marks may be put. In coming to this conclusion it is relevant that in *Philip Morris* and in *Pillbox* the Court of Justice rejected the submission that even outright prohibitions on the sale of a product or the dissemination of information affected the essence of the fundamental rights asserted by the tobacco companies. It is evident from the case law that the Court of Justice does not readily conclude that legislation impairs the essence of a fundamental right (see paragraph [270] above).

(6) The last sentence of Article 52(3): EU law goes beyond the ECHR

839. In view of my conclusion on what is meant by the substance or essence of the right it is not strictly necessary to consider the argument that the Fundamental Charter can go beyond the ECHR in the protection it confers. However, as to this I accept the Claimants' argument that at least in theory the Fundamental Charter can go beyond the ECHR.

840. In relation to the last sentence of Article 52(3) the possibility is not ruled out that the EU might provide more extensive protection than that afforded by the ECHR. On its

face this seems to assume that when incremental protection is afforded this will be pursuant to specific legislative measures which go beyond the Fundamental Charter. Support for this is found in the relevant text of the Explanations:

> "Paragraph 3 is intended to ensure the necessary consistency between the Charter and the ECHR by establishing the rule that, in so far as the rights in the present Charter also correspond to rights guaranteed by the ECHR, the meaning and scope of those rights, including authorised limitations, are the same as those laid down by the ECHR. This means in particular that the legislator, in laying down limitations to those rights, must comply with the same standards as are fixed by the detailed limitation arrangements laid down in the ECHR, which are thus made applicable for the rights covered by this paragraph, without thereby adversely affecting the autonomy of Union law and of that of the Court of Justice of the European Union.
>
> The reference to the ECHR covers both the Convention and the Protocols to it. The meaning and the scope of the guaranteed rights are determined not only by the text of those instruments, but also by the case-law of the European Court of Human Rights and by the Court of Justice of the European Union. *The last sentence of the paragraph is designed to allow the Union to guarantee more extensive protection. In any event, the level of protection afforded by the Charter may never be lower than that guaranteed by the ECHR.*
>
> …
>
> The list of rights which may at the present stage, without precluding developments in the law, legislation and the Treaties, be regarded as corresponding to rights in the ECHR within the meaning of the present paragraph is given hereafter. It does not include rights additional to those in the ECHR.
>
> …
>
> Article 17 corresponds to Article 1 of the Protocol to the ECHR".

(Emphasis added)

841. I do not consider that this conclusion is especially surprising. The reference to the "Union" is most aptly read as a reference to the Union in its legislative capacity. In contrast the ECHR is not a treaty which confers legislative powers, but the EU treaties do. It thus makes sense because in particular legislation the EU might, for instance, introduce a compensation scheme for farmers whose livestock has, for health reasons, had to be destroyed in circumstances where, strictly, there was no legal duty on the legislature to make compensation available. The legislature would hence go beyond the strict A1P1 right. Article 52(3) thus makes clear that the Convention creates floor

rights and it does not preclude bespoke legislative interventions of a more generous nature. Mr Eadie QC for the Secretary of State expressed the view that this was a difficult and controversial provision and issue. He mooted that it might in principle also embrace acts of judicial creativity with the Court of Justice on particular facts also going beyond the strict confines of the ECHR. I can see the force in this.

(7) Compensation

842. The Claimants' final retort is that the essence of a right may still be respected where a trade mark use is prohibited if compensation is paid. For the reasons given in relation to Ground J above (see paragraphs [789] – [812]) I do not accept that, even if the essence of the rights is impaired, there is then an obligation under EU law which becomes activated to pay compensation.

(8) Conclusion

843. In my judgment there is no basis for Article 17 going beyond A1P1. There is no judgment of the Court which expressly so provides; and there is no legislation which accords rights which are more generous than those set out in A1P1. Accordingly even if Article 52(3) last sentence provided a basis in principle for EU law to surpass the ambit of the protection accorded by the ECHR the law has not done so and I can see no proper or sensible basis for taking that novel step in a case such as this, for the self-same reasons that I have given for rejecting the claim to compensation under A1P1. I therefore reject the claim under Article 17 of the Fundamental Charter.

L. GROUND 8: LEGISLATIVE INTENT AND THE COMMON LAW RIGHT TO PROPERTY

(1) The issue

844. The third way in which the Claimants advance their compensation claim is under the common law. It is submitted that a right to property is protected in the common law and it cannot be intruded upon, whether by expropriation or control or restriction or use, in any way, save (a) by the express will of Parliament and (b) even then only upon the payment of full compensation. The Secretary of State counters that Parliament can both expropriate and curtail property rights and it has a discretion to pay compensation but on a proper interpretation of the Regulations and the relevant enabling legislation Parliament has by necessary implication decided that in this case in the public interest no compensation is payable (citing *R (Morgan Grenfell & Co Ltd) v Special Commissioners* [2003] 1 AC 563, HL, per Lord Hoffmann at paragraph [8]). He also submits that in any event the common law does not prevent the legislative control of use of property in the manner provided for in the Regulations. For the Claimants to succeed it is argued that they must establish (a) that there is such a property right under the common law and (b) that as a matter of interpretation Parliament has not taken away the right to compensation.

(2) The interpretation point

845. I start with the interpretation point since if the Secretary of State is correct in this argument then even if the common law did afford a right to compensation it has been nullified by Parliament and the Claimants' ground fails regardless. As to this I do not

however accept the Secretary of State's argument that Parliament has nullified such common law rights as might exist. In neither the Regulations nor its enabling legislation is there any mention of a right to compensation, nor is there any express exclusion of any pre-existing common law right, and no mention is made of any such rights being taken away. Parliament is simply silent on this issue.

846. Moreover, a right to compensation is provided for in domestic statute law by virtue of the Human Rights Act 1998 which incorporates the ECHR into domestic law and this includes A1P1. Parliament did not therefore need to address the issue of compensation in section 94 Children and Families Act 2014 or in the Regulations because it was already catered for in the 1998 Act. The Claimants cite the rule of construction which provides that "*unless the words of the statute clearly so demand, a statute is not to be construed so as to take away the property of a subject without compensation*": See *Attorney-General v De Keyser's Royal Hotel* [1920] AC 508 per Lord Atkinson at page [542]. Since the relevant legislation does not expressly take away or deny the statutory right to compensation then it must be assumed to remain and since the legislation is silent generally about compensation it has not taken away any such rights as otherwise exist in common law.

847. The Secretary of State adopts a different view. He submits that the omission by Parliament of a legislative compensation scheme must be seen to be deliberate and indicates that no compensation is payable at all. The Secretary of State submitted that the "*the 2014 Act and the Regulations are not ambiguous and leave no room for the application of the common law interpretative doctrine*". I do not agree. The submission ignores the principles which govern how Parliament is to act if it is to be taken as having precluded fundamental constitutional principles, such as the right to property. The tenor of recent case law on the ability of Parliament to cut back on the scope of human rights indicates that Parliament must express its will to do this in clear and unequivocal language. It must do so by words of "*…detailed, specific and unambiguous character*": *R (Gillan) v Comr of Police of* the *Metropolis* [2006] UKHL 12; [2006] 2 AC 307, paragraph [15]) or by "*irresistible inference"- Westminster Bank v Beverley BC*, [1971] AC 508, at 529C). As Lords Neuberger, Kerr and Reed emphasised, Parliament must make its intentions "*crystal clear"* if it sought to preclude individuals from relying upon constitutional principles: See *R (Evans) v Attorney General* [2015] UKSC 21; [2015] 2 WLR 813, paragraphs [56], [58] and [90]. In the absence of such clear language secondary legislation that failed to give effect to fundamental common law rights risked being unlawful: *R v Lord Chancellor, ex p Witham* [1998] QB 575 at page [581E].

848. In my judgment the present legislative framework comes nowhere close to being in a form sufficient to oust fundamental rights, such as the right to property. Given the incorporation of A1P1 into domestic law *via* the Human Rights Act 1998 had section 94 Children and Families Act 2014 or the Regulations purported to remove that right or an equivalent in common law then it would have been a hugely controversial measure and would, inevitably, have been achieved by express words and not by a silent interpretative side wind.

849. I turn therefore to the question whether there *is* a common law right in the form articulated by the Claimants.

(3) The nature and extent of the common law right to property

(i) Blackstone's Commentaries

850. The Claimants argue that under the common law they have an inalienable right to the free use of their property and the Regulations unlawfully curtail this right. And if Parliament does curtail this right it must provide "full indemnification". The Claimants take as their point of departure and as accurately representing the historic common law right to property the "Commentaries on the Laws of England" (1765-1769) by Sir William Blackstone (Vinerian Professor of Law and Solicitor General to King George III). In Chapter 1 "The Rights of Persons" Blackstone identified as an "*absolute right inherent in every Englishman*" that of "property". He defined the right as that:

> "…which consists in a free use, enjoyment, and disposal of all his acquisitions, without any control or diminution, save only by the laws of the land".

851. Blackstone was of the view that the origin of the principle of private property was to be found in "*nature*" but he acknowledged that the rules and regulations which surrounded property derived "*entirely…from society*". He stated that the principle relating to the protection of property emanated from "*the great charter*" (i.e. Magna Carta). In relation to the ability of the law to derogate or deviate from this fundamental right he stated as follows, in a passage relied upon by the Claimants:

> "So great moreover is the regard of the law for private property, that it will not authorise the least violation of it; no, not even for the general good of the whole community, if a new road, for instance, were to be made through the grounds of a private person, it might perhaps be extensively beneficial to the public; but the law permits no man, or set of men, to do this without consent of the owner of the land. In vain may it be urged, that the good of the individual ought to yield to that of the community; for it will be dangerous to allow any private man, or even any public tribunal, to be the judge of this common good, and to decide whether it be expedient or no. Besides, the public good is in nothing more essentially interested, than in the protection of every individual's private rights, as modelled by the municipal law. In this, and similar cases the legislature alone can, and indeed frequently does, interpose, and compel the individual to acquiesce but how does it interpose and compel? Not by absolutely stripping the subject of his property in an arbitrary manner; but by giving him a full indemnification and equivalent for the injury thereby sustained. The public is now considered as an individual, treating with an individual for an exchange. All that the legislature does is to oblige the owner to alienate his possessions for a reasonable price; and even this is an exertion of power, which the legislature indulges with caution, and which nothing but the legislature can perform".

852. The common law is, according to Blackstone, "*in point of honor and justice, extremely watchful in ascertaining and protecting*" the right to property.

853. There are a number of difficulties with this interpretation of the common law.

(ii) Lord Mansfield and the Slavery Abolition Act 1833

854. The first difficulty is that the proposition set out in Blackstone is too extreme and uncompromising. In the course of oral argument some reliance was placed upon the fact that Parliament had legislated for the payment of compensation to colonial slave owners upon the abolition of slavery in 1833 as an exercise in what was just and expedient in a case where property rights had been curtailed. It was contended that this reflected the trenchant common law approach to the legislative suppression of otherwise or erstwhile legal and/or commercial property rights. I do not agree. The abolition of slavery as a category of property had been abolished at common law in a series of earlier judgments by Lord Mansfield and there had never arisen the remotest prospect of the common law compensating the former slave owners for the deprivation of their property. In The Slavery Abolition Act 1833 Parliament addressed the manumission of slaves in the colonies. This awarded compensation to slave owners for being "*deprived of their right to such services*". The basis of both the abolition and the right to compensation was that it was "*just and expedient*". Section 1, which also serves as the preamble to the Act, stated as follows: "*WHEREAS divers Persons are holden in Slavery within divers of His Majesty's Colonies, and it is just and expedient that all such Persons should be manumitted and set free, and that a reasonable Compensation should be made to the Persons hitherto entitled to the Services of such Slaves for the Loss which they will incur by being deprived of their Right to such Services …".* The total compensation payable was specified under section 24 as £20 million, which historians have estimated is the equivalent of approximately £70 billion in present value terms and as having accounted for about 40% of the total expenditure of the State at that time. However, slaves had not been "property" at common law since the condemnation of slavery as abhorrent to the common law and not recognisable in the absence of an express Parliamentary measure. Lord Mansfield in *Somerset v Stewart* (1772) 98 ER 499 concerning *habeas corpus* ruled that the common "law of England" did not recognise slaves as property and only "positive law" (i.e. Statute law) could afford protection. He stated:

> "The state of slavery is of such a nature, that it is incapable of being introduced on any reasons, moral or political; but only positive law, which preserves its force long after the reasons, occasion, and time itself from whence it was created, is erased from memory: it's so odious, that nothing can be suffered to support it, but positive law. Whatever inconveniencies, therefore, may follow from a decision, I cannot say this case is allowed or approved by the law of England; and therefore the black must be discharged".

855. The 1833 Act cannot therefore be taken to support the proposition that curtailments or abolition of a right to property inevitably triggers a common law right to compensation. On the contrary the more apt interpretation is that Parliament stepped in because the common law refused to acknowledge a species of property, upon strong (moral) policy grounds. The judgment of Lord Mansfield pre-dated the

Commentaries of Sir William Blackstone but for whatever reason the implications of that judgment are not incorporated into the section on property rights. The fact that Parliament granted compensation is in any event clearly not an indication of what the common law is or was; Parliament intervened because the common law would not and what was "*just and expedient*" in the eyes of MPs in 1833 is not an indication of what would be so in 2016. It is inconceivable that anyone would be compensated for the manumission of a slave in a modern Western state. In 1833 slavery was integral to the economy and had compensation not be paid the economic consequences for the colonies would have been calamitous. The same cannot be said of the curtailing of the advertising of tobacco which on the basis of the 2014 Impact Assessment will result in a vast long term saving to the State in financial terms and a commensurate improvement in public health and welfare and to the extent that good health promotes happiness, then an increase in overall societal welfare. An Act of Parliament was thus required to sanction the payment of compensation since the earlier judicial decisions hostile to slavery had not contemplated the possibility of compensation as part of the common law and, as many historians have observed, whilst Parliament invoked "*justice and practicability*" as its guiding lights many members of Parliament stood to, and did, gain handsomely from the compensation package. It is perhaps not without some significance that the 1833 Act was repealed only in 1998 by the Statute Law (Repeals) Act 1998 upon the basis that by virtue of more recent legislation (including the Human Rights Act 1998) it was no longer necessary.

(iii) The Common law evolves

856. In any event, whatever might have been the status of the common law, there is an increasing recognition that the common law is not a defunct or moribund jurisprudence when it comes to the protection of human rights and that it can evolve and be capable of marching hand in hand with other internationally recognised fundamental rights, such as the ECHR. The Supreme Court in *Kennedy v Information Commissioner* [2014] 2 WLR 808 referred to the "*baleful and unnecessary tendency to overlook the common law"* (ibid paragraph [46] and see also paragraph [133]). See also to similar effect *A v BBC* [2014] 2 WLR 1243, paragraph [56]; *R (Osborn) v Parole Board* [2013] 3 WLR 1020, paragraphs [55] to [57]; and *Zaw Lin and Wai Phyo v Commissioner of Police for the Metropolis* [2015] EWHC 2484 (QBD) at paragraphs [49ff]). A1P1 is brought into domestic law through the Human Rights Act 1998. It reflects the common law tradition and, in my view, this includes not only the right but also its limitations. I can see no legal basis upon which at common law the Courts should be required to order the state to compensate the tobacco companies if the same would not be compelled by the operation of the ECHR.

(4) Conclusion

857. For the above reasons I reject the submission that the common law either prohibits the Regulations or provides a right to compensation.

