IN THE HIGH COURT OF JUSTICE **CLAIM NO. […]**

QUEEN'S BENCH DIVISION

ADMINISTRATIVE COURT

BETWEEN

THE QUEEN

ON THE APPLICATION OF

(i) PHILIP MORRIS BRANDS SARL
(ii) PHILIP MORRIS LIMITED

Claimants

and

THE SECRETARY OF STATE FOR HEALTH

Defendant

DETAILED STATEMENT OF GROUNDS

FOR JUDICIAL REVIEW

Suggested reading:

1. The contested Directive [**Auth/15**].
2. This Detailed Statement of Grounds.
3. The first witness statement of Drago Azinovic dated 26 June 2014 [**CB/3/66-79**].
4. The first witness statement of Kristof Doms dated 26 June 2014 [**CB/4/80-96**].
5. The executive summary of the report by Copenhagen Economics dated 19 June 2014 [**DA/3/226-229**].

* References in the form [**CB/(tab)/(page number(s))**] are to the Claimants' Bundle, references in the form [**DA/(exhibit number)/(page number(s))**] are to the exhibits to the first witness statement of Drago Azinovic dated 26 June 2014, references in the form [**KD/(exhibit number)/(page number(s))**] are to the exhibits to the first witness statement of Kristof Doms dated 26 June 2014, and, references in the form [**Auth/(tab)**] are to the legal authorities bundle.

A. INTRODUCTION AND SUMMARY

1. This case is about the proper constitutional boundaries between the powers of the European Union (the "EU") and those of the Member States. It is no coincidence that some of the most significant judgments of the Court of Justice of the European Union (the "CJEU") in relation to this issue have concerned EU legislation regulating tobacco. This is because the EU purported to enact those measures on the basis of its power to improve the internal market, a claim that is very far from self-evident and that, if left untested, would have far reaching consequences and expand the powers of the EU in a manner that is plainly prohibited by the EU Treaties (the "Treaties")[1]. It is precisely for this reason that the CJEU, in a similar case, struck down other tobacco-related legislation. This case calls for the same result.

2. The EU Legislature[2] is, as the Treaties state, a body of limited powers. While its powers are many, it does not have any power to enact measures solely on the basis of public health considerations. That power resides instead with the Member States, which, as can be expected in a "Union of Diversity",[3] may have very different views on which policy choices make the most sense for the health of their citizens. Indeed, the Treaties expressly prohibit the EU Legislature from harmonising the laws of the Member States, including tobacco laws, solely for reasons of public health.

3. Of course, the EU Legislature is not powerless to legislate in relation to public health matters. In order to do so, however, it must first establish that it has an independent legal basis to do so under the Treaties. Directive 2014/40/EU, the Second Tobacco Products Directive ("TPD2" or the "Directive")[4] fails to meet that requirement.

4. The EU Legislature purports to have enacted TPD2 on the basis of its internal market powers. According to the CJEU, however, the EU Legislature does not have a general power to regulate the internal market. Rather, the EU Legislature can only invoke its internal market powers if it can show – on the basis of objective evidence that is capable of judicial review – that the measure in question genuinely has as its object the *improvement* of the internal market

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1 The term "Treaties" refers to the Treaty on European Union and the Treaty on the Functioning of the European Union.

2 The term "EU Legislature" is used throughout these grounds to refer to the Council and the Parliament, which are the institutions that adopted the Directive. However, in adopting the Directive, the decisions of those institutions were informed largely by the work (including proposals and impact assessments) carried out by the European Commission. Any assessment of the legality of the Directive must therefore necessarily scrutinise the findings of the European Commission.

3 The EU motto, which came into use in 2000, is "United in Diversity".

4 Published in the Official Journal on 29 April 2014 [**Auth/15**].

by contributing in some appreciable degree to the elimination of *actual* or *likely* barriers to trade or distortions to competition caused by differences in Member State regulations. Otherwise, as the CJEU has emphasised, the powers of the EU Legislature "*would be practically unlimited*"[5] and the careful allocation of responsibilities between it and the Member States would be destroyed. This was the basis on which the CJEU struck down the Tobacco Advertising Directive[6] and on which its Grand Chamber carefully scrutinised the validity of the revised incarnation of that directive[7] and of Directive 2001/37/EC, *i.e.* the First Tobacco Products Directive ("TPD1").[8]

5. As the European Parliament's own Committee on Legal Affairs (the "Legal Affairs Committee") found,[9] TPD2 does not fall within the scope of the EU Legislature's internal market powers because it fails to improve the internal market in tobacco products, and actually undermines it in several key respects. For example, it: (i) eliminates the internal market for certain products by banning them throughout the EU; (ii) distorts competition by substantially limiting the ability of producers to differentiate their products via their packaging; (iii) unlike TPD1, contains no provision that ensures the free movement of products that comply with the Directive; and (iv) invites Member States to adopt additional barriers to intra-EU trade in the form of further product bans and packaging requirements.

6. TPD2 also offends other essential limitations on the EU Legislature's powers as contained in the Treaties and the Charter of Fundamental Rights of the European Union (the "Charter"). In particular, TPD2 prohibits tobacco manufacturers from making true and non-misleading claims about their products on their product packaging, but without any evidential basis in the legislative record to demonstrate that this restriction is proportionate. Further, TPD2 disregards the strict limits placed by the Treaties on the EU Legislature's ability to delegate powers to the European Commission (the "Commission"). As the Legal Affairs Committee itself noted, the EU Legislature has impermissibly given the Commission powers to amend fundamental aspects of the Directive without the approval of the Member States or the checks and balances that otherwise exist within the EU's democratic system of government.[10] Finally, TPD2 fails to respect the principle of subsidiarity, which requires the EU to refrain from regulating on issues that the Member States are capable of regulating themselves. That principle is especially relevant here, where Member States have very different views on which policy choices make the most sense for protecting the health

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5 Case C-376/98 *Germany v Parliament and Council* [2000] ECR I-8423, at [107] [**Auth/24**].

6 *Ibid.*, at [118].

7 Case C-380/03 *Germany v Parliament and Council* [2006] ECR I-11573 [**Auth/30**].

8 Case C-491/01 *British American Tobacco and Imperial Tobacco* [2002] ECR I-11461 [**Auth/26**]; see also Case C-434/02 *Arnold André* [2004] ECR I-11825 [**Auth/28**]; and Case C-210/03 *Swedish Match* [2004] ECR I-11893 [**Auth/29**] ("*Swedish Match*").

9 [**KD/40/156-199**].

10 [**KD/41/200-217**].

of their citizens.

7. For all of these reasons, the Claimants seek to challenge the intention and/or obligation of Her Majesty's Principal Secretary of State for Health (the "Secretary of State for Health") to implement TPD2 on the ground that TPD2 is unlawful. As explained below, the Claimants contend that the EU Legislature had no power to adopt TPD2 for the following reasons:

   (a) The EU Legislature purported to adopt TPD2 on the basis of Article 114 of the Treaty on the Functioning of the European Union ("TFEU") as a measure intended to improve the functioning of the internal market. But TPD2 does not meet the conditions for invoking Article 114 TFEU. The EU has therefore exceeded the limits of its legislative power;

   (b) Article 13 of TPD2, which prohibits the display on tobacco packaging of true and non-misleading statements, disproportionately infringes Article 11 of the Charter, which protects freedom of expression and the right of consumers to receive information. Article 13 of TPD2 is therefore unlawful;

   (c) TPD2 unlawfully delegates essential powers to the Commission, including a power (in Article 3(2) of TPD2) that would enable the Commission to prohibit the sale of every single type of cigarette in the EU; and

   (d) The prohibition on the sale of menthol tobacco products ("menthol cigarettes") in Article 7 of TPD2 violates the principle of subsidiarity because it fails to respect the substantial diversity that exists with respect to the Member States' views on menthol or to explain adequately why menthol cigarettes could not be regulated at the Member State level.

B. FACTUAL AND REGULATORY CONTEXT

Factual context

The Claimants

8. The Claimants are Philip Morris Brands SARL, a holding company based in Switzerland that directly and indirectly owns a number of subsidiaries that manufacture and sell tobacco products throughout the European Union and the rest of the world (excluding the United States), and Philip Morris Limited, a company based in the United Kingdom that has overall responsibility for and provides marketing services in relation to the sale of tobacco products in the UK. The Claimants are hereinafter collectively referred to as "PMI". References to "PMI" also include, where appropriate, references to their subsidiaries and affiliates.