M. GROUND 9: BREACH OF ARTICLE 16 FUNDAMENTAL CHARTER

(1) The issue

858. I shall deal with this submission briefly. It was referred to in written submissions but was not advanced as a free standing argument during the oral hearing. Article 16 provides:

> "Article 16
>
> Freedom to conduct a business
>
> The freedom to conduct a business in accordance with Community law and national laws and practices is recognised".

859. It was submitted that the Regulations interfered unlawfully with the fundamental right to conduct business. The Secretary of State submits (i) that there is no relevant interference with the freedom to conduct a business; and (ii) that even if there is it is not disproportionate and is justified for reasons of public health.

(2) Analysis and conclusion

860. There is no doubt that the right to conduct a business is a right recognised by EU law and, moreover, treated as a fundamental right. But, manifestly, it is not an absolute right and in ways far too numerous to mention that right is and always has been subjected to limitation: competition law, environmental law, health and safety law etc, all curtail in myriad ways a traders' freedom to act without limit. Thus in *Case C-4/73 Nold, Kohlen- und Baustoffgroßhandlung v Commission* [1974] ECR-I 00491 at paragraph [14] the Court stated:

> "… far from constituting unfettered prerogatives, [the right of property and the freedom to practise a trade or profession] must be viewed in the light of the social function of the property and activities protected thereunder. For this reason, rights of this nature are protected by law subject always to limitations laid down in accordance with the public interest. Within the Community legal order it likewise seems legitimate that these rights should, if necessary, be subject to certain limits justified by the overall objectives pursued by the Community, on condition that the substance of these rights is left untouched. As regards the guarantees accorded to a particular undertaking, they can in no respect be extended to protect mere commercial interests or opportunities, the uncertainties of which are part of the very essence of economic activity".

861. In *Swedish Match* (ibid) the Court of Justice laid down the limits of the right of the state to curtail the freedom to conduct business in very general terms which imported broad principles of proportionality and which drew the clear link with the right to property and which also made clear that the right to trade was not the same thing as the right to succeed or make a profit, and nor did the right concern any immunity from

subsequent interventions by the state which imposed shackles or limits upon the trader:

> "*The principle of freedom to pursue a trade or profession and the right to property*
>
> 72. According to the case-law of the Court, the freedom to pursue a trade or profession, like the right to property, is one of the general principles of Community law. Those principles are not absolute rights, however, but must be considered in relation to their social function. Consequently, restrictions may be imposed on the exercise of the freedom to pursue a trade or profession, as on the exercise of the right to property, provided that the restrictions in fact correspond to objectives of general interest and do not constitute, in relation to the aim pursued, a disproportionate and intolerable interference, impairing the very substance of the rights guaranteed (see, inter alia, Case 265/87 Schräder [1989] ECR 2237, paragraph 15; Case C-280/93 Germany v Council [1994] ECR I- 4973, paragraph 78; Case C-293/97 Standley and Others [1999] ECR I-2603, paragraph 54; Joined Cases C-37/02 and C-38/02 Di Lenardo and Dilexport [2004] ECR I-0000, paragraph 82, and Spain and Finland v Parliament and Council, paragraph 52).
>
> 73. The prohibition on the marketing of tobacco products for oral use laid down in Article 8 of Directive 2001/37 is indeed capable of restricting the freedom of manufacturers of such products to pursue their trade or profession, assuming that they have envisaged such marketing in the geographical region concerned by that prohibition. However, the operators' right to property is not called into question by the introduction of such a measure. No economic operator can claim a right to property in a market share, even if he held it at a time before the introduction of a measure affecting that market, since such a market share constitutes only a momentary economic position exposed to the risks of changing circumstances (Case C-280/93 Germany v Council, paragraph 79). Nor can an economic operator claim an acquired right or even a legitimate expectation that an existing situation which is capable of being altered by decisions taken by the Community institutions within the limits of their discretionary power will be maintained (see Case 52/81 Faust v Commission [1982] ECR 3745, paragraph 27).
>
> 74. As stated above, Directive 2001/37 pursues an objective in the general interest by ensuring a high level of protection of health in the context of the harmonisation of the provisions applicable to the placing on the market of tobacco products. It does not appear, as indicated in paragraph 58 above, that the prohibition laid down in Article 8 of that directive is inappropriate to that objective. In those circumstances, the

> obstacle to the freedom to pursue an economic activity constituted by a measure of such a kind cannot be regarded, in relation to the aim pursued, as a disproportionate interference with the exercise of that freedom or with the right to property".

862. All of this is common sense and should surprise no one. It means that the right is a heavily circumscribed right which is at all times subject to curtailment according to a more or less unlimited range of different public interests. This point was indeed recognised in *Philip Morr*is and in *Pillbox*: see paragraph [270] above.

863. The truth of the matter is that Article 16 adds little to the analysis: if the Claimants are correct that the Regulations are disproportionate or violate rights to property then it will not add to the consequential condemnation of this Court of the Regulations that the measure also infringes Article 16.

864. Since I do not accept the Claimants' submission under other, more precise and sharper edged tests, there is no basis upon which I could find a violation of Article 16.

N. GROUND 10: DO THE REGULATIONS VIOLATE THE UNITARY CHARACTER OF TRADE MARKS IN THE CTMR AND IN THE CDR?

(1) The Issue

865. It is said that the Regulations are unlawful because they result in an encroachment upon the "unitary" or universally effective character of trade marks contrary to the CTMR. This Ground concerns the scope and effect of Articles 1 and 110(2) of the CTMR. The nub of the point lies in 2 central premises: First, that the CTMR is exhaustive of all derogations from the unitary rights conferred on proprietors and, secondly, that there are no provisions in the CTMR which allow Member States to derogate from those rights. It is also argued (but only by ITL and BAT) that the Regulations are unlawful as being inconsistent with the "unitary" character of Community designs under Regulation 6/2002 on Community Designs (the "CDR"). I deal with this latter issue as a discrete point at paragraphs [880] – [882] below.

(2) Claimants' submissions: The Regulations unlawfully interfere with the unitary character of trade marks

866. I start by setting out in greater detail the steps which form the component parts of the Claimants' argument. The Claimants submit that the Regulations are unlawful since they depart from the unitary character of trade marks which is a guarantee that CTMs can have the same effect across the whole of the EU. I have set out at paragraph [209] – [223] above the relevant provisions of the CTMR. The Claimants' submission is put in the following way:

i) The guarantee of "*unitary character*" in Article 1(2) CTMR must be construed in accordance with the object and purpose of the CTMR. As the recitals make clear, Article 1(2) is designed to remove the "*barriers to free movement of goods and services*" and to guarantee legal conditions "*which enable undertakings to adapt their activities to the scale of the Community*" (Recital (2)). In order to achieve that end, the guarantee of "*unitary character*" enables the products and services of undertakings "*to be distinguished by identical*

means throughout the entire Community, regardless of frontiers" (Recital (2)). Guaranteeing the ability of a proprietor of a CTM to distinguish his goods and services by use of his CTM in the same way throughout the Community, in order to facilitate the operation of the internal market, is the essential purpose of the principle of the unitary character guaranteed by the CTMR.

ii) Derogation from the principle of "*unitary character*" guaranteed at Article 1(2) is permissible only in accordance with the express exceptions set out in the CTMR itself. As the final sentence of Article 1(2) makes clear, the principle of unitary character will apply "*unless otherwise provided in*" the CTMR (see also recital (3).

iii) The recognition of further exceptions or derogations not set out in the CTMR would undermine the express language of Article 1(2) and would impair the binding nature of EU law and its uniform application: see Case C-273/97 *Sirdar v Secretary of State for Defence* [1999] ECR I-7403 paragraph [16].

iv) The exceptions which are permitted under the CTMR must be strictly construed and applied only where strictly necessary: see, by analogy, Case C-119/12 *Josef Probst v mr.nexnet GmbH* (22 November 2012) paragraph [23]; Case C-16/10 *The Number (UK) and Conduit Enterprises* [2011] ECR I-691 paragraph [31]; Case C-287/98 *Linster* [2000] ECR I-6917 paragraph [49]; and Case C-328/91 *Thomas* [1993] ECR I-1247 paragraph [8].

v) All of the Claimants have a significant presence and operations in the EU and all possess CTMs which are of importance to the Claimants. They serve to protect their respective brands in their markets in the region. Some Claimants own CTMs that are used solely in the United Kingdom.

vi) The effect of the Regulations is that the Claimants will be forced to use completely different cigarette and tobacco packaging for the UK from that used in other EU Member States. The Regulations thus derogate unlawfully from the unitary nature of the CTM which is guaranteed by the CTMR. In response to evidence adduced by the Defendant to the effect that in real and practical terms the Regulations do not cause much prejudice in relation to CTMs the Claimants submit that their complaint is not about the costs or logistics of producing different packaging in different States, but rather that they are, in the UK, being deprived of the ability to communicate with consumers and distinguish their graphic CTM at all on any retail packaging. They will be prohibited from using a word-only CTM on any of their retail packaging, save in the form, including the standardised font and size, prescribed by the Regulations, which is entirely different from the ways in which it can be used in other EU Member States. The Tobacco Claimants' CTMs will therefore no longer have "*equal effect through the Community*", and their "*unitary character*" will be lost.

vii) There is no justification under Article 110(2) CTMR for the Regulations.

(3) The CTMR is not exhaustive of applicable limits

867. I start by rejecting the submission that, as a matter of interpretation, the CTMR is definitive and therefore that it is only from within the CTMR that any derogation could even in principle be found. First, the CTMR does not and cannot guarantee that every CTM has equal effect across the EU. For example, all CTMs are subject to overriding treaty obligations even though this is not expressly stated to be the case in the CTMR. When it was put to the Claimants' counsel in oral argument that all subordinate EU legislation had, as a matter of constitutional and administrative law, to be read as subject to the Treaty itself this was accepted as a correct statement of the law. Equally when I put to counsel that, for instance, all intellectual property rights were subject to the prohibitions in Article 101 and 102 TFEU on cartels and the abuse of a dominant position, again, this was fully accepted. It necessarily follows that the CTMR, as subordinate legislation, could not be wholly definitive in all circumstances. It had to be construed purposively in the light of superior obligations.

868. However, during closing submissions these (inevitable) concessions had disappeared from sight and it was submitted that the *only* departures which could lawfully exist to the rights in the CTMR were those explicitly set out *in* the CTMR itself. However, it is striking, for instance, that there is no express derogation in the CTMR for the case of a CTM which collides with competition law; yet – manifestly – nothing in the CTMR expressly or impliedly condones or could condone the use of trade marks to further illegal cartels or to abuse market dominance. And, moreover, the prohibitions in Article 101 and 102 TFEU frequently (by virtue of the fact that markets are often local in nature) apply to limited geographical markets only which, in the overwhelming majority of cases, are national or even sub-national, but most certainly not EU-wide in nature. As such without it being so expressly stated in the CTMR there simply have to be exceptions and derogations from the universal (EU wide) unity of Community trade marks.

869. There is nothing surprising in this conclusion. Over many decades the Court of Justice, in developments redolent of the incremental common law approach, has identified limitations to the right of proprietors of intellectual property rights to "exercise" their rights. This is the very essence of the fundamental distinction drawn between the existence and the exercise of rights: Yet, once again, those limitations are not listed anywhere in the Community legislation on the intellectual property rights in question. And, moreover, it is not to be thought that this dichotomy is not reflected in international law since, as already pointed out within TRIPS there are multiple provisions which confer upon contracting states the right to limit the right to use the intellectual property in question including for health grounds (See Section D(3)(iii)ff above). There is no canonical list of limits laid down in TRIPS; it is, essentially, open ended. It follows that legislation which is consistent with other superior EU law does not become unlawful simply because it creates a derogation from the unitary character of a CTM. Accordingly, the first reason for rejecting the argument is that the Claimants' case that nothing can undermine the universal application of a CTM is inconsistent with the elementary principles of EU constitutional law. Thus, insofar as EU law (here the TFEU and the TPD) permits and encourages Member States, in furtherance of public health, to introduce restrictions on the use of CTMs this is not, without more, a breach of the CTMR.

(4) Are the Regulations unlawful under Article 110(2) CTMR?

870. The second reason is that in my judgment (and regardless of the conclusion in Section (3) above) the Regulations are consistent with the CTMR which creates its own carve-out from the unitary nature of CTMs. The Secretary of State relies in this regard upon Article 110(2). However, the Claimants submit that the Regulations are inconsistent with Article 110(2) CTMR because of Regulation 13.

871. Regulation 13 by a variety of legislative devices seeks to create a protective shield for trade marks that are otherwise adversely affected by the other provisions of the Regulations. Regulation 13(1) is said to be "*for the avoidance of doubt*" and it stipulates that nothing done in accordance with the Regulations forms an obstacle to registration or gives rise to grounds for a declaration of invalidity of a registered trade mark under section 47 of the Trade Marks Act. Regulation 13(2) provides that nothing in or done in accordance with the Regulations causes any trade mark to be subject to proceedings on grounds of bad faith, or lacking a *bona fide* intention, etc. Regulations 13(5) and (6) provide protection in relation to alleged non-use in relation to earlier trade marks. Regulation 13(9) seeks to afford equivalent protection to international trade marks: "(9) To the extent that any provision of the Trade Marks Act 1994 mentioned in this regulation (a "relevant provision") applies to international trade marks (UK) (whether by virtue of that Act, the Trade Marks (International Registration) Order 2008 or otherwise, and whether with or without modifications), then provision made by this regulation in relation to that relevant provision shall also apply (with any necessary modifications) to international trade marks (UK)."

872. The Claimants submit that the Regulations are inconsistent with Article 110(2) CTMR which provides:

> "2. This Regulation shall, unless otherwise provided for, not affect the right to bring proceedings under the civil, administrative or criminal law of a Member State or under provisions of Community law for the purpose of prohibiting the use of a Community trade mark to the extent that the use of a national trade mark may be prohibited under the law of that Member State or under Community law."

It is important to consider what Article 110(2) does and does not concern. By its terms it exists to make clear that the CTMR is without prejudice to the pre-existing right on the part of Member States (for example under TRIPS) to prohibit the use of trade marks. Specifically, Article 110(2) is concerned only with confirming the right of Member States to prohibit the "*use*" of a CTM. It says nothing about registration or revocation proceedings in relation to CTMs and any issue relating to these remains governed by the rules in the CTMR. Therefore, any issue as to revocation or registrability which flowed from the fact that a Member State quite lawfully applied to domestic trade marks *and* CTMs a prohibition on *use*, remains a matter for EU law to be determined in accordance with the procedures under the CTMR, not national law. This is the division of labour and power between the Member States that the EU provided for under the CTMR. Further, nothing in Article 110(2) or the CTMR more generally prohibits or affects the right of the Member States to adjust their own domestic rules on registration and revocation of *national marks* to take account of the fact that certain uses of such national trade marks are prohibited.

873. Accordingly, the Regulations are, in my judgment, consistent with Article 110(2) and the CTMR. In accordance with Article 110(2) the Regulations *do* apply to *all* trade marks a prohibition on *use* and there is no distinction drawn between national rights and CTMs in this regard. The Regulations thus reflect no more and no less than they are permitted to do under Article 110(2). This in my view is an answer to the Claimant's submission. To the extent therefore that the Claimant's argue that the Regulations are illegal then this is, in substance, a challenge to the legality of Article 110(2) itself. But no such challenge has been advanced in these proceedings.

874. I propose now however to go on and to consider in a more formalistic manner the Claimant's specific arguments. I consider the following: (i) whether there is a difference in treatment between national trade marks and CTMs under the Regulations; (ii) whether if there is a difference it is objectively justified; (iii) if it is not objectively justified whether it is unlawful and can be cured by a remedy falling short of nullity; and (iv) if only nullity would be appropriate whether the offending Regulation is severable from the Regulations as a whole.

875. As to whether there is a difference in my view there is clearly one. It lies in the fact that under Regulation 13 if registration / revocation proceedings do arise then certain issues are in effect predetermined in favour of the Claimants. As such national trade marks are protected from revocation proceedings under domestic trade mark law, but CTMs have no equivalent protection under the CTMR. If Regulation 13 did not exist then all trade marks, both national and CTM, would be vulnerable to revocation and the policy issues which have been relied upon to found Regulation 13 would then have to be deployed in specific proceedings. Regulation 13 has taken away this regulatory or litigation risk for national trade marks but not from CTMs. If it was possible to predict that these same policy arguments would be effective in revocation proceedings under the CTMR then the difference might only be procedural and not substantive. However, although there would be a good case to be made in such revocation proceedings that registration should remain, for similar reasons to those which have led to Regulation 13 being promulgated, it is not possible to be sure of this. In my view the difference might be both procedural and substantive.

876. Is the difference in treatment objectively justified? In my view it is. This is because, for the reasons set out above, the position vis-à-vis registrability and revocation of national marks and CTMs are to be addressed in different ways under different legal regimes and this therefore reflects rational and considered legislative policy choices made at the EU level. The conditions governing revocation and registration are within the legislative power of the Member States in relation to national trade marks but they are not in the case of CTMs. Parliament had no power at all to provide a shield to CTMs equivalent to that provided to national rights in Regulation 13. It is however open to the EU under either the TPD or under relevant trade mark legislation or as a matter of ministrative practice at the behest of the European Trade Mark Office (as of the date of this judgment still the Office for Harmonisation in the Internal Market (trade marks and designs)) to achieve the same degree of protection for CTMs as exists for national trade marks, but it has yet to do so (because of course as of the present time the issue is entirely hypothetical). In my judgment the fact that Parliament had power over only one type of trade mark but not the other and that national trade marks and CTMs are subject to different regimes represents relevant and objective considerations justifying the difference in treatment. To put the point

shortly it is objectively justified because it is what the combined effect of the TPD, the TMD and the CTMR require.

877. If I am wrong in the above conclusion then I have to decide whether any unjustified differentiation can be remedied. Differences in treatment can be cured by levelling up or levelling down. It is within the power of Parliament to level down, by removing the shield afforded by Regulation 13 to national trade marks; but it is not within Parliament's jurisdiction to level up by affording equivalent protection to CTMs, since only the EU legislature can do this by amending the CTMR. It is possible that this might happen in the future but it has not occurred to date. If therefore I were to find that Regulation 13 was unlawful the logical solution would be to declare the offending provision (Regulation 13) to be unlawful. An alternative form of relief which might have been better suited to the peculiar circumstances of this case would have been to make a declaration that the unlawful discrimination could be removed by the EU ensuring equivalent protection to CTMs and then awaiting to see if curative action was taken. A further alternative could have been to refer the issue, including that of the proper remedy in these usual circumstances, to the Court of Justice. Nonetheless because I do not accept the basic premise underlying the objection these considerations are academic.

878. If Regulation 13 is unlawful and cannot be cured or saved by a process of levelling up for CTMs then I next consider whether it is severable from the Regulations as a whole. In my view the proper way to analyse this is by reference to the analysis conducted by the Government prior to the promulgation of the Regulations by Parliament. And as to this it is plain, and in particular from the 2014 Impact Assessment, that Regulation 13 played virtually no or no material part in the justification for the Regulations. Accordingly if Regulation 13 is unlawful it is severable from the Regulations as a whole and nothing has changed since Parliament acted which would affect that conclusion as of the date of this judgment.

879. Finally, there are two peculiarities about this argument advanced by the Claimants to be noted. First, I observe that the position adopted by the Claimants in this litigation has been that Regulation 13 is worthless and, as such, its excision from the Regulations as a whole would not, on the Claimants' analysis at least, have made any difference. Secondly, I also observe the artificial nature of the argument since Regulation 13 is the single saving grace for the tobacco companies so far as they are concerned. The Regulations are intended to curtail to a very high degree the ability of the tobacco companies to use trade marks in promoting their products and Regulation 13 is just about the only silver lining to this otherwise dark cloud. Yet, in order to attack the Regulations, the tobacco companies have sought to challenge the one part thereof which is to their advantage. I have not relied upon either point as part of the overall analysis; but they do place the argument into context.

(5) Are the Regulations unlawful under Article 1(3) of Council regulation (EC) No 6/2002 of 12 December 2001 on Community Designs ("the CDR")

880. ITL and BAT (only) also allege that under Article 1(3) of Council Regulation (EC) No 6/2002 of 12 December 2001 on Community Designs[32] ("*the CDR*") Community designs, like CTMs, also enjoy an unassailable "*unitary*" character. ITL argues that, for instance, its Glide Tec pack design (which I have already described at paragraph [319] above) is protected by the CDR but would be unlawfully prohibited by the Regulations in the United Kingdom and that thereby its "*unitary*" EU wide character is undermined. It is said that ITL has paid for these design rights to include coverage for the UK and will continue to have to pay fees in the future, even though it gets no protection in the United Kingdom.

881. These Claimants argue that there is no equivalent in the CDR of Article 110(2) of the CMTR (see above). Whilst that is technically true in linguistic terms, Article 96(1) CDR entitled "Relationship to other forms of protection under national law" acknowledges that the CDR does not prejudice the application of national legislation to Community designs: "*The provisions of this Regulation shall be without prejudice to any provisions of Community law or of the law of the Member States concerned relating to unregistered designs, trade marks or other distinctive signs, patents and utility models, typefaces, civil liability and unfair competition*." Recital 31 explains the scope of this acknowledgement of the existence of the right of national law to operate in relation to Community designs in broad terms:

> "(31) This Regulation does not preclude the application to designs protected by Community designs of the industrial property laws or other relevant laws of the Member States, such as those relating to design protection acquired by registration or those relating to unregistered designs, trade marks, patents and utility models, unfair competition or civil liability".

And Recital 32, in similar terms, makes it clear that the CDR is a measure of partial harmonisation and that Member States "*remain free*" to determine the "*extent*" of copyright protection:

> "(32) In the absence of the complete harmonisation of copyright law, it is important to establish the principle of cumulation of protection under the Community design and under copyright law, whilst leaving Member States free to establish the extent of copyright protection and the conditions under which such protection is conferred".

882. I accept the submission in this regard of the Secretary of State that Article 96 CDR thus empowers Member States to regulate the "*extent*" of protection of Community designs by reference to other relevant laws, of which the Regulations are an example. This necessarily creates an exception to the unitary nature of the right conferred under

[32] As amended by Council Regulation No 1891/2006 of 18 December 2006 amending Regulations (EC) No 6/2002 and (EC) No 40/94 to give effect to the accession of the European Community to the Geneva Act of the Hague Agreement concerning the international registration of industrial designs.

the CDR, This reflects the fact that the CDR is a measure of partial harmonisation (to which the principles in *Philip Morris* (ibid) would hence apply). I would accept, at the level of basic principle, however that whilst there may be no limitation imposed by the CDR the relevant national laws would still have to be consistent with other relevant EU law and international law. There is in this regard no need to repeat analysis set out elsewhere in this Judgment to the effect that the Regulations are consistent with the EU treaties, with the TPD, with TRIPS and with other potentially applicable measures of international law.

(6) Conclusion

883. In conclusion: (i) The Regulations are consistent with Article 110(2) CTMR; (ii) insofar as there are differences in treatment between national marks and CTMs these are logical and objectively justified by the legislative regime itself; but (iii), even if Regulation 13 was unlawful and the appropriate remedy was nullity it would be severable from the remainder of the Regulations which would remain valid and effective. Further, the Regulations are consistent with the CDR.

O. GROUND 11: MISDIRECTION IN LAW – FAILURE TO APPLY THE TEST IN ARTICLE 24(2) TPD

(1) The issue

884. The Claimants submit that in promulgating the Regulations Parliament erred in law in failing properly to take into account the test in Article 24(2) TPD which provides that when a Member State adopts measures in the field of standardised packaging it must take account of the "*high level of protection of human health achieved through this Directive*". It states:

> "This Directive shall not affect the right of a Member State to maintain or introduce further requirements, applicable to all products placed on its market, in relation to the standardisation of the packaging of tobacco products, where it is justified on grounds of public health, *taking into account the high level of protection of human health achieved through this Directive*".
>
> (Emphasis added)

(2) Claimants' submissions

885. Article 24(2) TPD requires Member States to take the high level of protection provided for by the TPD "into account". It is argued that the decision to adopt the Regulations was taken without any consideration being given to the possibility that implementation of the TPD would, in and of itself, be sufficient to achieve Parliament's aims and objectives. As such Parliament failed to have regard to a relevant consideration and erred in law. The time for assessment of the issue is said to be the date of promulgation of the Regulations. This is not a proportionality challenge hence (a) it is not open to the Secretary of State to rely upon evidence post-dating the adoption of the Regulations and/or (b) this is not a decision the Court can take for itself.

886. It is argued that the Secretary of State has not proven that implementation of the mandatory provisions of the TPD would not suffice to achieve Parliament's goals and the Secretary of State cannot meet his burden of proof unless he is able to produce evidence to show: (i) what level of health protection (i.e. effects on the intermediate outcomes and on prevalence and consumption) would be achieved by the measure required to be implemented under the TPD; and (ii) that the Regulations will achieve a higher level of health protection than the TPD. An important part of the purpose of the TPD was to reduce the attractiveness of packaging; increase the prominence of the health warning; and ensure that no misleading information could be included on packs (see Articles 9, 13 and 14 TPD). The extent to which those objectives will be achieved by the TPD, and would or would not be further advanced by the Regulations on standardised packaging was the question at issue. It could not be assumed. However, Stirling and Chantler never considered the question (see paragraphs [1.19] – [1.21] of Chantler). A significant part of Chantler's reasoning (concerning the evolution of branding in the absence of other forms of advertising) is striking for its failure to take account of the effects of the TPD: see paragraph [3.10]. Equally the Pechey experts (see paragraphs [139] – [142] above) were never asked the crucial questions (i) how much they considered that the TPD would affect prevalence or consumption in children or adults; and (ii) whether they thought plain packaging would have a greater effect, and if so, how much greater. The Australian evidence cannot assist either way.

887. In relation to the Irish study prepared by Professor Hammond which did address this issue this provides no answer since it post-dated the Regulations. In any event, the Defendant did not seek to dissent from the limitations in the single Irish study. The researchers themselves accepted that it was impossible to address the extent to which the identified flaws concerning the actual smoking habits of the age group concerned may have affected the results. If the question is asked: would the Regulations ever have been introduced on the strength of this piece of evidence? The answer is obviously that they would not. The only other response to this argument put forward by the Defendant is to rely on Annex E to the 2014 Impact Assessment. However, that annex is not sufficient to satisfy the burden on the Defendant since (a) that material was irrelevant to the intermediate outcomes and there was no evidence that plain packaging would have any greater effect on intermediate outcomes than the TPD packaging; (b) the baseline of the anticipated effects of TPD on consumption was derived from the EU's impact assessment relating to draft provisions which were different from those finally adopted; (c) for that reason, the Defendant decided arbitrarily to reduce the anticipated effects of the TPD on consumption by an amount that had no evidential foundation at all: it was a figure plucked from the air; and (d) that percentage applied to all age groups. The Annex E conclusion was then erroneously applied to the Pechey prediction for children. This was calculated to exaggerate the incremental impact of plain packaging, since Pechey anticipated a much greater effect on children than adults; (e) there was no evidence of the anticipated effect of the TPD on prevalence or consumption in children; (f) in the absence of such evidence there was no basis for any calculation of the additional benefits which might accrue from plain packaging. These defects were compounded by the unexplained failure to address the relevant issue with the Pechey experts at all, and by the high degree of uncertainty and wide range of their opinions.

(3) Analysis

888. This argument has been advanced essentially as a pure error of law though the Claimants added that even were there to have been an assessment the end result was irrational. It takes effect as a submission that the decision maker failed to address a relevant consideration. It is not therefore an argument that the Regulations are disproportionate because an equally effective yet less restrictive measure – i.e. implementation of the TPD itself – will achieve Parliament's objective. As such it does not turn on an assessment of the evidence generated after the decision was taken. In the text below I consider, first, the relevant standard of proof and, secondly, whether there is evidence that the effect of the TPD was taken into account.

(i) What is the standard of proof under Article 24(2) TPD?

889. Article 24(2) requires Member States to "*take into account*" the high level of protection provided for under the TPD. This limited duty is understandable since, under Article 24(2) TPD, it was contemplated that Member States might possibly adopt additional measures, such as standardised packaging, before the introduction of the TPD and as such when a Member State adopted additional measures there might be little if any evidence as to how effective the TPD would be. This might especially be the case because the effects of these sorts of measures may not be instantaneous and might take quite a long time to become evident. In the UK aspects of the TPD and the Regulations became effective upon the same day in May 2016 so it was therefore impossible for Parliament to know, with any degree of certainty, what the effect of the TPD would be when it promulgated the Regulations in 2015. The same applies as of the date of this judgment.

890. The Claimants however submit that the standard of proof upon the Secretary of State to prove that there would be health benefits over and above those achieved by the TPD is very high. They do this by reference to Article 114 TFEU. They argue that Article 24(2) represents a bespoke derogation from the harmonising provision in Article 24(1) which is analogous to the default derogation provisions at Article 114(4) and (5) TFEU and was drafted with Article 114 in mind, given the linguistic and substantive similarities between the provisions. It is said that Article 24(2) TPD, like Article 114 TFEU, reflects the particular care and scrutiny which must be applied by a Member State seeking to exceed the harmonised standard provided for under Article 24(1). Accordingly, the proper approach to Article 24(2) is strict since it is a derogation from the norm in Article 24(1) guaranteeing free movement for tobacco products that meet the requirements of the TPD. A State seeking to introduce stricter measures than those provided for in the TPD must be able to prove that the measures are justified with evidence that those stricter measures will achieve a higher level of health protection than that achieved by the Directive. Moreover, it is also a necessary part of the justification of such a measure that it must be shown that there is no less onerous means available which is equally effective to meet the objective pursued.

891. The Claimants cited Case T-198/12 *Germany v Commission* (14th May 2014) (which concerned the different procedure under Article 114 TFEU) at paragraphs [70] and [90] as authority for the proposition that Member States must "*ensure*" that the new measure is efficacious beyond that achieved by the TPD. Though it was also accepted (somewhat inconsistently) in their closing submissions that "*...there [was] room for argument about the degree of likelihood to which this must be established".* It will be

apparent from my opening observations on this argument that I do not accept the Claimants' submissions. They impose an impossible standard of proof on the Member State; something which Advocate General Jacobs in Case C-427/93 *Bristol Myers Squibb* (ibid) at page [3501] paragraph [103] (on the scope and effect of the TMD) described as an unacceptable and diabolical principle: "*None of the parties should be subjected to a probatio diabolica: that is to say, compelled to prove something which cannot be proved or can only be proved with the utmost difficulty*."

892. The present case is a very good illustration of just how very difficult it would be to prove what the Claimants argue must be proven. In particular it is very difficult to untangle the effects of one measure from the multiplicity of parallel counter-measures which are in place and this would include the TPD when its raft of new measures becomes effective. The duty on Member States to "*take into account*" the high level of protection provided for by the TPD cannot act as a duty to prove with exactitude that the TPD *will* be effective and/or that standardised packaging measures *will* provide incremental efficacy.