9. PMI manufactures and sells cigarettes and other tobacco products in more than 180 markets. As the witness statement of Mr Drago Azinovic, President of PMI's European region, notes "*PMI's operations in the EU comprise a significant part of PMI's business*".[11] In 2013, PMI's share of cigarette sales in PMI's "European Region"[12] was roughly 38.5%.[13] PMI's share of cigarette sales in the UK was approximately 7.3%.[14] PMI's European Region generated approximately US$8.6 billion of revenues in 2013.[15] PMI employs around 11,500 people in the EU.[16]

10. As explained below, tobacco advertising and promotion is severely restricted in the EU and, indeed, largely prohibited in many Member States. As a result, manufacturers like PMI rely on price, product characteristics and packaging to differentiate their products from those of their competitors. As Mr Azinovic explains in his witness statement, product differentiation is "[t]*he key*" to PMI's strategy of "*capturing market share from* [its] *competitors*".[17]

11. Mr Azinovic explains that TPD2 will significantly affect PMI's activities. For example, the prohibition in Article 13 of TPD2 on manufacturers providing consumers with information about their products (including information about reduced health risks) on the product packaging would be "*deeply problematic for PMI and for consumers generally*"[18] and would "*distort competition in favor of companies who have not made any investments to develop* [reduced-risk products]"[19]. The menthol ban in Article 7 of TPD2 will also prevent an important aspect of competition between tobacco companies given that menthol cigarettes represent "*the most important point of taste differentiation in the EU cigarette market at the present time*".[20] The packaging and labelling elements of TPD2 will also "*significantly* [reduce PMI's] *ability to differentiate cigarette packets in relation to their shape, material, opening and dimensions*".[21]

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11 See [11] [**CB/3/68**].

12 As noted in [1] of the witness statement of Mr Azinovic, PMI's European Region comprises PMI's operations in the EU other than in Slovenia, Bulgaria, Croatia and Romania, and also includes Switzerland, Norway and Iceland.

13 See [11] [**CB/3/68**].

14 *Ibid.*, at [12] [**CB/3/69**].

15 *Ibid.*, at [11] [**CB/3/68**].

16 *Ibid*.

17 *Ibid.*, at [21] [**CB/3/71**].

18 *Ibid.*, at [45] [**CB/3/77**].

19 *Ibid.*, at [53] [**CB/3/79**].

20 *Ibid.*, at [32] [**CB/3/74-75**].

21 *Ibid.*, at [39] [**CB/3/76**].

Overview of the tobacco industry in the EU

12. In 2010, the total value of the EU tobacco market was €136.5 billion.[22] Cigarette sales represented 88.1% of that market and sales of "*roll your own*" tobacco products represented 6.8%.[23] Around 90% of EU cigarette sales in 2010 derived from products produced by the four major manufacturers: PMI, British American Tobacco, Japan Tobacco International and Imperial Tobacco.[24] As Mr Azinovic explains, smoking prevalence in the EU has declined in recent years, in line with other OECD countries. Eurobarometer reports have registered a decline from 39.4% in 2003 (for the EU-15, as it then was) to 32% in 2006 and 28% in 2012 (both for the EU-27).[25]

13. Cigarette production in the EU is concentrated in nine Member States.[26] Thus, as Mr Azinovic explains, PMI is already "*able to benefit from the internal market by concentrating manufacturing activities in the most efficient locations and at the most efficient scale*."[27] Nevertheless, consumer preferences, both as to taste and as to packing, vary significantly across the EU. In relation to taste, the most important example is menthol.[28] Although menthol cigarettes are permitted in every Member State and account for 5% of the EU tobacco market, demand varies greatly between Member States.[29] For example, menthol cigarettes represent about 25% of the tobacco market in Finland and only 0.1% in Greece.[30] Similarly, consumer tastes in relation to packaging also vary across the EU. For example, in Germany there is a growing market for "big packs" containing more than 20 cigarettes. As Mr Azinovic explains, PMI therefore introduced a number of products in this category in Germany but not in most other EU countries.[31]

14. Illicit trade in tobacco products is a serious problem. Sales of illicit cigarettes

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22 See the report by Matrix Insight (the "Matrix Report") entitled "*Economic analysis of the EU market of tobacco, nicotine and related products*", p. 21 [**KD/23/24**].

23 *Ibid*., at pp. 20-21 [**KD/23/23-24**].

24 *Ibid*., at p. 61 [**KD/23/64**].

25 See the witness statement of Mr Azinovic at [13] [**CB/3/69**].

26 See the Commission's Impact Assessment (the "Impact Assessment"), pp. 9-10 [**KD/25/79-80**] and the Matrix Report, pp. 60-61 [**KD/23/63-64**]. See also the report by Copenhagen Economics [**DA/3/244**].

27 See the witness statement of Mr Azinovic at [22] [**CB/3/71-72**].

28 *Ibid.*, at [32] [**CB/3/74-75**].

29 *Ibid.*, at [17] [**CB/3/70**]. See also the Roland Berger Strategy Consultants paper entitled "*The New Tobacco Products Directive – Potential Economic Impact*" (the "Roland Berger Paper"), p. 10 [**KD/37/48**].

30 Impact Assessment, p. 13 [**KD/25/83**]; see also the Matrix Report, p. 32 [**KD/23/35**].

31 See the witness statement of Mr Azinovic at [18] [**CB/3/70**].

represent around 11% of total consumption in the EU.[32] The volume of illicit trade in the EU is expected to reach around 83.25 billion cigarettes by 2015.[33] It has been estimated that the EU and the Member States lose around €10 billion each year in unpaid taxes as a result of illicit sales of tobacco products.[34]

Legislative context

TPD1

15. TPD2 repeals and replaces TPD1.[35] TPD1 contains a number of harmonisation measures. In particular, it imposes limits on the maximum tar, nicotine and carbon monoxide ("TNCO") yields of cigarettes;[36] specifies how those yields are to be measured;[37] and requires TNCO yields to be printed on cigarette packaging [38] TPD1 prohibits manufacturers from including misleading statements on tobacco packaging[39] (for example, terms such as "*low-tar*", "*light*" and "*mild*"[40]).

16. TPD1 also requires tobacco packaging to include a general warning that must cover 30% of the front of the packet (for example, "*Smoking kills*") and an additional warning covering 40% of the back of the packet (for example, "*Smokers die younger*").[41] The packaging of smokeless tobacco products must also carry a health warning ("*This tobacco product can damage your health and is addictive*").[42] TPD1 also prohibits the sale of tobacco for oral use,[43] although Sweden has an exemption from that provision for snus.

17. Challenges to TPD1 were brought in Case C-491/01 *R v Secretary of State for Health ex p. British American Tobacco (Investments) Ltd* (the "*BAT* case"),[44]

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32 See a report by the Huggard Consulting Group dated May 2013 (the "Huggard Report"), p. 21, footnote 45 [**KD/39/149**]. See also: the Matrix Report, p. 30 [**KD/23/33**]; and the illicit trade data sheet sent to the Commission by PMI, p. 1 [**KD/16/1-3**].

33 Matrix Report, p. 29 [**KD/23/32**].

34 *Ibid*., at p. 27 [**KD/23/30**].

35 Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products [**Auth/11**].

36 *Ibid*., at Article 3.

37 *Ibid.*, at Article 4.

38 *Ibid.*, at Article 5(1).

39 *Ibid*., at Article 7.

40 *Ibid*., at recital 27.

41 *Ibid*., at Articles 2 and 5. The percentages differ for Member States with more than one official language.

42 *Ibid*., at Article 5(4).

43 *Ibid*., at Article 8.

44 [2002] ECR I-11453 [**Auth/26**].

Case 210/03 *R (Swedish Match AB) v Secretary of State for Health*[45] and Case C-434/02 *Arnold André GmbH & Co. KG v Landrat des Kreises Herford*.[46] Each of these references was considered and rejected by the Grand Chamber of the CJEU. As explained below, the CJEU's reasons for rejecting those challenges have important implications and, in fact, support the case that TPD2 is unlawful.