893. The obligation only to "*take into account*" the level of protection provided for by the TPD also makes sense in the context of an area of policy which: (a) is directly focused upon public health; (b) where the assessment of effects is predictive; and (c) where the exercise is precautionary. These are all factors which, in law, apply to the promulgation of the Regulations and they support the conclusion that a standard of proof requiring the degree of certainty demanded by the Claimants is not one supported by legal principle.

894. The Claimants' argument is redolent of that advanced and rejected in *Scotch Whisky* (ibid) in relation to the necessity limb of the proportionality test and, as set out at paragraphs [659] – [662] above, the Court of Justice made clear that Member States were not obliged to prove necessity with any degree of certainty and that a considerably lower standard of proof was sufficient. In paragraph [52] the Court of Justice accepted that it was for the Member State to decide on the level of protection of human life and health which they proposed to provide, for the purposes of Article 36 TFEU, whilst "***taking into consideration*** *the requirements of the free movement of goods within the European Union*" (emphasis added). Accordingly, in the context of a test whereby Member States had to *take account of* broader free movement rules the Member States nonetheless had a generous margin of appreciation including deciding upon the level of protection they wished to provide. And this translated into a standard of proof which whilst requiring specific evidence and proof (cf. paragraph [53]) did <u>not</u> extend to a requirement that Member States had to *"... prove, positively, that no other conceivable measure could enable the legitimate objective pursued to be attained under the same conditions..."*.

895. In my judgment taking into account the high level of protection means that the Member State must address itself to the issue and it must factor it into its analysis of the evidence. In conducting this exercise the Member States have a broad margin of appreciation and the level of the standard of proof must take into account that by its very nature the exercise is precautionary, predictive and related to public health.

(ii) The evidence taken into account by the Secretary of State

896. I turn now to the actual evidence taken into account by the Secretary of State.

897. It is evident from, *inter alia*, the terms of the 2014 Impact Assessment that consideration *was* in fact given, at a point of time prior to the promulgation by Parliament, to the existence of the level of protection set out in the TPD. This is explicitly recorded in paragraphs [17], [18] which are set out in Section C(14) above. I set out some of the principal illustrations of this.

898. The option of doing no more than await the introduction of the TPD was moreover specifically set out as one of the three options consulted over. Consultees were able to and did make submissions about this option. It was hence squarely put to consultees, as Option 1, that it sufficed to do nothing more than implement the bare minimum set out in the TPD. Paragraph 95 of the 2015 Impact Assessment, which introduced Option 1, thus stated:

> "Option 1: This constitutes the baseline against which standardised tobacco packaging is assessed. It incorporates all existing tobacco control measures currently in place and expected measures, including legislation to end the open display of tobacco products and the revised TPD which will be implemented in 2016. By definition, this option involves zero costs and zero benefits in this IA".

899. Next, the incremental effect that standardised packaging was intended to exert over and above the minimum set out in the TPD was also explicitly addressed based upon an impact assessment conducted by the European Commission. Paragraph 45 of the 2014 Impact Assessment thus stated:

> "In March 2014 the European Commission's revised Tobacco Products Directive (TPD) was officially adopted by the Council following its formal approval by the European Parliament in February 2014.25 Most of the new rules will apply in the first half of 2016 following a two year transposition period for Member States, of which the UK is one. The TPD covers how tobacco products are to be manufactured, produced and presented in the EU. The expected impact of the TPD on tobacco consumption used in this IA is around 1.9% reduction over five years. This value is derived from the European TPD IA (see Annex E). Whilst some of the requirements included in the TPD bear slight resemblances to the rules prescribed under standardised packaging, the TPD still allows for packaging to display logos, colours and brand images. Please see Annex E for a more detailed overview of the TPD requirements".

900. The assessment in Annex E referred to in the above quotation specifically focused upon the TPD. The assessment considered the area of overlap between the TPD and the proposed standardised packaging regulations (cf. paragraphs [368] and [369]); it pointed out that the EU impact assessment was itself based in significant part on the earlier UK research in 2007 on warnings and, as such, the UK was likely to have already experienced some of the reduction in smoking prevalence associated with larger visual health warnings, though it was also acknowledged that the UK warning was one sided whereas the TPD required two sided warnings (cf. paragraph [370ff]).

And it makes an assessment of the incremental benefits attributable to standardised packaging.

901. It follows from even this limited review of the evidence that the submission that no account of the TPD or the existing high level of protection reflected therein is unsubstantiated on the evidence. In relation to the Claimants' submission that, in any event, the Regulations are irrational: (i) As set out in paragraph [889] above at the date of their adoption it was impossible for Parliament to take account of the TPD when deciding to proceed to promulgate the Regulations; (ii) Parliament was entitled to adopt a precautionary approach and not therefore wait to see how effective the TPD proved to be over the ensuing years (see paragraphs [465] – [472] above); (iii) Parliament was entitled to take into account that under the FCTC and WHO Guidelines contracting States were urged to go beyond the mandatory measures in the FCTC, which essentially coincides with the mandatory provisions of the TPD. The Court of Justice in *Philip Morris* has reinforced the substantial legal significance of the FCTC and Guidelines in the formulation of national policy especially given the addictive nature of tobacco and its adverse impact upon children (see paragraphs [256] – [260]); (iv) The evidence base relied upon generally by Parliament was significant and pertinent in relation to the types of measure encompassed by the Regulations which is distinct from TPD type measures. I reject the submission of irrationality.

902. I should add that the incremental approach was also set out in a Report dated March 2014 prepared by Professor Hammond on behalf of the Department of Health in the Republic of Ireland in a consultation that it conducted during 2014. In that report Professor Hammond took account of the TPD. The Claimants say however that a report conducted in Ireland is irrelevant.

903. For present proposes whether that be a good point or not the fact remains that the fact that the issue *wa*s addressed is reflected in the 2014 Impact Assessment and since the gravamen of the objection is based upon misdirection it simply fails on the facts. In any event even if I had found that the ground was *prima facie* made out it necessarily falls away given that I have conducted an up to date analysis of the evidence so any prior misdirection is of historical interest only and of no materiality.

(4) Conclusion

904. In conclusion I reject the complaint that Article 24(2) TPD has been misapplied.

P. GROUND 12: PARLIAMENT HAD NO COMPETENCE (JURISDICTION) TO ADOPT THE REGULATIONS

(1) The issue

905. It is submitted that following the judgment in Case C-414/11 *Daiichi Sankyo Co. Ltd, Sanofi-Aventis Deutschland GmbH v DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon* (18th July 2013) *("Daiichi*") Parliament acted unlawfully in relying upon Article 24(2) TPD to introduce measures which concern the commercial aspects of trade marks and international trade. This is because, in the light of that judgment, any matter which concerns the common commercial policy and intellectual property

is reserved to the exclusive competence and jurisdiction of the EU to the exclusion, therefore, of measures of national law in those areas.

906. The Claimants argue therefore that the United Kingdom acted *ultra vires* EU law in adopting the Regulations and that it had no "competence" or jurisdiction to do so.

907. They advance this proposition even though; (a) Articles 7, 8, 17 and 20 of TRIPS; (b) A WTO Declaration of 2001; (c) the FCTC, and in particular Article 13 thereof; (d) the interpretation of the TMD (in its original and recast form) by the Court of Justice; (e) Article 110 of the CTMR (in its original and recast form); and (f) the TPD, all recognise that the use of trade marks may be curtailed by the Member States according to their own public interest considerations. See the analysis of those provisions in Section D above.

(2) Analysis: Shared competence or exclusive competence?

908. I do not accept this analysis for three reasons.

909. The first reason for rejecting the submission is that the TPD and the Regulations are primarily and overwhelmingly health measures adopted and it is this characteristic that governs legislative competence, not the fact that tangentially or secondarily the Regulations affect international trade and trade marks. This is clear from the recitals to the TPD itself and from the fact that in Article 1 it is stated that the purpose of the TPD is to implement the FCTC and it is also evident from the legal basis of the Regulations, namely Section 94 Children and Families Act 2014 (see paragraphs [241] above). The Regulations do not lose the character of a health measure (involving shared competence with the EU) simply because they cover, in part, other matters such as trade or intellectual property. It is well established in case law that if a particular measure pursues a two-fold aim then it is the "*main*" or "*predominant*" purpose which governs competence. The mere fact that an act has implications for international trade is not enough for it to become a matter of common commercial policy and hence the exclusive competence of the EU. This is clear from numerous judgments of the Court of Justice: See e.g. Case C-137/12 *Commission v Council* (22nd October 2013) at paragraphs [53] and [57] and Case C-491/01 *R (SSH) ex p. British American Tobacco* [2002] ER I-11550 at paragraphs [94] and [96]. Standardised packaging measures are thus "shared" competence matters even though they impact upon intellectual property rights. Common sense dictates this answer as well. If the trade mark tail were allowed to wag the health dog this would prevent the Member States from adopting any health measures which indirectly affected international trade. A health measure governing for instance ingredients in food or beverages or building materials would become a matter for the EU's exclusive competence simply because it affected a product in international trade. The purpose of the Regulations is health based, not trade mark based. This governs competence and the Member States have power to adopt measures such as the Regulations.

910. Second in *Philip Morris* the Advocate General and the Court of Justice both proceeded upon the basis that the exercise of the power under Article 24(2) TPD: (a) would inevitably involve an impact on trade marks and branding; but (b) was nonetheless a legitimate exercise of jurisdiction by Member States; because (c), this was an area of shared competence since it related to the internal market and health: see Advocate General's opinion paragraphs [118]-[120], Court of Justice paragraph

[219]. Indeed, the Court even contemplated the possibility (which had been advanced by the Claimants themselves) that standardised packaging measures to regulate and control tobacco might be better adopted by the Member States themselves (see ibid paragraph [221]). The argument now (belatedly) raised by the tobacco companies is inconsistent with the opinion and judgment of the Court of Justice in *Philip Morris*. The judgment confirms that adoption by Member States of standardised packaging rules which adversely affect trade mark rights represent areas of shared competence between the EU and Member States concerning the internal market and public health.

911. Third, and in any event, I do not accept that the ruling in *Daiichi* reverses the overwhelming conclusion to be drawn from the extensive array of international and EU legislative measures that I have referred to above which confer upon Member States the competence to restrict trade mark use in furtherance of public health. In *Daiichi* an issue arose as to whether a provision of TRIPS had direct effect because it fell within a field where the Member States had primary competence (cf. paragraph [40]). The Court considered whether TRIPS was, following the coming into force of the Lisbon Treaty, a matter of shared competence between the EU and the Member States or one of exclusive competence for the EU alone. The Court held that the effect of the Lisbon Treaty was that TRIPS was an aspect of the common commercial policy of the EU and that this fell within the exclusive legislative competence of the EU. It is argued that the conclusion which flows from this judgment is that Parliament had no jurisdiction to adopt the Regulations since this, in effect, trespassed into a field of jurisdiction (intellectual property and trade) over which the United Kingdom has, following the Lisbon Treaty, no competence. As such the Regulations are unlawful.

912. The actual ruling of the Court of Justice in *Daiichi* does not in my view support the Claimant's conclusion about it. Paragraphs [45ff] of the judgment, relied upon by the Claimants, are in the following terms:

> "45. In accordance with Article 207(1) TFEU, '[t]he common commercial policy shall be based on uniform principles, particularly with regard to changes in tariff rates, the conclusion of tariff and trade agreements relating to trade in goods and services, and the commercial aspects of intellectual property, foreign direct investment, the achievement of uniformity in measures of liberalisation, export policy and measures to protect trade … The common commercial policy shall be conducted in the context of the principles and objectives of the Union's external action.'
>
> 46. That provision, which entered into force on 1 December 2009, differs noticeably from the provisions it essentially replaced, in particular those in Article 133(1), (5), first subparagraph, (6), second subparagraph, and (7) EC.
>
> 47. It differs even more from the provision that was in force when the TRIPs Agreement was concluded, namely Article 113 of the EC Treaty (subsequently, after amendment, Article 133 EC). Paragraph 1 of that article stated that '[t]he common commercial policy shall be based on uniform principles, particularly in regard to changes in tariff rates, the conclusion

of tariff and trade agreements, the achievement of uniformity in measures of liberalisation, export policy and measures to protect trade'. Commercial aspects of intellectual property were mentioned neither in that paragraph nor in any other paragraph of Article 113.

48. In view of that significant development of primary law, the question of the distribution of the competences of the European Union and the Member States must be examined on the basis of the Treaty now in force (see, by analogy, Opinion 1/08 [2009] ECR I-11129, paragraph 116). Consequently, neither Opinion 1/94 ([1994] ECR I-5267), in which the Court established in relation to Article 113 of the EC Treaty which provisions of the TRIPs Agreement fell within the common commercial policy and hence the exclusive competence of the Community, nor the judgment in *Merck Genéricos – Produtos Farmacêuticos*, defining, at a date when Article 133 EC was in force, the dividing line between the obligations under the TRIPs Agreement assumed by the European Union and those remaining the responsibility of the Member States, is material for determining to what extent the TRIPs Agreement, as from the entry into force of the FEU Treaty, falls within the exclusive competence of the European Union in matters of the common commercial policy.

The concept of 'commercial aspects of intellectual property'

49. In accordance with Article 207(1) TFEU, the common commercial policy, which under Article 3(1)(e) TFEU falls within the exclusive competence of the European Union, relates inter alia to 'the commercial aspects of intellectual property'.

50. As follows from that provision, in particular the second sentence which states that the common commercial policy is within the context of 'the Union's external action', that policy relates to trade with non-member countries, not to trade in the internal market.

51. It is also common ground that the mere fact that an act of the European Union, such as an agreement concluded by it, is liable to have implications for international trade is not enough for it to be concluded that the act must be classified as falling within the common commercial policy. On the other hand, a European Union act falls within the common commercial policy if it relates specifically to international trade in that it is essentially intended to promote, facilitate or govern trade and has direct and immediate effects on trade (Opinion 2/00 [2001] ECR I-9713, paragraph 40; Case C-347/03 *Regione autonoma Friuli-Venezia Giulia and ERSA* [2005] ECR I-3785, paragraph 75; and Case C-411/06 *Commission* v *Parliament and Council* [2009] ECR I-7585, paragraph 71).

52. It follows that, of the rules adopted by the European Union in the field of intellectual property, only those with a specific link to international trade are capable of falling within the concept of 'commercial aspects of intellectual property' in Article 207(1) TFEU and hence the field of the common commercial policy.

53. That is the case of the rules in the TRIPs Agreement. Although those rules do not relate to the details, as regards customs or otherwise, of operations of international trade as such, they have a specific link with international trade. The TRIPs Agreement is an integral part of the WTO system and is one of the principal multilateral agreements on which that system is based.

54. The specific character of the link with international trade is illustrated in particular by the fact that the Understanding on Rules and Procedures governing the settlement of disputes, which forms Annex 2 to the WTO Agreement and applies to the TRIPs Agreement, authorises under Article 22(3) the cross-suspension of concessions between that agreement and the other principal multilateral agreements of which the WTO Agreement consists.

55. Moreover, when providing in Article 207(1) TFEU that the 'commercial aspects of intellectual property' are now fully part of the common commercial policy, the authors of the TFEU Treaty could not have been unaware that the terms thus used in that provision correspond almost literally to the very title of the TRIPs Agreement.