The Tobacco Advertising Directive

18. The First Tobacco Advertising Directive, Directive 98/43/EC,[47] prohibited all forms of tobacco advertising and sponsorship within the EU. That directive was adopted on the basis of what is now Article 114 TFEU. It was annulled by the CJEU in Case C-376/98 *Germany v Parliament and Council* (the "*First Tobacco Advertising* case")[48] on the grounds that the requirements of Article 114 TFEU were not fulfilled.

19. The invalidated directive was replaced by the Second Tobacco Advertising Directive, Directive 2003/33/EC,[49] which prohibits tobacco advertising in the print media, on the radio and internet, and also prohibits tobacco sponsorship at events involving multiple Member States (such as Formula One races). That directive was upheld in Case C-380/03 *Germany v Parliament and Council* (the "*Second Tobacco Advertising* case").[50] Tobacco advertising and sponsorship via audio-visual media is prohibited by Directive 2007/65/EC, the Audio-visual Media Services Directive.[51] These measures leave packaging as a particularly important channel of communication between tobacco manufacturers and consumers. Packaging is also an important tool to enable competition between manufacturers.

C. THE CONTESTED DIRECTIVE

Legislative process

20. As explained in the witness statement of Mr Kristof Doms, Vice President of European Union Affairs at PMI, and as summarised below, the tobacco industry and many other interested parties, including PMI, made a number of submissions and adduced material evidence to the Commission and the EU

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45 [2004] ECR I-11893 [**Auth/29**].

46 [2004] ECR I-11825 [**Auth/28**].

47 [**Auth/10**].

48 [2000] ECR I-8419 [**Auth/24**].

49 [**Auth/12**].

50 [2006] ECR I-11573 [**Auth/30**].

51 [**Auth/14**].

Legislature at every stage of the legislative process that led to the adoption of TPD2.

21. In November 2009, RAND Europe ("RAND Europe"), third-party consultants for the Commission's Health and Consumer Directorate-General ("DG SANCO"), produced an interim report assessing the impacts of various policy options concerning the revision of TPD1.[52] As Mr Doms explains, on 18 January 2010, PMI provided detailed submissions in response, highlighting, among other things, that the interim report failed to analyse how the proposed measures could improve the functioning of the internal market.[53]

22. RAND Europe failed to take account of those submissions and published its final report on 22 September 2010.[54] As Mr Doms explains, PMI responded to the final report as well, both in writing and at a meeting with the Commission on 20 October 2010. PMI made detailed submissions noting that RAND Europe's final report suffered from the same fundamental defects as its interim report.[55] Although the Commission never addressed those concerns, it appeared to distance itself from RAND Europe's final report, stating on its website that "*This document does not represent the point of view of the European Commission. The interpretations and opinions contained in it are solely those of the authors*".[56] Moreover, the Commission, in its impact assessment (the "Impact Assessment"), acknowledged that the report "*was criticised by many stakeholders for its actual and perceived inaccuracies"* and that the information in that report "*was verified on the basis of other sources*".[57] As Mr Doms notes, however, the Commission has never identified those "*other sources*", notwithstanding that PMI filed an access request for any such documents under the Transparency Regulation.[58]

23. Between 24 September and 17 December 2010 the Commission conducted a public consultation seeking views on the policy options that it was considering. Notably, the consultation document stated: "*At the present stage, the Union competence to adopt the different options, their implications on the functioning of the internal market and their proportionality have not yet been fully examined*".[59] As Mr Doms explains, PMI submitted to DG SANCO substantial responses to the consultation questions on 15 December 2010, making many of the points that it had made previously in response to the

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52 [**KD/3/7-89**].

53 See [13] [**CB/4/83-84**].

54 [**KD/5/1-334**].

55 See the witness statement of Mr Doms at [14] [**CB/4/84**].

56 [**KD/8/62**]

57 Impact Assessment, p. 7 [**KD/25/77**].

58 See [28] [**CB/4/87-88**].

59 DG SANCO, Public Consultation Document – Possible Revision of the Tobacco Products Directive 2001/37/EC, at p. 3 [**KD/9/74**].

RAND Europe reports.[60]

24. The Commission published the results of the consultation in July 2011. As Mr Doms explains, the overwhelming majority of responses were opposed to the proposals.[61]

25. As Mr Doms explains, on 2 December 2011 PMI attended a meeting with the Commission, held at the request of PMI and other companies in order to discuss their concerns about the proposed Directive. PMI and the other companies explained their criticisms of the Commission's proposals and "*stressed that any measures needed to be effective and proportionate and actually improve the functioning of the internal market in tobacco products*".[62]

26. The Commission produced draft impact assessments in March[63] and June[64] 2012. The Commission's Impact Assessment Board (the "IAB", a central quality control function working under the authority of the Commission President that is responsible for reviewing and issuing opinions on all of the Commission's draft impact assessments) published opinions in respect of those drafts in April and July 2012.[65] Both opinions criticised the Commission's draft impact assessments because, *inter alia*, they did not adequately assess whether the proposed measures were needed in order to improve the functioning of the internal market (the purported legal basis for the legislation) and because they failed adequately to assess the effectiveness of the proposed measures.

27. Notwithstanding those criticisms, the Commission proceeded to publish its proposal and the Impact Assessment on 19 December 2012. The Commission's preferred policy options, set out in the Impact Assessment, included: (i) banning all tobacco products with a "*characterising flavour*" (including menthol cigarettes); (ii) requiring health warnings on smokeless tobacco products; (iii) restricting the information that a tobacco manufacturer may provide about its products to consumers; (iv) requiring health warnings covering 75% of the front and back of cigarette packages; and (v) introducing minimum packet sizes for cigarettes.

28. The Impact Assessment suffered from many of the same defects as the IAB had identified in its opinion on the second draft. In the months following the publication of the Commission's proposal, as Mr Doms explains, PMI and other tobacco product manufacturers submitted numerous documents to the various participants in the legislative process detailing the flaws in the Impact

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60 See [16] [**CB/4/84**].

61 See [17] [**CB/4/84-85**].

62 See [19] [**CB/4/85**].

63 [**KD/19/26-100**].

64 [**KD/21/104-235]**.

65 [**KD/20/101-103**] and [**KD/22/1-3**].

Assessment and the Commission's proposals.[66]

29. Several committees of the European Parliament reviewed the Commission's proposal and expressed concerns. The Committee on Legal Affairs, which is responsible for scrutinising the legality of draft EU legislation, published two opinions, in June and July 2013, respectively. The opinions stated that there was no legal basis for the proposed measures and that they involved excessive delegation of powers to the Commission.[67] Similarly, the Parliament's Impact Assessment Unit expressed criticisms about the Impact Assessment, including its failure to analyse the potential impact of the Directive on the illicit trade.[68] The Committees on Agriculture and Rural Development and Industry Research and Energy also voiced concerns about the excessive delegation of powers in the proposal or the lack of evidence as to the effectiveness of the proposed measures in terms of reducing smoking prevalence.[69]Furthermore, the Parliament and Council consulted the European Economic and Social Committee, which stated that the proposed packaging standardisation measures would lead to lower prices and increased consumption of cigarettes.[70] So too was the Committee of the Regions, which voiced concerns about the legality of the delegation of powers to the Commission.[71]

30. National parliaments also expressed reservations about the proposal. In fact, nine parliamentary chambers issued reasoned opinions[72] expressing serious doubts about whether the proposal complied with the principle of subsidiarity.[73]

31. Despite these substantial concerns raised by a number of legislative committees and by several national parliaments, the Council and the European Parliament approved a final text of TPD2 via the "*trilogue*" procedure. It was signed on 3 April 2014 and was published in the Official Journal on 29 April 2014.

Overview of TPD2

32. Articles 1 and 2 of TPD2 set out the scope of the Directive and provide

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66 In particular, Mr Doms refers at [31] to: (i) a submission by António Vitorino (a former EU Commissioner for Justice and Home Affairs) [**KD/36/28-36**]; (ii) the Roland Berger Paper [**KD/37/37-90**]; (iii) a report by Oxera, an economic advisory firm engaged by JTI [**KD/38/91-128**]; and (iv) the Huggard Report [**KD/39/129-155**].