56. The existence of a specific link between the TRIPs Agreement and international trade justifying the conclusion that the agreement falls within the field of the common commercial policy is not rebutted by the argument of the governments which took part in the oral proceedings that at least the provisions of Part II of the TRIPs Agreement, concerning the availability, scope and use of intellectual property rights, which include Article 27 of the agreement, fall within the field of the internal market, by virtue in particular of Articles 114 TFEU and 118 TFEU.

57. That argument does not take sufficient account of the objective of the TRIPs Agreement in general and Part II of the agreement in particular.

58. The primary objective of the TRIPs Agreement is to strengthen and harmonise the protection of intellectual property on a worldwide scale (Case C-89/99 *Schieving-Nijstad and Others* [2001] ECR I-5851, paragraph 36). As follows from its preamble, the TRIPs Agreement has the objective of reducing

> distortions of international trade by ensuring, in the territory of each member of the WTO, the effective and adequate protection of intellectual property rights. Part II of the agreement contributes to attaining that objective by setting out, for each of the principal categories of intellectual property rights, rules which must be applied by every member of the WTO.
>
> 59. Admittedly, it remains altogether open to the European Union, after the entry into force of the TFEU Treaty, to legislate on the subject of intellectual property rights by virtue of competence relating to the field of the internal market. However, acts adopted on that basis and intended to have validity specifically for the European Union will have to comply with the rules concerning the availability, scope and use of intellectual property rights in the TRIPs Agreement, as those rules are still, as previously, intended to standardise certain rules on the subject at world level and thereby to facilitate international trade.
>
> 60. Consequently, as the Commission observes, to regard the rules on patentable subject-matter in Article 27 of the TRIPs Agreement as falling within the field of the common commercial policy rather than the field of the internal market correctly reflects the fact that the context of those rules is the liberalisation of international trade, not the harmonisation of the laws of the Member States of the European Union.
>
> 61. In the light of the above considerations, the answer to the first part of Question 1 is that Article 27 of the TRIPs Agreement falls within the field of the common commercial policy".

913. Applying the principles set out above the following conclusions arise. First, as is evident from paragraph [59] it is open to the EU to legislate in the area of the internal market - which is explicitly an area of shared competence between the EU and the Member States - in a manner which impacts upon intellectual property provided that this is consistent with TRIPS and the mere fact that intellectual property is touched upon is not sufficient to make a measure one for the exclusive competence of the EU. As the Court explained when the EU legislates its rules *"... will have to comply with the rules concerning the availability, scope and use of intellectual property rights in the TRIPs Agreement"*. TRIPS makes it abundantly clear that the scope and effect, including usage, of intellectual property rights may be subject to limitations on grounds of public health; and the TPD which is an internal market (shared competence) measure expressly aspires to be compliant with relevant international law obligations (such as TRIPS): see Recital [59]. Accordingly in principle provided that the TPD is consistent with TRIPS it can perfectly lawfully reserve or delegate to the Member States the power to act in relation to trade marks; and it would follow from *Daiichi* that provided the national measures are themselves consistent with TRIPS then, again, there is no ground for asserting that they are illegal or *ultra vires*.

914. Second, the Claimants assume - wrongly: (i) that when the EU does initiate legislation in an area where it enjoys exclusive competence and, in exercising its discretion, leaves certain matters to the Member States that this is not the exercise by the EU of its exclusive competence. Exclusive competence prevents the Member States initiating legislation but it does not prevent the EU, in accordance with the overriding principle of subsidiarity, choosing to exercise its exclusive power by then delegating certain measures to Member States. There is thus a distinction to be drawn between the EU initiating legislation which includes a power to delegate and the Member State initiating regulation. The common commercial policy of the EU, by Article 207(1) TFEU, "*shall be conducted in the context of the principles and objectives of the Union's external action*". Article 207(6) TFEU then explicitly provides:

> "6. The exercise of the competences conferred by this Article in the field of the common commercial policy shall not affect the delimitation of competences between the Union and the Member States, and shall not lead to harmonisation of legislative or regulatory provisions of the Member States in so far as the Treaties exclude such harmonisation".

(3) The Regulations are compatible with TRIPS (Article 15(4))

915. It follows from the earlier parts of this judgment that I am of the view that the Regulations are consistent with TRIPS. For the sake of completeness however I address a contrary argument advanced by the Claimants based upon Article 15(4) TRIPS which provides that: "*The nature of goods or services to which a trade mark is to be applied shall in no case form an obstacle to registration of the trade mark".* It is argued that this reflects the broad principle that intellectual property protection does not depend on whether the goods or services can actually legally be sold or provided within a country and it prohibits any discrimination with regard to the availability of trade mark protection based on the particular types of products or services involved[33]. The Claimants cite in support the dictum of the Court of Justice in Case C-533/06 *02 Holdings Ltd v Hutchinson* 3G *UK Ltd* (12th June 2008) at paragraph [66] to the effect that : "*...once a mark has been registered its proprietor has the right to use it as he sees fit... ".* The nub of the point is that (a) the nature of a product is irrelevant to its registration and (b) once registered the principle of non-discrimination as between types and categories of product means that it is unlawful to impose product specific restrictions on the use of tobacco related trade marks compared with (say) pens or paint or foodstuffs or baby clothes, etc. The net effect of this argument is very similar to the argument advanced by the Claimants under Ground 7 (see section K above and in particular paragraph [825]) which is that in law there is an untouchable and inalienable right and freedom for the tobacco manufacturers to use their trade marks, quite irrespective of whether that actual use of the trade mark, *in causal terms*, exerts a toxic and lethal impact upon vulnerable consumers.

916. It is apparent that I do not agreement with the Claimant's analysis. I now summarise my reasons why:

[33] Based upon: (i) "The TRIPS Agreement, Drafting History and Analysis" (Gervais, 3rd edition (2008) page [270]; and (ii) "Trade Related Aspects of Intellectual Property Rights, A commentary on the TRIPS Agreement, Correa, 1st edition (2007) page [182].

i) Article 15(4) TRIPS is expressly drafted in terms of rights to registration only; it is silent as to the rights which thereafter flow from registration. Article 16 TRIPS makes clear that the most elemental, bottom line, right attached to a registered trade mark is the right to exclude third persons from using the trade mark (see paragraph [177] above). Regulation 13 (set out at paragraph [249] above) protects both the right to registration and the right to exclude (see analysis of Regulation 13 under Ground 10, Section N at paragraphs [870]-[883] above) and ensures consistency between the Regulations and TRIPS. As to rights of use Article 16 TRIPS does no more than afford to the Contracting States the "*possibility*" that they should extend the basic right to use rights, and in the EU and in the UK no such extension has occurred (see Section D(4) and (5) above).

ii) As to the rights which flow from registration Article 7 TRIPS (see paragraph [178] above) stipulates that "*protection*" and "*enforcement*" should contribute in a manner conducive to "*social ... welfare*". On the Claimants' interpretation if the Contacting States cannot draft product specific legislation in the health field (which applies to particular products but not others) then TRIPS confers upon the tobacco companies a degree of "*protection*" which is profoundly harmful to social welfare, contrary to the sprit and intent of TRIPS.

iii) Article 8(1) TRIPS (see paragraph [179] above) permits Contracting States when they formulate their laws to adopt "*measures necessary to protect public health*". The Regulations do this. However, on the Claimants analysis, such legislation may not be adopted even though it is or may be both (i) necessary and (ii) directly related to the protection of public health (both of which are conclusions that I have arrived at on the facts of the present case in relation to the Regulations: See analysis under Grounds 3 and 4, Sections G and H above). In my view the Regulations are measures which balance trade mark rights with public health protection in the manner contemplated by Article 8 TRIPS and they are consistent therewith.

iv) The DOHA Declaration 2001 on the relationship between TRIPS and public health states that *"...the TRIPS Agreement does not and should not"* prevent Contracting States from taking measures to protect public health. Under the Vienna Convention (on the Law of Treaties) this is relevant as a guide to the construction of TRIPS (see paragraphs [180] - [182] above). On the Claimants' construction however TRIPS does hinder the adoption of public health measures and should be construed so as to preclude such health measures, which is inconsistent with the DOHA Declaration principles.

v) Article 17 TRIPS (see paragraph [183] above) permits Contracting States to make "*limited*" exceptions to the rights conferred. The example given is "fair" use of descriptive terms, but this is illustrative only. Any such exception must "*take account of the legitimate interests of the owner of the trade mark and of third parties*". On its face Article 17 permits of derogations to trade mark rights but the Claimants submit that "*limited*" means, in essence, small and certainly not limitations by category or type.[34] In my judgment Article 17 must

[34] The Claimants cite various WTO panel decisions which suggest that limited means "*make only a small diminution of the right in question*" and that an "*exception which results in a substantial curtailment*" of the rights conferred cannot be

be read in conjunction with and take account of the remainder of TRIPS which includes all of the other provisions cited above. It cannot be construed as stripping from Contracting States the right to adopt necessary and proportionate health measures The exception created by the Regulations preserves registration and the right to exclude and strikes a proportionate (and hence necessary) balance between the interests of rights owners and third parties. The Regulations are thus carefully drafted so as to be "limited" to that which is necessary.[35]

vi) The Claimants submit that TRIPS takes precedence over the FCTC. In my view they must be read consistently one with the other and this is done by rejecting the Claimants construction which otherwise effectively emasculates the FCTC. There is nothing in ordinary principles of international law (cf. Article 30 of the Vienna Convention on the interpretation of successive treaties on the same subject matter) which would require the FCTC to be read down in this way.

vii) The reliance placed upon the observation in the ruling of the Court of Justice in *02 Holdings Ltd v Hutchinson* 3G *UK Ltd* that once registered a proprietor may use a trade mark "*as he see fit*" reads too much into an observation made by the Court which was not intended to suggest that the use of a trade mark under the TMD could not in any way be fettered because of TRIPS, and was in any event concerned with a question referred by the High Court which was about a very different matter under Article 5(1) TMD. The difference in context is evident from the terms of the question asked on the reference from the High Court: "Where a trader, in an advertisement for his own goods or services, uses a registered trade mark owned by a competitor for the purpose of comparing the characteristics (and in particular the price) of goods or services marketed by him with the characteristics (and in particular the price) of the goods or services marketed by the competitor under that mark in such a way that it does not cause confusion or otherwise jeopardise the essential function of the trade mark as an indication of origin, does his use fall within either (a) or (b) of Article 5[(1)] of Directive 89/104?"

viii) Finally, as to the submission that TRIPS incorporates an immutable and unyielding principle of non-discrimination as between different categories of goods and services there is nothing in TRIPS or Article 15(4) to this effect.

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considered a "limited" right: citing Canada – Patent Protection of Pharmaceutical Products WT/DS/114/R. That case concerned Article 30 TRIPS and was brought by the EU and alleged that Canada, by allowing manufacturing and stockpiling of pharmaceutical products without the consent of the patent holder during the six months immediately prior to the expiration of the 20-year patent term by virtue of the provisions of Section 55.2(2) and 55.2(3) of the Patent Act together with the Manufacturing and Storage of Patented Medicines Regulations, violated its obligations under Article 28.1 together with Article 33 of the TRIPS Agreement. Article 30 is entitled *"Exceptions to Rights Conferred*"; it is in different terms to Article 17, albeit that it includes the expression "limited exception" (as in Article 17) and it provides: *" Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties*." The WTO was dealing with a very different set of circumstances and arguments to those arising in the present case.

[35] On necessity the Claimants cite the WTO Appellate Body *in Korea - Measures Affecting Imports of Fresh Chilled and Frozen Beef*, WT/DS 161/AB/R at paragraph [161] where the Body observed that in its view "*necessary*" was closer on the continuum from "*indispensable"* to "*making a contribution to*", to indispensability. In *United States – Measures Affecting the Cross-Border Supply of Gambling and Betting Services* WT/DS 285, A/ R at paragraph [308] the WTO Appellate Body stated that something was "*necessary*" if there was no "*reasonable alternative*", thereby importing a principle of reasonableness into the concept. I do not read these ruling as inconsistent with a properly rigorous proportionality test.

> The latter by its express terms is concerned with registration only and not use and to the extent that it implicitly goes beyond registration and covers subsequent use, nothing in case law or literature states that such a principle would prevent differences in treatment of use based upon objective factors, such as public health. It stands to reason that not every product or service which is covered by a registered trade mark exerts the same impact upon health and TRIPS is not to be construed as preventing the adoption by Contracting States of focused and proportionate legislative measures which curb the use of *specific* product specific trade marks where those trade marks, but not others, cause harm to health.

(4) Conclusion

917. In short; the TPD is an internal market measure which involves shared competence with the Member States who quite plainly have a power to introduce standardised packaging which by its very nature will fetter the use to be made of trade marks and other intellectual property rights. This is evident from a perusal of the TPD itself and is confirmed by the ruling of the Court of Justice in *Philip Morris*. The Regulations are, moreover, consistent with TRIPS.

918. It follows that this ground of challenge fails.

Q. GROUND 13: ALLEGED UNLAWFUL CONSULTATION

(1) The issue

919. This ground was advanced by BAT alone.

920. At the outset of this litigation in its written submission BAT submitted that the consultation exercise conducted by the secretary of State was a "*sham*", that it smacked of predetermination, and that the Government had a "*crusade*" against the tobacco companies. In oral submissions this was toned down and three particular and narrow issues only were advanced for determination. I need deal only with two of the complaints in this section since I have addressed the complaint that only "limited" weight was accorded to BAT's evidence under Ground 2. The two matters left for determination are as follows.

921. First, an alleged unfairness in the fact that a particular report - the "Hammond Ireland" Report had not been made a formal part of the consultation process in the United Kingdom even though it had acquired a significant importance and had been specifically included in the submissions made to the Secretary of State in the December 2014 Submission (see paragraphs [125] – [134] above).

922. Second, that the civil servants had unfairly downplayed the expert evidence of BAT by omitting it from the material submitted to the Minster as part of the December 2014 Submission.

(2) The law on consultations

923. The law on consultations was not materially in dispute. The core principle of application to this case can be stated very briefly. First, where a decision is to be taken

following a consultation then it must be performed fairly. Secondly, one aspect of the duty of fairness in this connection is the duty on the part of the decision maker to review and consider the evidence submitted conscientiously.

(3) The Hammond Ireland report

924. The first submission is that the Hammond Ireland Report was given considerable weight by the Defendant. It was treated as of probative value and it was specifically included with the papers submitted by civil servants to the Minister in the December 2014 Submission. However it was not, but should have been, made a formal part of the consultation process and, in effect, put out to consultation for all affected persons to comment upon. It is said that this amounts to vitiating unfairness.

925. This submission is not tenable. The Hammond Ireland Report was commissioned by the Government of Ireland as part of its own review into the adoption of restrictions upon tobacco advertising. Professor Hammond, in relation to Ireland, played a role which was described by Mr Eadie QC for the Secretary of State as similar to that played by Sir Cyril Chantler in the United Kingdom.

926. However his report was dated March 2014 and was placed into the public domain by publication on 16th June 2014. There is no evidence before the Court that BAT was unaware of the Report or did not have it squarely on its radar or was in any way prevented from advancing submissions about it. Indeed, it is hard to see how it could have overlooked the Report. Further, anyone who reads the Hammond Ireland Report will immediately have understood that it was relevant. There is no evidence that BAT was unaware of the Report. BAT has not adduced evidence upon this to suggest otherwise. The tobacco companies were not shy about making submissions to the Government and they did so even after the formal expiry of the consultation exercise. BAT had the chance to make submissions about Hammond Ireland. For whatever reasons it chose not to.

927. I reject the submission that the Secretary of State was bound, specifically, to put out for consultation the Hammond Ireland Report. It was a document generated for a third state which was in the public domain. There was no unfairness in the Secretary of State's leaving it up to consultees to decide whether to make submissions about it.

928. In any event I can see no way in which even if there was a breach any prejudice arose. BAT was in possession of the Hammond Ireland Report before Parliament promulgated the legislation. BAT had ample chance to put in submissions on this right up until the issue came before Parliament and as is clear from a reading of the Hansard debates there were many parliamentarians who spoke out on behalf of the tobacco companies and who quite apparently would have been ready to advance a proper argument in relation to this point.

(4) Civil Servants gave BAT's expert evidence insufficient weight or prominence in the submission to Ministers

929. The second submission was that the Secretary of State erred in that when civil servants were drafting the December 2014 Submission to Ministers they attached insufficient prominence or coverage to the expert reports of BAT. This was a different argument to the complaint about the "limited" weight attached to BAT's evidence and

focuses upon the prominence of BAT's evidence (or rather the lack of it) as presented. It was submitted to me that what differentiated BAT from the other tobacco companies was the volume of expert material submitted in the consultation exercise.

930. First, in so far as it was the view of the civil servants that BAT's expert evidence did not warrant extra or particular weight this was justified: See Ground 2 above.

931. Second, and in any event, there is in fact no hint in the December 2014 Submission that any such view on the part of the civil servants was in fact incorporated into the final submission to the Minister. In any event it is quality and not quantity that counts. Quantity alone cannot sensibly equate to a right to greater representation in a final submission. If this were otherwise then all consultees would be perversely incentivised to flood the decision maker with paper in order to secure greater prominence in the final submission to Ministers.

932. Third, on a fair reading of the final submissions to Ministers, BAT had ample representation of its views. This can be seen from the fact that its submissions were specifically annexed and its expert views were also summarised, along with those of the other tobacco companies whose views it shared. It is significant that no other Claimant has supported BAT in this complaint. There is no basis for submitting that BAT's point of view was not conveyed to Ministers. It was submitted alongside other evidence some of which was consistent and supportive (for example that of the other Claimants) and some of which was inconsistent and hostile. In oral submissions it was suggested that BAT's points were submerged amongst the welter of other evidence, i.e. that in the noise its views were drowned out. The implication of this seems to be that the civil servants should have been more selective and, in their selection, have given greater prominence to BAT than to other tobacco companies. This is unsustainable. This submission was cast at the highest level of generality and did not descend at any point to a detailed, forensic, analysis of the submission in order to support a contention that in particular respects and ways the document conveyed an inaccurate or unfair impression or view.

R. GROUND 14: THE REGULATIONS INFRINGE ARTICLE 34 TFEU

933. The Claimants contend, albeit lightly, that the Regulations infringe Article 34 TFEU which prohibits quantitative restrictions and measures of equivalent effect upon imports. It is submitted that the Regulations will deter imports of legitimate product coming into the United Kingdom. Pursuant to Article 36 TFEU Member States may justify restrictions upon grounds, *inter alia*, of "*the protection of health and life of humans*". The Claimants accept that the Regulations are concerned with this objective and that the only question is whether the Regulations were in fact justified on such grounds. In their written and oral submissions before the Court the Claimants did not develop this argument. They did, however, refer to the way in which the point was put in their initial pleaded Grounds served at the outset of the litigation. There, the Claimants advanced arguments which, in effect, are subsumed within the other Grounds relating, in particular, to proportionality. The particular points raised at that stage included the following: First, the decision to introduce standardised packaging was premature given the extant reference to the Court of Justice; second, the experience of standardised packaging in Australia established that the Regulations would have no meaningful effect upon prevalence levels; third, the Regulations would be ineffective and counterproductive because they would lead to the growth of illicit

trade; and fourth, the 2014 Impact Assessment undervalued the loss in brand value to the Claimants and this was relevant to the fourth balancing limb of the proportionality test.

934. All of these matters are in any event addressed under other Grounds, where I have rejected them. It necessarily follows that I reject the Ground based upon Article 34.

S. GROUND 15: THE FAILURE TO AWAIT THE OUTCOME OF THE REFERENCE IN *PHILIP MORRIS*

(1) The issue

935. I propose to address this ground briefly; in my view it is not sensibly arguable. It was addressed in writing but not orally. The Claimants submit that Parliament acted illegally (irrationally) in not delaying the introduction of the Regulations pending the outcome of the reference to the Court of Justice in *Philip Morris* on the validity of Article 24(2) TPD. The challenge is as to the decision taken to promulgate the Regulations and is a classic judicial review challenge and must be assessed as of the date of the impugned decision.

936. I propose to analyse the position from the perspective of strict law i.e. as of the date of the decision. Given the passage of time and the fact that in the event this judgment post-dates the judgment of the Court of Justice the issue has become moot. Nonetheless, since the point is potentially of some broader significance I will address it.

(2) Claimants' submissions

937. The position of the Claimants is as follows. It was said that as of the date of promulgation of the Regulations the Court of Justice could be anticipated to give judgment in early 2016. If Article 24(2) was found to be invalid, Parliament would have no power to make the Regulations because they would be incompatible with the remaining provisions of the TPD harmonising the regulation of tobacco products sold in the EU.

938. This was apparently acknowledged by the Under-Secretary of State before the House of Commons European Scrutiny Committee on 17 July 2013. By letter dated 7 January 2015, ITL sought confirmation that no steps would be taken to introduce the then draft Regulations until the issues regarding the lawfulness of Article 24(2) had been determined by the Court of Justice. The letter noted that the introduction of the Regulations could expose the UK Government to significant damages claims, and set out the significant detrimental and, it was said, irreversible effects that would follow from the introduction of standardised packaging, including: the significant costs to ITL and the other tobacco manufacturers (including, in particular, the loss of brand equity and goodwill, which were worth billions of pounds); the broader implementation costs that would be felt across the economy and in particular in the manufacturing and retail sectors; and the significant boost to illicit trade. The Government responded on 20 February 2015. The letter confirmed that the Minister proposed to lay regulations for standardised packaging before Parliament to allow time for them to come into force at the same time as TPD. The letter noted "*the UK is*

under an obligation to implement the [TPD] in any event, and must therefore be ready to implement the [TPD] by 20 May 2016".

939. The Regulations were tabled three days later, on 23 February 2015. Against this background, it is argued that it was irrational to decide to make the Regulations in circumstances where there was an extant challenge to the only provision (Article 24(2)) that could provide an adequate legal basis for the Regulations, and regardless of the risk that: (i) Article 24(2) could be found to be invalid by the Court of Justice; (ii) the introduction of standardised packaging would in that event be unlawful; and (iii) the UK would then be exposed to significant *Francovich* damages claims.

(3) Analysis and Conclusion

940. Was the decision of Parliament irrational in these circumstances? The answer is clearly "no".

941. No application was made in the present case for interim relief to prevent Parliament from promulgating the Regulations. Indeed, no application was even made to me to stay the giving of *this* judgment pending the ruling of the Court of Justice and it was on my initiative that I raised the issue of timing with the parties as work progressed on drafting this judgment and the date for the coming into force of the Regulations loomed.

942. This challenge is as to the rationality of the decision to implement the Regulations. As is clear from the 2014 Impact Assessment Parliament, in adopting the Regulations, made a judgment call that the health benefits of introducing the measures forthwith outweighed the risks of delay. As such there was a balance to be struck. The view was taken in the assessment, which it can be assumed Parliament shared, that real and tangible public interest benefits to the health of children and young adults and older consumers could be lost if the Regulations were delayed (for example to await further information and data from Australia); further that any delay could have adverse long term repercussions for the public purse. In other words given the importance of the issue every day of delay risked serious adverse societal costs. This was the value judgment that Parliament made.

943. The downside of not delaying was, of course, that <u>if</u> Article 24(2) had been struck down and if, in consequence, any national measure on standardised packing had become unlawful, then the tobacco companies would have had to alter their advertising in a manner harmful to them and as was accepted during the hearing this risked hitting the tobacco companies' profits.

944. These are the relevant competing interests. In forming a view upon the balance of these interests Parliament acted rationally.

945. As for the losses sustained by the tobacco companies on the timescales predictable as of the date of the decision to promulgate the Regulations the actual amount of time that the tobacco companies would sustain losses for was likely to be short. Even then it could be anticipated, by reference to the normal time-scales for a reference to the Court of Justice to be heard and ruled upon, that the Court of Justice might very well have ruled by the time of the implementation of the TPD. And as such if the Court of Justice had declared Article 24(2) to be invalid the position would be known and the

Secretary of State would have had to work out his position in the light of the judgment; and of course if Article 24(2) was upheld then the issue would disappear. But even if at the time it was predictable that the ruling would post-date the coming into force and effect of the Regulations if loss was in fact sustained it is the tobacco companies' stated position that they could recover for any loss by claiming damages from Parliament[36].

946. Weighing these competing interests indicates clearly that the decision of Parliament was rational. Parliament acted on a precautionary basis treating public health as superior on the facts to the risk of lost tobacco company profits. I can conceive of no test of judicial review, howsoever strict and intensive, which would lead to the conclusion that in these circumstances Parliament would be bound to refrain from pursuing its preferred course in order to save some hypothetical lost profits on the part of tobacco companies.

947. As a matter of case management the logical solution for the Tobacco Claimants would have been to await the turn of events and if it emerged that the ruling of the Court of Justice was likely to post-date the coming into effect of the Regulations then to consider seeking a stay of the Regulations pending the ruling. That was an ongoing option which was open to the Claimants from the outset of the litigation and the fact that such an option was available amounts to a further reason why Parliament acted rationally in not awaiting the ruling. There was no need to delay because if the matter truly became acute a remedy lay in the hands of the Claimants.

948. For all of these reasons this ground of challenge fails.

T. GROUND 16: THE TIPPING PAPER CHALLENGE: REGULATION 5 IS *ULTRA VIRES*

(1) The issue

949. The Tipping Claimants produce tipping paper either within the UK or the EU. This is the paper part that wraps around the filter and joins the filter to the tobacco rod. The Claimants challenge the validity of Regulation 5 of the Regulations. The text of Regulation 5 is set out at paragraph [248] above. This restricts the permissible colour of tipping paper to either a plain white or cork-effect and it prohibits all branding, save for the identification of the cigarette brand and variant in 8 point, Helvetica font. The effect will be to prohibit a substantial portion of the range of tipping paper presently manufactured by the relevant Claimants and their output will henceforward be restricted to these two basic styles. The Tipping Claimants, in summary, advance four main points.

950. First, Regulation 5 is *ultra vires* Article 24(2) TPD which is limited to packaging and not to the product itself. Tipping paper is not part of the packaging of a cigarette but, rather, an integral part of the cigarette product itself. The distinction between the packaging of cigarettes and the appearance of cigarettes is clear from the ordinary meaning of the language used in the TPD. This distinction is evident from the *travaux préparatoires* to the TPD which is valid as a guide to interpretation of the TPD itself

[36] I express no view as to the merits or otherwise of the prospects of any such claim for damages.

and, therefore, to the Regulations which must be construed to be consistent with the Directive. Regulation 5 is therefore invalid as *ultra vires* the TPD.

951. Second, the Defendant's claim that Regulation 5 will improve public health by reducing the number of smokers is incapable of being proven. There is no evidence to demonstrate that restricting the colour of tipping paper to white and cork-effect, and restricting brand names to a Helvetica 8 point font, will make any contribution towards the public health aim sought to be achieved by the Regulations. The Defendant's claim that plain or cork-coloured tipping paper is justified on public health grounds is unsubstantiated pure assertion.

952. Third, (and in common with the other Claimants) the Tipping producers submit that the Regulations will be counterproductive. In particular, studies indicate that the tip colours required by Regulation 5 are precisely those that are likely to have the *greatest* appeal to smokers.

953. Finally, Regulation 5 will facilitate the counterfeiting of cigarettes and thereby thwart the avowed health objective.

(2) The Tipping producers

954. The Tipping Claimants produce tipping paper in the UK (Tann UK and Benkert UK), Austria (Tannpapier) and Germany (Deutsche Benkert). Tipping paper production is said to be a complex and sophisticated process. The image to be displayed on the paper is etched onto the surface of a cylinder, that cylinder is then rotated through an ink fountain, and the surface of the cylinder is scraped, leaving the ink to be transferred onto the paper within the cylinder's recesses. The paper is then pressed to the cylinder and the image is transferred to the paper. The paper is dried at particular temperatures which take account of the inks and printing substrates being used. Each individual product may require the use of several different inks. After the initial printing process, the paper may also be subject to foiling, perforation and embossing. The evidence indicates (and this is not challenged by the Defendant) that the Claimants have invested in product innovation within the tipping paper market and seek intellectual property protection for the fruits of their endeavours. For instance the Tann companies alone have 32 patents registered around the world. These Claimants produce a diverse product range that is said to include at least 8,000 different colours, textures and designs of tipping paper. The evidence indicates that the range includes multi-coloured products (up to five colours), electrostatic and micro/macro laser perforations, and hot foil stamping. Their turnover is tens of millions of Euros each year, with the European market accounting for the majority of that turnover. The two key "inputs" into the printing process (other than the paper itself) are ink and the print cylinders.

(3) The Tipping Claimants' submissions on the scope and effect of the Regulations in relation to tipping paper

955. The nub of the complaint is that tipping paper is not "packaging" as that term is defined in the TPD. Article 24(2) applies only to measures concerning the standardisation of the *"packaging of tobacco products"* which tipping paper is not. The word *"packaging"* does not encompass the product that is being packaged and the common meaning of the phrase cannot therefore extend to the constituent parts of

the cigarette itself. Further, the TPD distinguishes in its language between packaging and the tobacco product itself. Article 1 TPD thus, in setting out the objectives of the Directive, distinguishes between *"tobacco products*", in respect of which, for example, the Directive regulates the ingredients and emissions, and the *"labelling and packaging of tobacco products"*, in respect of which the Directive regulates certain matters such as the health warnings that have to appear on that packaging.

956. Article 2 separately defines *"tobacco products"*, *"outside packaging"* and *"unit packet"*. The TPD clearly specifies where the relevant provision applies to the physical tobacco product itself. This is so in relation, for instance, to the rules on emission levels which relate to the product or in contrast the requirement to carry health warnings which concerns the packaging.

957. The distinction is also evident in the provisions that refer to both the tobacco product and the packaging of the product. Thus Recital 27 provides that:

> "*Tobacco products or their packaging* could mislead consumers, in particular young people, where they suggest that these products are less harmful. … *Certain packaging and tobacco products* could also mislead consumers by suggesting benefits in terms of weight loss, sex appeal, social status, social life or qualities such as femininity, masculinity or elegance. Likewise, the size and appearance of individual cigarettes could mislead consumers by creating the impression that they are less harmful".
>
> (Emphasis added)

958. Article 13 (which corresponds to Recital 27) provides that the *"labelling of unit packets and any outside packaging and the tobacco product itself"* must not include any element or feature that promotes a tobacco product or its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions, or suggests that a particular tobacco product is less harmful than others.

959. The tipping Claimants also point out that the European Impact Assessment accompanying the TPD did not suggest that cigarettes themselves were intended to fall within the scope of the term "*packaging*". Rather it defined "*plain packaging*" as:

> "full standardisation of the packages, including brand- and product names printed in a mandated size, font and colour on a given place of the package; standardised package colour; standardised size and appearance of the package; display of required (textual and pictorial) health warnings and other legally mandated product information, such as tax-paid stamps and marking for traceability and security purposes".