67 [**KD/40/156-199**] and [**KD/41/200-217**].

68 [**KD/42/218-229**].

69 [**KD/44/35-76**] and [**KD/45/77-122**].

70 [**KD/46/123-152**].

71 [**KD/47/153-167**].

72 Bulgaria, the Czech Republic, Denmark, Greece, Italy (a reasoned opinion was issued by each of the two chambers of the Italian legislature), Portugal, Romania, Sweden.

73 In accordance with the Protocol on the Application of the Principles of Subsidiarity and Proportionality [**Auth/2**].

relevant definitions. Articles 3 to 7 regulate the reporting and use of certain ingredients in tobacco products. In particular, Article 3 sets maximum cigarette emission levels for TNCO and Article 4 prescribes the method for measuring those levels. Article 7 prohibits the placing on the market of tobacco products with a characterising flavour, including menthol.

33. Articles 8 to 16 (which together form Chapter II of Title II of the Directive) set out requirements for tobacco packaging and labelling. In particular, Article 9 specifies the general health warnings required on the packaging of tobacco products (for example "*Smoking kills*"). Article 10 requires combined text and pictorial warnings covering 65% of the front and back of the packaging in addition to the display of smoking cessation information. Article 12 sets out the warning that must appear on the packaging of smokeless tobacco products, such as nasal tobacco ("*This tobacco product damages your health and is addictive*").[74] Article 13 prohibits tobacco manufactures from printing certain statements about their products on the product packaging (regardless of the accuracy of such statements). Article 14 requires cigarette packets to have a cuboid shape and to include a minimum of 20 cigarettes.

34. Articles 17 to 22 contain various provisions concerning tobacco for oral use, cross-border sales, novel tobacco products, electronic cigarettes and herbal products for smoking. Articles 23 to 33 contain general provisions, including the date for transposition of TPD2 and transitional provisions.

35. Article 24(2) permits Member States to adopt more restrictive measures concerning tobacco packaging than those contained in TPD2. Article 24(3) permits Member States to ban additional categories of tobacco or related products.

Provisions under challenge

36. PMI contends that Article 7, Chapter II of Title II and Article 24(2) and (3) of TPD2 are invalid for lack of a legal basis. As explained in Section D below, the EU does not have competence to enact those measures under Article 114 TFEU. Article 13 is also invalid on the basis that it constitutes a disproportionate infringement of rights guaranteed by the Charter, namely freedom of expression and the right of consumers to receive information (see Section E below).

37. In addition, Articles 3, 4, 7, 9, 10 and 12 are unlawful because they involve excessive delegation of powers to the Commission and, accordingly, infringe Article 290 TFEU (see Section F below). A further reason for the invalidity of Article 7 is the fact that it violates the principle of subsidiarity, as explained in Section G below.

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74 [**Auth/15**].

D. GROUND OF CHALLENGE 1: NO LEGAL BASIS

Overview

38. PMI's first ground of challenge is that the EU Legislature had no power to adopt TPD2. Whilst it has purported to rely on its powers to adopt measures designed to improve the functioning of the internal market, the EU Legislature has failed to demonstrate that the Directive does in fact genuinely have as its object the improvement of the functioning of the internal market and that the legal requirements for legislating on the basis of Article 114 TFEU are fulfilled.

Applicable legal principles

The relevant Treaty provisions

39. The EU has no inherent powers to legislate. It can only act if the Member States have, through the Treaties, conferred powers upon it. The principle of conferral is enshrined in Articles 4 and 5 of the Treaty on European Union (the "TEU"), which embody the important constitutional agreement reached by the Member States in relation to the division between their competences, on the one hand, and those of the EU, on the other. Thus, Article 4 TEU provides that:

> In accordance with Article 5, competences not conferred upon the Union in the Treaties remain with the Member States.[75]

40. Article 5 TEU provides:

> 1. The limits of Union competences are governed by the principle of conferral. The use of Union competences are 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.[76]

41. TPD2 is purportedly based on Articles 53(1), 62 and 114 TFEU.[77] These three provisions confer powers on the EU to adopt internal market legislation. However, Article 53(1) (freedom of establishment) and Article 62 (freedom to provide services) are each specific aspects of the internal market and do not

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75 [**Auth/3**].

76 *Ibid.*

77 See the preamble to TPD2 [**Auth/15**].

serve to expand the scope of the powers conferred by Article 114 TFEU.[78] The following analysis therefore proceeds by reference to Article 114 TFEU.

42. Article 114 TFEU provides:

> 1. Save where otherwise provided in the Treaties, the following provisions shall apply for the achievement of the objectives set out in Article 26.[79] 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.
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> …
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> 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.
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> 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.
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> 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, it shall notify the Commission of these provisions as well as the grounds for maintaining them.
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> 6. The Commission shall, within six months of the notifications 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

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78 The *First Tobacco Advertising* case at [87] [**Auth/24**].

79 Article 26 provides, materially, as follows: "*(1) The Union shall adopt measures with the aim of establishing or ensuring the functioning of the internal market, in accordance with the relevant provisions of the Treaties. (2) The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties.*"

> 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 shall be deemed to have been approved.
>
> 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.
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> 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.[80]

43. Article 168 TFEU sets out the EU's powers to adopt measures on grounds relating to public health. Article 168(1) provides that a "*high level of public health protection shall be ensured in the definition and implementation of all Union policies and activities*".[81] Critically, however, Article 168(5) makes clear that the EU has no power to adopt harmonisation measures directed solely at the protection of public health:

> 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 object the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.[82]

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80 [**Auth/1**]. Emphasis added.

81 *Ibid.*

82 *Ibid.* Emphasis added.

44. Article 168 TFEU therefore states in terms that the EU Legislature has no power to adopt measures that have as their "*direct object the protection of public health regarding tobacco*" [83] and that harmonise the laws and regulations of the Member States. Member States retain the exclusive power to choose their own level of protection of public health, subject only to the other express conferrals of power to legislate found elsewhere in the Treaties. The CJEU has made clear that the EU Legislature cannot "*circumvent the express exclusion of harmonisation laid down in* [Article 168(5)]".[84]

The EU's internal market powers are strictly circumscribed

45. In the *First Tobacco Advertising* case, the CJEU addressed the proper ambit of Article 114 TFEU and laid down its limits.[85] That case raised the issue of whether the EU's internal market powers provided a broad power to regulate the internal market. The CJEU rejected that proposition. The CJEU said that:

> [to construe Article 114 TFEU] as meaning that it vests in the Community legislature a general power to regulate the internal market would not only be contrary to the express wording of [the various Treaty provisions concerning the internal market] but would also be incompatible with the principle embodied in [Article 5 TEU] that the powers of the Community are limited to those specifically conferred on it.[86]

46. Instead of endorsing a broad interpretation of Article 114 TFEU, the CJEU set out the following limiting principles that it has repeated in its subsequent case law and that are applicable in the present case:

(a) **First**, a measure adopted on the basis of Article 114 TFEU "*must genuinely have as its object the improvement of the conditions for the establishment and functioning of the internal market*";[87]

(b) **Second**, a "*mere finding of disparities between national rules and of the abstract risk of obstacles to the exercise of fundamental freedoms or of distortions of competition liable to result therefrom*" is insufficient to engage Article 114 TFEU;[88]

(c) **Third**, the EU Legislature may base a measure on Article 114 TFEU where "*there are differences between national rules which are such as*

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83 *Ibid.*

84 The *First Tobacco Advertising* case at [79] [**Auth/24**].

85 Referred to in that judgment by its old numbering, *i.e.* Article 100a of the EC Treaty [**Auth/5**].

86 The *First Tobacco Advertising* case at [83] [**Auth/24**].

87 *Ibid.*, at [84] [**Auth/24**]; the *BAT* case at [60] [**Auth/26**]; Case C-58/08 *Vodafone Ltd and others v Secretary of State for Business, Enterprise and Regulatory Reform* [2010] ECR I-04999 (the "*Vodafone* case") at [32] [**Auth/33**].

88 The *First Tobacco Advertising* case at [84] [**Auth/24**]; the *Vodafone* case at [32] [**Auth/33**].

to obstruct the fundamental freedoms and thus have a direct effect on the functioning of the internal market"[89] and where "*the distortion of competition which the measure purports to eliminate is appreciable*";[90]

(d) **Fourth**, recourse to Article 114 TFEU is also possible "*if the aim is to prevent the emergence of such obstacles to trade resulting from the divergent development of national laws. However, the emergence of such obstacles must be likely and the measure in question must be designed to prevent them*";[91] and

(e) **Fifth**, where an act based on Article 114 TFEU has already removed any obstacle to trade in the area that it harmonises, "*the Community legislature cannot be denied the possibility of adapting that act to any change in circumstances or development of knowledge having regard to its task of safeguarding the general interests recognised by the Treaty*".[92]

47. The purpose of harmonising disparate national rules would be defeated if Member States were then individually permitted to adopt stricter standards. That is why Advocate General Ruiz-Jarabo Colomer stated in Case C-374/05 *Gintec International Import-Export GmbH v. Verband Sozialer Wettbewerb* (the "*Gintec case*") [2007] ECR I-9517, at paragraphs 26-29, [93] that harmonisation under Article 114 TFEU must be exhaustive (*i.e.* comprehensive) subject only to the exceptions provided under that Article (as set out at paragraph 42 above). If a directive adopted under Article 114 TFEU permits Member States to adopt stricter standards than the harmonised standards, then it must contain a "*mutual recognition*" provision that guarantees free movement for products that comply with the directive.[94] Otherwise, a Member State would be able to defeat the internal market objective of the directive by blocking imports of products that comply with the standards contained in it but that do not comply with the stricter standards the Member State has unilaterally adopted.

48. The CJEU struck down the First Tobacco Advertising Directive because it failed to provide for mutual recognition of the minimum standards laid down by that directive. In particular, the CJEU held that this directive did not pursue

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89 The *Vodafone* case at [32] [**Auth/33**]. Emphasis added.

90 The *First Tobacco Advertising* case at [106] [**Auth/24**]. Emphasis added.

91 *Ibid.*, at [86]; the *Vodafone* case at [33] [**Auth/33**]. Emphasis added.

92 The *BAT* case at [77-78] [**Auth/26**]; the *Vodafone* case at [34] [**Auth/33**].

93 [**Auth/31**].

94 A mutual recognition provision would permit a Member State from applying stricter standards to its own domestic products but preclude it from applying them to products from other Member States which comply with the standards contained in the Directive. For an example of a case in which stricter standards were applied to domestic production in the context of tobacco regulation, see Case C-11/92 *R (Gallaher) v Secretary of State for Health* [1993] ECR I-3545 [**Auth/21**].

an internal market objective because, in contrast to other directives allowing Member States to introduce stricter standards, it contained "*no provision ensuring the free movement of products which conform to its provisions*".[95] By contrast, the CJEU considered the Second Tobacco Advertising Directive to be lawful because it did not permit Member States to institute stricter measures and because it guaranteed the free movement of goods that complied with that directive.[96]

49. TPD1 was held to be lawful for the same reason. The CJEU held that, "*unlike the* [First Tobacco Advertising Directive], *the Directive contains a provision, Article 13(1), which guarantees the free movement of products which comply with its requirements. By forbidding the Member States to prevent, on grounds relating to the matters harmonised by the Directive, the import, sale or consumption of tobacco products which do comply, that provision gives the Directive its full effect in relation to its object of improving the conditions for the functioning of the internal market*".[97]

Summary of legal principles

50. As explained above, the Treaties are thus explicit as to the limits of the EU's legislative power:

(a) The EU does not have any general power to regulate the internal market; it may only enact measures that *genuinely* have as their object the improvement of the internal market;

(b) The EU does not have any general power to regulate on public health grounds. It can only regulate on public health grounds if it has an independent legal basis to act (such as its internal market competence);

(c) As a corollary, the EU is not empowered to harmonise Member State tobacco regulations solely for reasons of public health. Rather, it must have some other legal basis (such as its internal market competence) in order to enact such legislation; and

(d) Accordingly, the EU's power to legislate on these matters depends entirely on its ability to show that TPD2, even if motivated primarily by concerns relating to public health, genuinely has as its object the improvement of the internal market in tobacco products.

Legal basis must be subject to proper scrutiny

51. It is essential that the CJEU can properly scrutinise whether or not the conditions for the application of Article 114 TFEU have been satisfied in

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95 The *First Tobacco Advertising* case at [104] [**Auth/24**].

96 The *Second Tobacco Advertising* case at [73] [**Auth/30**].

97 The *BAT* case at [74] [**Auth/26**].

every case where the EU Legislature seeks to rely on that provision. This is especially important in the present context given the prohibition contained in Article 168(5) and the risk that an overly broad approach to its powers under Article 114 may lead the EU Legislature to trespass into areas that remain within the exclusive remit of the Member States.

52. The CJEU emphasised the importance of rigorous judicial review of legislation made under Article 114 TFEU at paragraph 84 of its judgment in the *First Tobacco Advertising* case.[98] The need for such judicial review follows from the principle of effective judicial protection enshrined in Article 47 of the Charter. Article 47 requires that the EU Legislature properly explain the basis on which it has determined that a measure is lawful and appropriate so that the CJEU is in a position effectively to review it.[99] In the present case, the principle of effective judicial protection required the EU Legislature properly to explain during the course of the legislative process the basis on which its recourse to Article 114 TFEU was justified in light of the conditions laid down by the CJEU and summarised above.

53. In order to carry out the task entrusted to it by the Treaties of ensuring that the EU Legislature acts within the bounds of its powers, the CJEU must examine the documentary record of deliberation created during the legislative process. The Treaties require all EU legislation to provide a short but clear statement of reasons in its recitals. Those recitals are then supported by a large volume of *travaux préparatoires*, including an explanatory memorandum and impact assessment produced by the Commission, public reviews of the quality of the impact assessment by the IAB, and scrutiny by various committees of the European Parliament and the Council. There is no equivalent in EU law of the English law rule in *Pepper v Hart*. On the contrary, these *travaux* provide the material with which the CJEU interprets EU legislation and with which the CJEU tests whether the EU Legislature has satisfied the strict constitutional limits on the EU's legislative power laid down by the Treaties.

Submissions

54. PMI contends that the EU Legislature exceeded the powers conferred on it by Articles 53(1), 62 and 114 TFEU in adopting the following provisions of TPD2:

    (a) Article 24(2), which permits Member States to adopt measures stricter than those contained in the Directive in relation to the standardisation of the packaging of tobacco products;

    (b) Chapter II of Title II (Articles 8 to 16), relating to "*labelling and packaging*";

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98 [**Auth/24**].

99 See, for example, Joined Cases C-584/10 P, C-593/10 P and C-595/10 P *European Commission and others v Kadi (Bulgaria and others, intervening)*, 18 July 2013 at [100] [**Auth/36**].

(c) Article 7, which imposes a ban on tobacco products with a characterising flavour, including menthol cigarettes; and

(d) Article 24(3), which permits Member States to prohibit yet further categories of tobacco products.

55. As explained in greater detail below, TPD2 does not genuinely have as its object the improvement of the functioning of the internal market. The evidence on which the EU Legislature relies is not sufficient to make out its case. For that reason, TPD2 is unlawful. Before turning to that evidence, however, PMI draws to the Court's attention a report by Copenhagen Economics, commissioned by PMI, to put these measures in their relevant economic context.[100] The key points of the report are summarised below by way of introduction, but it bears reading in its entirety.

56. Unlike the Commission, Copenhagen Economics started with an analysis of how the internal market in tobacco products is currently functioning. It pointed out that tobacco manufacturers such as PMI already "*flexibly supply their products across EU borders to meet different consumer preferences in individual Member State markets, taking advantage of the free movement of goods to achieve economies of scale*".[101] It follows that differences in national regulations "*do not constitute a barrier for manufacturers*".[102] Thus, despite the fact that tobacco manufacturers such as PMI produce different packages for different Member States, there are no internal market obstacles that need to be dismantled. That starting point sets a high hurdle for the EU Legislature to show that TPD2 will genuinely improve the functioning of the internal market.