960. The European Impact Assessment also, when setting out possible policy options within the TPD, described plain packaging as something distinct from regulating the appearance of "FMC" (Factory Manufactured Cigarette) sticks. Option 2 was thus described as: "*Option 1 plus: 1) The tobacco labelling and packing and the tobacco*

product itself shall not include any promotional and misleading elements (e.g. misleading colours, symbols, slim FMC)…" (emphasis added).

961. Option 3 was described as: "*Option 2 plus: standardised colour, font, size and position of brand name and brand variant on packages (plain packaging) and a readable health warning on each FMC stick*".

962. Next it was contended that the *travaux preparatoire* also distinguished between the packaging and the products themselves. Section 3.2 of the Explanatory Memorandum accompanying the Commission's proposal for the TPD stated that:

> "… Packaging of tobacco products, or the products themselves, shall not include any elements that promote tobacco products or mislead consumers to believe that the product is less harmful than others, refers to flavours or tastes or resembles a food product. The proposal also includes requirements for packages, e.g. cuboid shape for cigarette packages and minimum number of cigarettes per package".

963. Under the proposal, Member States retained the power to regulate the area of the package not regulated by the directive or other EU legislation, including implementing provisions providing full standardisation of packaging of tobacco products (including colours and font), as far as these provisions were compatible with the Treaty.

964. Finally, the Tipping Claimants rely upon the market context which is that the packaging industry is distinct from the tipping paper industry, and businesses that operate within one field do not cross-over into the other.

(4) Analysis and conclusions: The construction of the TPD – does it contain a power to regulate advertising *on* tobacco products?

965. My conclusion on these issues (which I elaborate upon below) is as follows. First, the phrase "packaging" in the Regulations is undefined and ambiguous; however, when read purposively in the light of the FCTC it means all that which covers, surrounds or encases tobacco. This includes tipping paper. Second, even if that is wrong, nothing in EU law would prevent Member States from introducing an extra restriction on advertising and branding <u>on</u> tobacco products as an anti-avoidance measure to increase the *effet utile* of the restrictions on packaging. Third, and even if the first two arguments are wrong, the TPD is a measure of partial harmonisation such that it is open to Member States to introduce restrictions going beyond the TPD, including therefore <u>on</u> tobacco products. In order to determine the proper scope of the TPD I address the following series of questions which breaks the issue down into its constituent components: (i) Whether the FCTC embraces as part of its overall policy the regulation of advertising and promotion *on* tobacco products themselves; (ii) whether that policy has been adopted by the EU and incorporated into the TPD; and (iii) whether the substantive provisions of the TPD on standardised packaging reflect that policy, applying an appropriate approach to interpretation; (iv) whether even if Article 24(2) does not cover the product itself the Member States have the power/competence in law to legislate in relation to the product either because this is not a field covered exclusively by the TPD and/or because it is necessary to prevent

circumvention of rules prohibiting advertising on outer packaging and to protect the *effet utile* of such rules.

(i) First question – the purpose of the FCTC includes the suppression of advertising, including trade marks, on the tobacco products themselves

966. In relation to the first question it is clear both from the terms of the FCTC and from the Guidelines thereto that there is a strong policy imperative in the "*comprehensive*" suppression of all advertising irrespective of whether it is on tobacco products or on the packaging that surrounds the product. The Guidelines to Article 13 thus state as guiding broad "principles":

> "The following principles apply:
>
> (a) It is well documented that tobacco advertising, promotion and sponsorship increase tobacco use and that comprehensive bans on tobacco advertising, promotion and sponsorship decrease tobacco use.
>
> (b) An effective ban on tobacco advertising, promotion and sponsorship should, as recognized by Parties to the Convention in Articles 13.1 and 13.2, be *comprehensive* and applicable to *all* tobacco advertising, promotion and sponsorship.
>
> (c) According to the definitions in Article 1 of the Convention, a comprehensive ban on all tobacco advertising, promotion and sponsorship applies to *all* forms of *commercial communication, recommendation or action* and all forms of *contribution* to any event, activity or individual with the *aim, effect, or likely effect* of promoting a tobacco product or tobacco use either *directly or indirectly*".

967. The FCTC is aimed at all forms of advertising relating to tobacco. There is no policy differentiation between different types of tobacco products or between the myriad ways in which tobacco can be promoted or advertised. The thesis of the Convention is that tobacco is an unequivocal social evil and that an aspect of the cure to the ill is the wholesale elimination of all advertising; hence Article 13(1) which expresses the basic position: "*Parties recognize that a comprehensive ban on advertising, promotion and sponsorship would reduce the consumption of tobacco products*".

968. Paragraph 7 of the Guidelines is also in uncompromisingly broad terms:

> "To implement the comprehensive ban laid down in Articles 13.1 and 13.2 of the Convention, Parties should ban advertising, promotion and sponsorship as defined in Article 1(c) and (g) of the Convention. Article 1(c) defines "tobacco advertising and promotion" as "any form of commercial communication, recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly". Article 1(g) defines "tobacco sponsorship" as "any form of contribution to any event, activity

> or individual with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly".

969. Paragraph 10 of the Guidelines emphasises the need to avoid loopholes emerging and suggests as an appropriate drafting technique, avoiding the use of purportedly exhaustive lists of banned forms of advertising: "*Legislation should avoid providing lists of prohibited activities that are, or could be understood to be, exhaustive. While it is often useful to provide examples of prohibited activities, when legislation does so, it should make clear that they are only examples and do not cover the full range of prohibited activities. This can be made clear by using terms like "including but not limited to*" or catch-all phrases such as "*or any other form of tobacco advertising, promotion or sponsorship*".

970. The imposition of restrictive measures which fall short of an outright prohibition on "all tobacco advertising, promotion and sponsorship", is recognised as a second best alternative to an outright ban under Article 13 FCTC. Article 13(4) describes a list of "minimum" requirements but contracting states are encouraged to go further: see Article 13(5). It is perfectly clear that the logic of the Convention is that wherever advertising occurs it should be proscribed to the maximum degree, and that self-evidently includes *on* the cigarette itself.

971. The drafters of the Convention did not descend to definitional precision. There is no definition of "*packaging*" in either the FCTC or the Guidelines. Paragraph 15 of the Guidelines (concerning Article 13 FCTC) is set out below. The first sentence contains a broad statement about "*packaging*"; but the second sentence refers to "*tobacco pack or product features*" and seems, linguistically, to be a follow-on elaboration of what is meant by "*packaging*" in the first sentence. The conclusion that packaging means everything that packages or wraps around tobacco is, in my view, a fair and logical reading of the Convention. I accept that another possible reading, and that advanced by Ms Bacon QC for the Claimants, is that packaging has a narrow meaning and covers only the outer packaging. But this interpretation is inconsistent with the purpose of the FCTC which the TPD sets out to implement and the Guidelines which, as the Court of Justice, confirmed strongly in *Philip Morris* were to be given very great probative evidential value and could even be decisive. The underlying vice is the attractiveness of the advertising or promotion and this is common to both the pack and the features on the product and no distinction is drawn between these two locations for advertising in terms of that vice. It is in this context that reference is specifically made to advertising "*on individual cigarettes or other tobacco products*":

> "Packaging and product features
>
> *15. Packaging is an important element of advertising and promotion. Tobacco pack or product features* are used in various ways to attract consumers, to promote products and to cultivate and promote brand identity, for example by using logos, colours, fonts, pictures, shapes and materials on or in packs or *on individual cigarettes or other tobacco products*".
>
> (Emphasis added)

972. Read in context and purposively the condemnation of advertising and promotion would make no sense if what was to be curtailed applied only to the outer packaging and not to the actual tobacco product itself. This paragraph can, in my view sensibly, only have a broader meaning whereby the undefined notion of packaging encompasses everything in which tobacco is encased or packaged and thus includes the outer box and the product itself.

973. Support for this broad understanding of "packaging" is found in paragraph 16 of the Guidelines which treats a ban on advertising "on packaging" as including prohibitions on the product itself. Paragraph 17 in the Guidelines makes clear that if "plain" packaging is not mandated then the ("packaging") restrictions should also cover "*coloured cigarette papers*":

> "16. The effect of advertising or promotion *on packaging* can be eliminated by requiring plain packaging: black and white or two other contrasting colours, as prescribed by national authorities; nothing other than a brand name, a product name and/or manufacturer's name, contact details and the quantity of product in the packaging, without any logos or other features apart from health warnings, tax stamps and other government-mandated information or markings; prescribed font style and size; and standardized shape, size and materials. *There should be no advertising or promotion inside or attached to the package or on individual cigarettes or other tobacco products.*
>
> 17. If plain packaging is not yet mandated, the restriction should cover as many as possible of the design features that make tobacco products more attractive to consumers such as animal or other figures, "fun" phrases, *coloured cigarette papers*, attractive smells, novelty or seasonal packs".
>
> (Emphasis added)

974. The formal WHO Recommendation whilst seemingly differentiating between "packaging" and "product design" makes clear that the logic and purpose of the Convention is that restrictions should apply to all species of advertising wherever located:

> "*Recommendation*
>
> Packaging and product design are important elements of advertising and promotion. Parties should consider adopting plain packaging requirements to eliminate the effects of advertising or promotion on packaging. Packaging, individual cigarettes or other tobacco products should carry no advertising or promotion, including design features that make products attractive".

975. Lest there be any doubt about it, the FCTC and the Guidelines expressly identify trade marks as amongst the forms of adverting to be prohibited.

(ii) Second question – has this policy been adopted by the EU and translated into the TPD?

976. As to this the answer is "yes", as the Court of Justice made clear in *Philip Morris* (See analysis at Ground 1 above, Section E). This is evident from Recital 7 to the TPD which is set out at paragraph [229] above. This makes clear that the FCTC is "*binding*" on the EU and its Member States and is (therefore) a legislative measure which it was "*necessary*" for the Union to "*implement*". This is also reflected in Article 1 TPD. Recitals 7 and 24 endorse the Guidelines which are said to reflect the international "*consensus*". Case law establishes that when the EU and the Member States are all signatories to a measure of international law then the implementing Union measure will be interpreted so as to conform with the source international measure: See paragraphs [153] – [156] above.

(iii) Third question - construed in the light of the legislative purpose do the substantive measures of the TPD embrace restrictions on advertising and promotion on tobacco products?

977. In my judgment the answer to this question is in the affirmative. I accept the analysis of Ms Kelyn Bacon QC, for the Tipping Claimants, that the language of the TPD does not provide a wholly satisfactory answer to the question. Where I part company with her analysis is in her submission that the TPD is unambiguous and that, as such, there is no room for any form of purposive construction. She submitted that based upon the unambiguous terms of the TPD there was no power for Member States to impose restrictions on advertising on the product itself. In my judgment the phrase is ambiguous and must be construed in conformity with the purpose of the TPD which is to (i) introduce as a first stage controls on advertising which are consistent with the FCTC; and (ii) to recognise the competence and power of the Member States to maintain or introduce additional or further restrictions. There are a number of indications in the TPD that it is intended to embrace restrictions upon branding and promotion on tobacco products themselves:

i) Recital 53 (set out at paragraph [235] above) is relevant to the construction of Article 24(2) TPD and refers to Member States retaining the power to impose further restrictions: "*in relation to the **presentation** and the packaging, including colours, of tobacco product…*" (emphasis added). This contemplates that Member States may legislate to regulate the "*presentation*" of tobacco products, which would include the paper surrounding the tobacco. The recital also appears to equate the colour of a tobacco product as being part of its packaging: pink (to attract females), green (to suggest health) or black (to suggest sophistication) cigarette papers are examples of the colour of a tobacco product.

ii) The definition section in Article 2 TPD does not contain a definition of "*packaging*". It does however (cf. Article 2(29)) contain a definition of "*outside packaging*" which suggests that there are different types of packaging and that the concept of "*packaging*" includes but also goes beyond the "*outside*" wrapping and pack which is hence only an exemplar of "*packaging*". This would be consistent with the FCTC which targets all forms of advertising wherever located and which also seems to accord to the concept

of "*packaging*" a wide remit to embrace all that which surrounds the tobacco and is capable of being used to promote it, in whatever guise or form.

iii) Article 2 includes also a definition of a "*tobacco product*" which means *"… a product that can be consumed and consist, even partly, of tobacco, whether genetically modified or not*". Ms Bacon QC suggested that the paper was part of the tobacco product because it was burned and hence consumed. But this is not, in its context, a reading of the term which sits easily with the FCTC or its logic or the TPD which is directed at any advertising which seeks to promote the particular element which is harmful, namely the tobacco itself. The burning of the paper is not toxic in the way that the tobacco is. To equate the paper with the tobacco is to conflate two quite different things and would serve to undermine the policy objective of the TPD. It makes greater sense to see the paper surrounding the tobacco as something which packages the tobacco.

iv) Article 13 TPD is headed "*Product presentation*" and prohibits certain types of promotion and marketing on "*The labelling of unit packets and any outside packaging and the tobacco product*". Under Article 13(3) the prohibition extends to "*texts, symbols, names, trade marks, figurative or other signs*". Unquestionably the substantive provisions of the TPD extend to the product itself. Though it is right to observe that "packaging" and "the tobacco product" are referred to separately.

v) Article 24(2) reflects the partial nature of harmonisation achieved by the TPD and it acknowledges therefore that Member States may legislate in those areas where the EU has not occupied the field. This explains why the provision is expressed in the negative: "*This Directive shall not affect the right of a Member State to maintain or introduce further requirements, applicable to all products placed on its market, in relation to the standardisation of the packaging of tobacco products…*". If my conclusion that "*packaging*" is to be broadly interpreted is correct then Article 24(2) covers advertising on the packaging surrounding or encasing the tobacco itself. But even if that is wrong it still begs the question whether because the TPD is a measure of partial harmonisation it must be construed as necessarily preventing Member States going further and restricting advertising on the product itself.

(iv) Fourth question – whether even if Article 24(2) is to be narrowly interpreted Member States nonetheless have competence to regulate advertising on the product.

978. In any event even if it were correct to say that Article 24(2) was concerned with outer packaging, and not the inner product, that is not the end of the construction question. First, under ordinary principles of interpretation it is open to Member States to introduce anti-avoidance measures which ensure that the packaging restrictions achieve their intended effect. All measures of EU law are to be interpreted to achieve their effect; this is the doctrine of "effet utile". If the TPD permitted Member States only to regulate the outer packaging but not the product itself this would create an incentive for the tobacco manufacturers to enlarge to the maximum degree the advertising and promotions potential of the product itself. In other words limiting regulation to packaging would stimulate avoidance strategies on the part of the

tobacco manufacturers. The adoption of future proofing and anti-avoidance measures is, as I have already emphasised, a recognised part of the overall policy as set out in the FCTC which the TPD seeks to introduce and it is therefore consistent with the legislative policy behind the TPD that Member States should be able, when they introduce packaging restrictions, simultaneously to introduce measures designed to ensure that the positive health effects of those measures achieve their end and are not undermined or circumvented by advertising placed elsewhere. Support for this conclusions in found in *Philip Morris* (ibid) where the Court of Justice, at paragraph [131], reiterated the principle that in relation to measures adopted under Article 114 TFEU the EU could adopt measures designed to ensure that the basic rules were not "circumvented". Second, and in any event, as a measure of partial harmonisation the Member States are entitled to enact legislation controlling branding and promotion on tobacco products themselves. I have set out fully at paragraphs [263] – [266] above the reasons why the Member States enjoy a pre-existing competence to regulate in this area which jurisdiction includes the imposition of branding and promotional restrictions and curbs on tobacco products themselves and I do not repeat those reasons here. The judgment of the Court of Justice in *Philip Morris* also addresses an argument advanced by Ms Bacon QC for the Tipping Claimants which was that since in Article 13 TPD the EU legislature had addressed restrictions on tobacco products themselves it was therefore to be assumed that the EU had fully occupied this field to the exclusion of supplementary legislation by the Member States. In fact the Court made clear that the competence of the Member States was fettered only to the extent that it adopted measures which conflicted with express provisions of the TPD and/or thereby replaced them. The fact, therefore, that the EU has taken some measures is not an indication that Member States may not take further measures. In this regard it is plain that the measures of control in the Regulations neither conflict with nor replace any measure set out in the TPD. The judgment of the Court of Justice in *Philip Morris* confirms that Member States can adopt additional control measures provided they are not inconsistent with those "aspects" of tobacco control regulated by the TPD (ibid paragraphs [71] – [84]).