57. Copenhagen Economics also analysed the impact that TPD2's packaging and labelling provisions and its menthol ban would have on the internal market. Those are two of the aspects of TPD2 in relation to which PMI contends that the EU Legislature failed to establish any internal market competence.

58. In relation to packaging and labelling, Copenhagen Economics pointed out that "*cigarette packaging will remain country-specific under TPD2 and manufacturers will still have to familiarise themselves (and comply) with* [several] *country-specific aspects of labelling…*".[103] Moreover, the packaging standardisation measures "*reveal a remarkable lack of basic economic understanding*". Copenhagen Economics further pointed out that:

> [i]f economic operators truly thought they could attain benefits through uniformity, they would implement this of their own accord … In reality, economic operators prefer product differentiation to uniformity, because it allows them to tailor their products to different

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100 [**DA/3/223-303**].

101 [**DA/3/226**].

102 [**DA/3/241**].

103 [**DA/3/228**].

> consumer preferences and to distinguish their products more effectively in a competitive marketplace. With low barriers to trade and open national markets, economic operators can compete, for instance, by differentiating their products and offering a wider choice. By removing these elements of competition, TPD2 distorts the market.[104]

59. In relation to the menthol ban, Copenhagen Economics pointed out that it may lead to "*the growth of illicit trade, in addition to the elimination of the internal market for menthol cigarettes*" and that it will "*remove an important element of product differentiation, which will have adverse effects on competition*".[105]

60. In summary, Copenhagen Economics found that "*the EU could not reasonably have concluded in its IA* [*i.e.* the Impact Assessment] *that TPD2 removes obstacles to cross-border trade or improves the internal market*".[106] As explained below, nothing in the Commission's Impact Assessment comes close to undermining that conclusion.

Article 24(2) undermines the free movement of goods

61. Article 24(2) of TPD2 is a startling provision because it gives Member States the power to adopt stricter provisions than those contained in the Directive despite the fact that the Directive purports to harmonise the field that it occupies. It thereby deprives TPD2's packaging and labelling provisions of any genuine internal market purpose.[107] While those provisions purport to harmonise several aspects of tobacco packaging in order to improve the internal market, Article 24(2) undermines those purported benefits by permitting Member States to adopt additional requirements. Moreover, Article 24(2), read together with Article 24(1), permits Member States to prohibit imports of tobacco products from other Member States even if those products comply with the packaging requirements in TPD2. In other words, TPD2's packaging and labelling provisions fail even to establish a system of mutual recognition. Article 24(2) stands in stark contrast to the corresponding provision under the TPD1 (Article 13). The CJEU upheld the legality of TPD1 precisely because Article 13 guaranteed the free movement of goods complying with the minimum standards of that directive.

62. By way of illustration, a Member State could purport to mandate that all tobacco product packages sold on its territory have a particular colour or texture in addition to the health warnings and other packaging requirements of TPD2. The consequence would be that tobacco manufacturers could not, in that Member State, market products that they legally manufacture and sell in other Member States even though such products comply fully with the

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104 [**DA/3/229**].

105 [**DA/3/227**].

106 [**DA/3/229**].

107 For the reasons set out at paragraphs 69-83, PMI contends that Chapter II of Title II of the Directive does not in any event satisfy the conditions for the application of Article 114 TFEU.

packaging and labelling requirements of TPD2. It follows that any purported benefits that the packaging and labelling measures might otherwise have had for the internal market in tobacco products are lost.

63. Article 24(2) therefore directly contradicts the EU Legislature's stated justification for basing TPD2 on Article 114 TFEU. As can be seen both from the recitals to the Directive and from the Impact Assessment, the stated objective of TPD2 was to "*improve the functioning of the **internal market** by removing current disparities in national legislation, ensure homogenous development and facilitate the creation of a level playing field among economic actors*".[108]

64. In order to achieve that internal market objective, the CJEU has emphasised that directives such as this one should prohibit Member States from restricting the importation of products that comply with the directive for reasons relating to the subject matter of the directive: see paragraphs 47 to 49 above. Otherwise, the directive's internal market purpose would be undermined, as Advocate General Ruiz-Jarabo Colomer explained in the *Gintec* case.[109]

65. Accordingly, Article 114 TFEU places strict limits on the circumstances in which a Member State may maintain or introduce national standards once a harmonising measure has been adopted thereunder:

    (a) Pursuant to Article 114(4), a Member State has the power, under certain strict conditions, to maintain (but not to introduce) national legislation "*on grounds of major needs referred to in Article 36*"[110] which include the protection of human health;

    (b) In order to do so, however: (i) the Member State must notify the Commission of the national provisions and the grounds for maintaining them (Article 114(4)); (ii) the Commission must examine and then approve or reject the national provisions (Article 114(6)); and (iii) if the Commission approves a national provision that derogates from the harmonised measure, it must immediately decide whether to adapt the harmonised measure (Article 114(7));

    (c) Pursuant to Article 114(5), a Member State has the power to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment. This is subject to the same conditions set out in (b) above. It follows that there is no power for a Member State to introduce new national provisions relating to the protection of health;

    (d) The introduction of health measures is expressly addressed by Article 114(8). When a Member State raises a specific problem on public

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108 Impact Assessment, pp. 120-121 [**KD/25/190-191**]. No emphasis added.

109 The *Gintec* case, Opinion at [AG27]-[AG28] [**Auth/31**].

110 [**Auth/1**].

health in a field that has been the subject of prior harmonisation measures, it must bring it to the attention of the Commission, which must then immediately examine whether to propose appropriate measures to the Council. In other words, Member States are not permitted to take action themselves, they can only raise issues with the Commission; and

(e) Finally, Article 114(10) provides that, in appropriate cases, harmonisation measures adopted under Article 114 shall "*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*".[111]

66. Article 114(10) strictly confines the scope of safeguard clauses contained in a harmonisation measure adopted under Article 114. Such clauses must: (i) relate to one of the non-economic reasons in Article 36 (that include the protection of health); (ii) be of a provisional (*i.e.* temporary) nature; and (iii) be subject to a Union control procedure.

67. Article 24(2) does not comply with the requirements for safeguard clauses contained in Article 114(10) because:

(a) The national provisions they permit are not confined to "*provisional*" measures; and

(b) The introduction of such measures is not subject to a "*Union control procedure*" but must merely be notified to the Commission.

68. Article 24(2) of TPD2 is therefore invalid because:

(a) It does not meet the strict conditions that Article 114 places on the introduction of national measures once a harmonisation measure has been adopted; and

(b) It is inconsistent with TPD2's internal market objective because it permits Member States to introduce national standards in addition to those contained in TPD2, and thereby prohibits the importation and sale of products that comply with the harmonised standards set out in TPD2.

Chapter II of Title II on labelling and packaging does not improve the functioning of the internal market

69. The EU Legislature has also failed to demonstrate that the packaging and labelling measures in Chapter II of Title II of the Directive are genuinely intended to improve the internal market in tobacco products. The EU Legislature: (i) has not identified any differences between national rules that are (or are likely) to obstruct the internal market; and (ii) has not demonstrated

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111 [**Auth/1**] emphasis added.

that the packaging and labelling measures are genuinely capable of addressing any problems caused by such differences (if any). In fact, many aspects of Chapter II of Title II do not even address packaging differences caused by different Member State regulations, but rather seek to harmonise elements that tobacco companies use to differentiate their products in response to differing consumer preferences in those Member States.[112]

70. In the recitals to TPD2, the EU Legislature invokes the following factors in relation to the provisions under challenge:

(a) The need to update certain provisions that were harmonised in TPD1, such as the size and format of health warnings, in order to reflect new developments and scientific evidence suggesting that large graphic health warnings are more effective than warnings comprising only text;[113] and

(b) In other areas that were not harmonised, the recitals claim that there are still substantial differences between the laws of the Member States that present obstacles to the smooth functioning of the internal market. According to the recitals, these discrepancies can be expected to increase as Member States take different approaches to regulating these non-harmonised areas in light of scientific, market and international developments such as the guidelines issued under the Framework Convention on Tobacco Control ("FCTC").[114] TPD2 therefore purports to eliminate these obstacles by harmonising those rules.[115]

71. The Commission also addressed this internal market rationale in its Impact Assessment[116] and in the explanatory memorandum accompanying the draft of TPD2.[117]

72. For much of Chapter II of Title II of the Directive, the EU Legislature's analysis of internal market benefits fails at the first hurdle: it cannot even identify divergences in Member State regulations that cause the differences that one observes in tobacco product packaging throughout the EU. In particular, as Mr Azinovic explains, the different shapes and materials that PMI uses for its packaging in different Member States are driven not by differences in regulation, but rather by the tobacco companies' efforts to tailor their product offering based on the differing consumer preferences in the

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112 See, in particular, the witness statement of Mr Azinovic at [29-30] [**CB/3/74**] and [37-40] [**CB/3/76**].

113 See recital 3 [**Auth/15**].

114 Those guidelines appear at [**Auth/53**] and the FCTC appears at [**Auth/7**].

115 See recitals (4), (5), (22) and (23) [**Auth/15**].

116 [**KD/25/64-339**].

117 [**KD/24/2-13**].

Member States and to compete with each other.[118] Accordingly, there is no valid internal market justification for Article 14 of TPD2. Similarly, the EU Legislature has not identified any valid internal market basis to ban tobacco companies from making true and non-misleading statements on tobacco product packaging. Article 13 of TPD2 cannot therefore be based on Article 114 TFEU.

73. Even where packaging differences are necessary to comply with different regulations in different Member States, the EU Legislature has failed to establish that those differences give rise to any obstacles to the effective functioning of the internal market. As Mr Azinovic explains, even if the Member States' regulations were exactly the same throughout the EU, PMI would still tailor its "*product offerings and packaging in order to satisfy the very different consumer preferences that exist in each Member State*".[119] That sets a high bar for what the Commission needed to show in its impact assessment. Far from meeting that target, the Commission failed to engage with this issue at all.

74. Indeed, a vivid example of the EU Legislature's inadequate analysis in this regard is the fact that the EU Legislature has applied new labelling and packaging regulations to snus (Article 12), a product that is prohibited in all Member States other than Sweden. It is difficult to conceive how this measure could be genuinely intended to improve the internal market when there is no internal market for snus.

75. These points should have been obvious to the EU Legislature from the outset. But even if they were not, Mr Doms explains that PMI and others repeatedly drew them to the attention of the EU Legislature.[120] For example, PMI made these points in response to RAND Europe's final report and in person when PMI met with the Commission in October 2010.[121] Following the publication of the Impact Assessment, António Vitorino, a former European Commissioner, made a submission in which he noted that the Impact Assessment "*focuses almost exclusively on purported cost savings it expects manufacturers to realize from reduced paper and printing costs*".[122] That is wholly inadequate to justify action under Article 114 TFEU. As Mr Vitorino put it, "[t]*he internal market is intended to secure the free flow of <u>different</u> products; not to mandate the <u>uniformity</u> of products*".[123] As Mr Doms explains, similar criticisms were made by both Oxera and Huggard Consulting.[124]

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118 See [38-39] [**CB/3/76**].

119 *Ibid.*, at [26] [**CB/3/73**].

120 See [36-37] [**CB/4/91-92**].

121 *Ibid*., at [36] [**CB/4/91-92**].

122 [**KD/36/33**].

123 *Ibid*. The underlined words were italicised in the original.

124 See [36-37] [**CB/4/91-92**].

76. The IAB raised the same substantive concerns in its two opinions, stating that the Commission had failed to provide concrete evidence establishing that the conditions of the internal market justified EU action. In its second opinion, for example, the IAB said that the Commission had not adequately taken into account the fact that "*the presented evidence does not suggest any significant negative impacts of the current situation on the functioning of the internal market*."[125] The Commission failed to address that criticism in its final Impact Assessment. The Commission also failed to credit the fact that the tobacco industry had not identified any problems with respect to the functioning of the internal market. Instead, it chose to interpret that silence as meaning not that "*the problem does not exist"* but rather as *"a sign that the industry might expect a harmonisation at a higher level*".[126] This kind of unfounded speculation falls far short of establishing that there is an internal market problem that requires and justifies EU harmonisation.

77. The submissions and opinions referred to above identified the basic flaw in the EU Legislature's analysis; the assumption that harmonisation of divergent national rules is in itself sufficient to satisfy the requirements of Article 114 TFEU. That circular assumption, implicit throughout the Impact Assessment, is stated clearly in an internal Commission document produced as part of the dialogue between DG SANCO, which held the dossier for the Directive within the Commission, and the IAB. In the course of explaining its justification for the legal basis of the Directive, DG SANCO stated that "*a harmonisation of product specific measures is per definitionem beneficial for the internal market*".[127]

78. That reasoning is fundamentally flawed as a matter of law. If it were correct, the EU Legislature could arrogate to itself almost limitless powers simply by purporting to harmonise national laws. However, in accordance with the Treaties, the EU Legislature is required carefully to demonstrate that the particular harmonisation measures proposed genuinely have as their object the improvement of the functioning of the internal market.

79. The EU Legislature's failure to identify internal market benefits of the Directive's packaging and labelling measures is reflected in recital 23 to TPD2, which purports to summarise the internal market justification for these measures. After repeating the stock phrase that "*disparities are liable to constitute a barrier to trade and to impede the smooth functioning of the internal market in tobacco products*", the recital adds that "*consumers in some Member States are better informed about the health risks of tobacco products than consumers in other Member States*".[128] But, as noted above, that

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125 Opinion of 12 July 2012, section (C)(1), p. 2 [**KD/22/2**]. See also the IAB's first opinion of 20 April 2012, which expressed the concern (section (C)(1), p. 2) that the "*report should better demonstrate that the conditions for recourse to Article 114 TFEU are fulfilled*." [**KD/20/102**].

126 Impact Assessment, p. 33 [**KD/25/103**].

127 See a document headed "*Impact Assessment Quality Checklist for Impact Assessment Board Opinion*" Annex 24, p. 4 [**KD/49/177**].

128 [**Auth/15**].

objective cannot provide a basis for EU legislation: Member States expressly withheld from the EU the power to harmonise public health legislation.

80. Quite aside from failing to identify any internal market benefits for Chapter II of Title II of TPD2, the EU Legislature also failed adequately to consider the potential for those measures positively to damage the internal market in tobacco products. For example, the EU Legislature did not address the evidence suggesting that the labelling and packaging provisions could increase illicit trade and thereby undermine the legal market for these products.[129] In footnote 31 to the Impact Assessment, the Commission simply asserted, without evidence or analysis, that "*the preferred policy options do not – in the assessment of the Commission – lead to increased illicit trade*".[130] However, the European Parliament's own Impact Assessment Unit noted the inadequacy of the Commission's analysis on this point in a report dated May 2013 in which it commented that "*many stakeholders expressed concern about an increase in illicit trade following the directive, which is ruled out by the Commission without further explanation*".[131]

81. Indeed, it appears that the Commission ruled out those concerns without even investigating them. Pursuant to the EU access to documents regime, PMI applied for disclosure of any assessments prepared by the European Anti-Fraud Office ("OLAF") on the potential for TPD2 to increase illicit trade and of any requests for such assessments that the Commission might have made.[132] OLAF is the EU body responsible for investigating fraud and other illegal activities, including the illicit trade in tobacco products, and also for advising the EU institutions on the development and implementation of anti-fraud legislation and policies. Given the importance of the issue, and the evidence put forward in relation to it by interested parties during the consultation process, the Commission should have sought OLAF's advice on the point. Yet the Commission responded to PMI's request by confirming that no responsive documents could be found.[133]

82. The failure of the EU Legislature to address the substantial objections set out above demonstrates that it has failed to establish that recourse to Article 114 TFEU is justified. Its reasoning consists largely of assertion and conjecture, an inadequate foundation to apply Article 114 TFEU. If such assertion and conjecture were sufficient, the powers of the EU Legislature "*would be practically unlimited*"[134] and the careful allocation of responsibilities between

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129 See, for example, PMI's submissions to DG SANCO on RAND Europe's interim report, pp. 13-15, 22 and 25 [**KD/4/105-107, 114 and 117**]; PMI's public consultation submissions, p 9 [**KD/10/91**]; PMI's submissions on RAND Europe's final report, p. 20 [**KD/6/21**]; the Oxera Report, p. 15 [**KD/38/109**]; the Clifford Chance paper, p. 19-20 [**KD/11/291-292**] and the Huggard Report, pp. 20-21 [**KD/39/148-149**].