979. For all the above reasons I reject the submission that Regulation 5 is unlawful as being *ultra vires.*

U. GROUND 17: REGULATION 5 IS DISPROPORTIONATE

(1) The issue

980. The alternative submission of the Tipping Claimants is that if, *ex hypothesi*, Parliament has jurisdiction to enact Regulation 5 the Secretary of State has nonetheless never produced evidence establishing to the requisite standard the purported public health benefits of introducing Regulation 5.

(2) Preliminary observations about the need for additional evidence

981. I start with two broad observations.

982. First, the evidence which was before Parliament when it adopted the Regulations was extensive in its analysis of all of the different types or genres of advertising regardless of where that particular advert was physically located or placed. So, for illustration there was a significant and discrete body of evidence relating to the attractive power

of colour on consumers. For instance, research suggested that pink coloured products were seen as attractive to some types of female consumer; and green colours were associated with a fresh and healthy image. There was no evidence which suggested that colour exerted a materially different effect depending upon whether it was on the outside packaging or on the cigarette itself. This evidence also makes it plain that packaging is simply a larger "billboard" than the cigarette stick; yet the stick still remains an important space for advertising to be placed upon. Everything that physically surrounds or encases or packages the tobacco itself creates a potential location for some form of promotion. The intrinsic advertising force, for instance, of colour or symbols thus remains regardless of the location of the advert. A smoker might buy a pack, because it is attractive, and then take out a cigarette and its colour and design may, whilst the cigarette is being consumed, exert a promotional effect.

983. The Secretary of State placed before the Court multiple illustrations of tobacco sticks which exhibited a variety of attractive features. Sobranie Black Russian cigarettes, for example, are black with a gold tip and are long and thin and have a symbol on the tip; a smoker can strike an alluring pose of sophistication and elegance whilst holding and consuming such a cigarette, which is precisely the effect intended by placing advertising and branding on the cigarette itself. There is thus, on the evidence, no clear and identifiable distinction which can be drawn in terms of the types of advertising and promotion between the outer packaging and other locations for advertising. The only difference will be in the extent of the impact. As such it is not correct to say that only research specifically targeted at the impact of advertising on the product is relevant. In my view other research which considers the generic effect of different types of advertising is also relevant. Internal documentation disclosed in the US shows that the tobacco companies are all too aware of the benefits of advertising and promotional features focused upon the product itself.

984. Second, a point which runs throughout the FCTC and is set out in the conclusions of the UK consultation is the fact that in considering the health issues a precautionary and "loophole proof" approach is both necessary and justified. If the Claimants prevail the importance of the tobacco product itself as a location for advertising itself would commensurately grow as the overall "billboard" space shrinks and recedes. The product would become the last remaining space upon which advertising and promotion could occur. This, indeed, is the precise point made by the Director General of the WHO to the Parliamentary Under Secretary of State in a letter of 3rd September 2015 when she stated:

> "...the WHO has observed tobacco companies seek to circumvent and undermine the effectiveness of tobacco control measures all around the globe. Circumvention strategies include selling sleeves and stickers to obscure health warnings and using inserts within packaging. It is also common for branding to appear on tobacco products themselves. The long history of industry strategies such as these suggests that a comprehensive approach to plain packaging that extends the measures to the product itself, as well as to the sleeves, stickers and other similar devices, is necessary in order to prevent circumvention and ensure that plain packaging achieves its maximum effect".

985. Ms Bacon QC for the Tipping Claimants submitted that there was no logical evidential "bridge" which linked the position vis-à-vis the outer packaging with the stick itself. I cannot accept this; the link is self-evident and the policy imperative for Governments to adopt "comprehensive" and future-proofed policies is just such a logic bridge which means that if the Regulations were confined to the outer packaging this would leave an important and already recognised loophole which the tobacco manufacturers could and undoubtedly would exploit with concomitant risks to health. Professor Hammond pointed out in his analysis that branding on cigarette sticks operates in the same way as branding on the exterior of the packaging. Indeed, UK cigarette sticks use the same type of colour-coding as the brand imagery displayed on the exterior of packages. A review of UK brands from the 10 leading brand families in 2014 found that, in all cases, brand variants used different colour markings on sticks to distinguish brand variants, and that the colour of the brand names printed on tipping paper corresponded to the brand imagery and colours on the exterior of pack. Professor Hammond concluded that it was highly likely that tobacco companies would increase the amount of branding on sticks if standardised packaging only applied to exterior packages. In my judgment this is common sense and I accept the proposition.

986. In my view once it is established that there is a proportionate need to regulate the outer packaging of cigarette boxes then there arises a powerful – and proportionate – need to regulate the product itself on anti-avoidance grounds. The evidence – or "bridge" as Ms Bacon QC put it – does not require much if anything at all by way of extra evidence to support it. That follows from: (i) the logical inferences that can be drawn from the acceptance by the tobacco companies that the importance of (even a diminishing area of) particular surfaces increases as the scope for other forms of advertising decreases; (ii) the evidence of the correlation in design strategies between the packaging and the stick and tip; and (iii) the fact (which was unchallenged) that the only difference between advertising on the outer packaging and the product was physical location.

(3) The evidence on tipping

987. However, in any event, it is also possible to identify specific research evidence which has direct relevance to the attractive force of advertising upon the product itself. There is a small but consistent body of evidence specifically addressing the impact of colour and branding on cigarette sticks. This shows that the characteristics and appearance of the cigarette itself affect an individual's perception of the attributes of the cigarette. Different colours and brand images can impact upon the perceived levels of attractiveness of the product and can communicate messages as to the relative strength and harmfulness of different products. For example, in one study (Borland and Savvas, published online in Tobacco Control, March 2012), researchers conducted an investigation into adult smokers in Australia (N=160, aged 18-29). Their research suggested that a stick with a cork-patterned tipping paper and a gold band was seen as most attractive, of highest quality and strongest in taste compared to other tipping designs, while branded sticks were seen as more attractive, higher in quality and stronger tasting than non-branded designs, regardless of brand. In another study (Ford, Moodie, MacKintosh and Hastings, published in the European Journal of Public Health, in October 2013), conducted in Scotland (and cited by Professor Hammond (at paragraph [10.5.4] of his report) and by Mr Mean (in his evidence at paragraph

[121-125]) the researchers examine the perception of young women to different presentations of cigarette (N = 75 females, aged 12-24 years) entailing 2 standard cigarettes with cork filters, 2 coloured cigarettes (pink and brown) and 4 slim cigarettes. The results suggested that pink and slim cigarettes were perceived to be most appealing, pleasant tasting and least harmful.

988. In "*Effects of stick design features on perceptions of characteristics of cigarettes*" Borland and Savvas, Tobacco Control, 6 March 2012, a survey conducted amongst adolescents (N=48, aged 15), found that slim and superslim cigarettes with white tips and decorative elements were rated most attractive and they were perceived as weaker and less harmful. Long brown cigarettes were viewed as most unattractive and conveyed the message of a stronger and more harmful product.

989. A further 2015 Scottish study (Moodie, Ford, MacKintosh and Purves, published Health Education Res, 2015) evaluated the perceptions of a range of cigarettes among young women (N=75 females, aged 12-24 years). Each group was shown 11 cigarettes to rank. These included 2 standard cigarettes with cork filters, 2 coloured cigarettes (pink and brown), and 4 slim cigarettes. The pink and slim cigarettes were perceived as most appealing and pleasant tasting. They were also considered the least harmful.

990. Qualitative research conducted in 2011 on behalf of the Australian Government with adult smokers (N=122, aged 18-64), revealed strong associations with different stick colours and differentiating factors, such as patterned tips.

991. Professor Hammond, in his Report, cited 6 published pieces of research from Australia, Greece and Scotland, and, a number of unpublished studies from New Zealand. The thrust of this literature indicates that advertising on cigarettes themselves is seen as effective and its removal would exert some dissuasive effect. The Claimants advance a series of criticisms at this literature highlighting its limitations. Many of these points are fairly made. Ms Bacon QC highlighted variously, ambiguities in some of the research results, the small size of the sampling in some research studies, absence of peer review of some studies and the acknowledgement by researchers of the limitations of their findings highlighted by others.

992. The points made by the Claimants do carry some force. But they must be seen in context: There is a substantial volume of evidence concerning the impact of advertising on outer packaging and, in my judgment, this evidence must also be taken into account because logic dictates that if it is effective on the outer packaging it is capable of having some effect when on the product itself. Further, the submission that there is no evidence highlights the problems associated with the absence of disclosure. The criticism advanced by the Tipping Claimants, however, assumes a number of matters about the strategic intentions of the tobacco companies themselves. However, internal tobacco company documents refute these assumptions. Industry documents demonstrate that colour and brand imagery placed upon the cigarette sticks themselves operates in a manner which is similar to that upon the outer packaging. A number of internal documents are cited in the evidence of the Secretary of State. For example, a Memorandum produced by Philip Morris in 1989 in relation to internal consumer testing for an "ultra light" product concluded:

> "A red pack with cork tipping will position Marlboro Ultra Lights closely to Marlboro flavour heritage. A blue/grey pack with white tipping, although distant from the Marlboro flavour heritage, provides traditional ultra low tar reassurance. A red pack with white tipping represents a middle ground position with a flavour link to Marlboro via the red pack and ultra low tar reassurance via white tipping".

993. Similarly, in 1985, R J Reynolds undertook internal research to consider how the colour of the tipping paper impacted upon the perceptions of a brand marketed as "light". The conclusion to the study was in the following terms:

> "Tipping colour affects consumer perceptions of [full flavour low tar] products…the cork tipped product was perceived as stronger and having more tobacco taste than the white tipped product…These results are consistent with previous research…indicating that cork tipping enhances strength and decreases mildness perceptions… Modifications need to be made which reduce harshness and increase mildness and smoothness perceptions".

There is no evidence suggesting the psychological responses of consumers have changed in the intervening years.

994. Professor Hammond, in his conclusion concerning the independent research evaluating advertising and promotion upon the cigarettes themselves, stated as follows:

> "There is less independent research examining branding on cigarettes themselves; however, the literature that exists is highly consistent with findings on exterior packaging. In addition, industry documents demonstrates an association between branding elements, such as the colour of the tipping paper, and consumer perceptions of "light" cigarettes and reduced harm. Collectively, this literature indicates that the appearance of cigarettes themselves, in addition to the packaging, can alter consumer perceptions of appeal and harm".

(4) Secretary of State's submissions

995. The Secretary of State also submitted that the Claimants drew the public health objective too narrowly when they argued that evidence must show that Regulation 5 will reduce smoking. Parliament's objectives were broader. They include discouraging people from starting to use tobacco products, reducing the appeal or attractiveness of tobacco products, and reducing the opportunities for tobacco products to create false or misleading perceptions about the nature or effects of such products. The Secretary of State pointed out that there was evidence referred to during the consultation which focused upon these particular effects of advertising and promotion. The Secretary of State submits also that he was not required to adduce conclusive proof. It suffices to show that there were and are reasonable grounds for

believing there will be a beneficial effect on public health as a result of implementing the entire suite of measures (of which Regulation 5 is just one). Further there could be no objection to Parliament resorting to common sense and logic. I see force in all these points.

(5) Illicit trade

996. The next argument advanced by the Tipping Claimants is that the introduction of product restrictions will increase the incidence of illicit tobacco which will have adverse public health consequences. This was advanced very much by way of assertion and was not backed with any qualitative or quantitative evidence. The 2014 Impact Assessment concluded that there was a "sizeable likelihood" (ibid paragraph [280]) that standardised packaging (i.e. everything contained within the Regulations, including that pertaining to the product itself) would cause no discernible increase in the UK duty unpaid market. However it also concluded that there was "*a chance*" that there would be an increase in the UK duty unpaid market. The position was thus, on balance, there would be no impact upon the illicit market but that the possibility that there would be an impact could not be excluded. To quantify this possibility a critical value analysis was undertaken which examined what increase in the share of the market would be required to yield a zero NPV (Net Present Value) of the policy. Two models were developed of sources of possible increases in the UK duty unpaid market. These focused upon (a) the possibility that those who continued to smoke under standardised packaging diverted to the illicit market; and (b) that those that would otherwise quit smoking under standardised packaging also diverted to the illicit market. The models generated estimates of the rate of diversion from the licit to the illicit sector. However, the assessment went on to consider the extent to which any enhancement or diversification of the risk posed by the illicit market could be countered by improved monitoring and strengthened enforcement controls and regulation. The 2014 Impact Assessment has mooted the possibility of the introduction of enhanced criminal offences. The Assessment states:

> "HMRC's tobacco strategy remains in place and will adapt to any changes in risk as it has successfully done so over many years" (ibid paragraph [289]).

997. The assessment estimated that even if enforcement costs were to approximately double due to standardised packaging the NPV would remain positive reducing only from around £24.7 billion to around £24 billion. It is also observed that an EU wide initiative to curb cross-border illicit trading could occur within the confines of the TPD. I find this analysis entirely persuasive and there is no evidence or analysis which contradicts it.

(6) Counterfeiting

998. A further aspect of the illicit trade argument was the suggestion that the Regulations would lead to an increase in the counterfeiting of papers. This was an argument advanced at a high level of abstraction. The response of the Secretary of State, with which on the evidence I agree, was that standardised cigarette design was unlikely to exert any material impact upon the ease with which brands could be counterfeited on stick design because the vast majority of existing trade marks or designs on cigarettes were already straightforward to reproduce and counterfeit. A Witness Statement

produced on behalf of Tann suggested that standardised packaging would reduce distinguishable differences between brands which would ease the path of counterfeiters. However, differentiated brand information remains permitted under the Regulations and this includes the brand name and brand variety. Professor Hammond points out that such minor differences in what was now permitted and non-permitted would make no difference to the modern printing technology which was used to counterfeit designs. He then stated:

> "Perhaps most importantly…counterfeit cigarettes have not increased in Australia following the implementation of similar regulations with respect to branding on cigarette sticks".

(7) Increase in use of uncontrolled substances

999. There was also in the Tipping Claimants' submissions a suggestion that an increase in counterfeiting could result in uncontrolled substances being included which would be injurious to public health. There is again no qualitative or quantitative evidence to support this proposition and it is in any event parasitic upon the argument about counterfeiting. It is a proposition which needs to be placed into context. The existing scientific literature identifies approximately 7,000 compounds in "legal" cigarettes which are inhaled. The literature suggests that approximately 250 of such compounds have harmful effects. 70 are known to be carcinogenic. The scientific literature provides no support for the proposition that there is any difference in the risk of different cigarette brands given the magnitude of harm presented by any brand. There is no support in the literature for the proposition that restricting branding on cigarettes would lead to an increase in counterfeiting of any magnitude that would increase the health risk to consumers. I reject the argument.

(8) Conclusion

1000. In conclusion I reject the Claimants' submissions.