130 [**KD/25/76**].

131 [**KD/42/224**].

132 [**KD/50/216**].

133 [**KD/51/219**].

134 The *First Tobacco Advertising* case, at [107] [**Auth/24**].

it and the Member States would be destroyed.

83. Further, its failure to address the matters set out above means that it is impossible for the Court to conclude that Chapter II of Title II of TPD2 was properly adopted on the basis of Article 114 TFEU. It follows that the labelling and packaging provisions of the Directive should be annulled.

Article 7, which bans menthol cigarettes, does not improve the internal market

84. Article 7 of TPD2 bans products with a characterising flavour, including menthol cigarettes.

85. Menthol cigarettes represented approximately 5% of the EU tobacco market in 2011.[135] The ban on menthol cigarettes will have serious repercussions from the perspective both of the tobacco companies, which will lose an important element for differentiating their products, and for consumers, who will be deprived of their chosen cigarettes.

86. The EU Legislature cannot point to any current or planned divergence in regulation by Member States of menthol cigarettes that is capable of justifying its ban. As the Legal Affairs Committee pointed out, "*not a single Member State has banned...menthol or is even considering it. Thus the ban will neither remove nor prevent the emergence of obstacles to fundamental freedoms*".[136] In the absence of any basis for claiming actual or likely barriers to trade in menthol cigarettes, the EU Legislature speculates that it is possible that in the future such barriers might arise. In particular, the Commission referred in its Impact Assessment to the possibility that Member States might ban menthol as a result of their obligations under the FCTC.[137] But the FCTC does not, in fact, require Member States to ban menthol cigarettes.

87. If it were sufficient for the EU Legislature simply to speculate hypothetically that there might be future divergences in regulation, then there would be no limits to the EU Legislature's powers to regulate or ban products throughout the EU. In order to act under Article 114 TFEU, the EU Legislature must have a proper evidential basis for concluding that obstacles to trade are "*likely*".[138]

88. Indeed, as the CJEU has stated, even if there were a risk that Member States were likely to enact conflicting regulations on menthol, it is "*questionable whether a total ban* [of a product] *could ever contribute to the establishment and functioning of the internal market*".[139]

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135 See [17] [**CB/3/70**].

136 First Opinion of 25 June 2013, p. 3 [**KD/40/158**].

137 Impact Assessment, p. 41 [**KD/25/111**].

138 See paragraph 46(d) above.

139 Case C-434/02 *Arnold André* [2004] ECR I-11825, Opinion at [78] [**Auth/28**].

89. It is true that the CJEU held in *Swedish Match*[140] that the ban of snus in TPD1 was lawful. But the circumstances were very different to those in the present case. As the Advocate General and Court both noted, snus had been banned throughout the EU (other than in Sweden) by an EU directive since 1992 (*i.e.* for nearly a decade prior to TPD1).[141] At the time of that original EU-wide ban, three Member States had already banned it independently.[142] According to the Advocate General, the analysis would have been very different in the case of a ban of an established product for which there already was an internal market.[143] This is, of course, the case for menthol cigarettes.

90. Furthermore, it is clear from the language of both the Advocate General's Opinion and the CJEU's judgment in *Swedish Match* that such a product may only be banned pursuant to Article 114 TFEU where the ban improves the functioning of the market for a wider category of products that are not subject to the ban. Put simply, it is self-evident that a ban cannot improve the internal market in the banned product. But it may nevertheless be permitted under Article 114 if it "*contributes to the removal of barriers to trade in other products*".[144] This is why the CJEU, in its judgment, referred by way of illustration of acceptable product bans, to Council Directive 92/59/EEC.[145] The CJEU had held in its judgment in Case C-359/92 *Germany v Council* [1994] ECR I-3681 that the ban of unsafe products in that directive was lawful because it improved the functioning of the internal market for associated safe products.[146]

91. The menthol ban in TPD2 does not satisfy the test laid down in *Swedish Match* because it cannot be said to improve the functioning of the internal market in tobacco products generally. Banning menthol cigarettes will not remove barriers to trade in other tobacco products. Nor did the EU Legislature make any finding to that effect. As noted above, the reasoning of the EU Legislature focuses entirely on the hypothetical possibility that divergent national rules might arise in relation to the banned products themselves.[147] That hypothetical possibility does not come close to justifying a ban on menthol cigarettes. Far from <u>improving</u> the internal market in menthol cigarettes, the ban <u>eliminates</u> the market for those products.

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140 [**Auth/29**].

141 See [AG5] of the Advocate General's Opinion [**Auth/28**] and [36]-[37] of the judgment [**Auth/29**]. The Opinion of AG Geelhoed was given in the parallel case of Case C-434/02 *Arnold André* [2004] ECR I-11825 [**Auth/28**].

142 See [AG41] and [AG66] of the Advocate General's Opinion [**Auth/28**].

143 See [AG62] of the Advocate General's Opinion [**Auth/28**].

144 The Opinion of AG Geelhoed was given in the parallel case of Case C-434/02 *Arnold André* [2004] ECR I-11825 [**Auth/28**]. See [AG79] for the passage quoted in the text above.

145 Council Directive 92/59/EEC of 29 June 1992 on general product safety [1992] OJ L 228/24 [**Auth/8**].

146 [**Auth/22**].

147 See recital 16 to TPD2 [**Auth/15**]; see also the Impact Assessment, pp. 36 and 97-99 [**KD/25/106 and 167-169**].

92. For those reasons, Article 7 does not have an internal market object and is therefore invalid.

93. The EU Legislature also failed to give adequate consideration to whether a menthol ban could undermine the internal market in tobacco products as a consequence of a growth in illicit trade. Menthol products will remain readily available in neighbouring markets (such as those of Eastern Europe) but it does not appear that the EU Legislature conducted any analysis of whether the ban on menthol will stimulate an illicit market in those products from outside the EU. Nor did the Commission measure the potential impact of such illicit trade on the markets of those Member States most likely to be affected by it (*i.e.* those with the highest levels of menthol consumption and those that share borders with non-EU countries). The existence of this adverse consequence had specifically been pointed out by the CJEU in the *BAT* case which held that it was "*unarguable that the cigarette market particularly lends itself to the development of unlawful trade*".[148] As Advocate General Geelhoed stated at paragraph 158 of his Opinion in the same case: "*it is entirely reasonable to assume that an illegal market will be established in cigarettes that are banned within the European Union but which can be obtained outside it*".[149]

94. The Commission, in its Impact Assessment, claimed that "*it is impossible to predict with certainty the response of already established smokers of menthol* [cigarettes] *if these products were not allowed*", and acknowledged that "[s]*ales lost from menthol cigarettes would therefore be partially offset by … efforts to acquire the products outside the EU or illicitly*".[150] Yet, as noted above, the Commission concluded, without evidence or analysis or seeking advice from OLAF, that its policies, including the menthol ban, would "*not … lead to an increase in illicit trade*".[151] That conclusion is unsubstantiated.

95. In short, the EU Legislature has failed to establish that there is any legal basis to ban menthol:

    (a) The EU Legislature has not established that any Member States have or are likely to implement diverging menthol regulations. It has acted purely on the basis of speculation that such differences might arise in the future;

    (b) Even where there are actual differences in regulation, banning a product throughout the EU is very unlikely to improve the internal market;

    (c) The only possible justification for banning a product is that it improves the internal market for other products. But there is no evidence that this

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148 See [87] [**Auth/26**].

149 [**Auth/26**].

150 Impact Assessment, p. 100 [**KD/25/170**].

151 *Ibid.*

is the case in relation to the ban on menthol cigarettes; nor did the EU Legislature even claim it to be the case; and

(d) The EU Legislature failed to investigate the adverse effect of the menthol ban on the internal market resulting from an increase in illicit trade.

Article 24(3) is unlawful and undermines any internal market case for the menthol ban

96. Article 24(3) of TPD2 provides that a Member State "*may also prohibit a certain category of tobacco or related products, on grounds related to the specific situation in that Member State and provided the provisions are justified by the need to protect public health*".[152] Article 24(3) is unlawful because it amounts to an unlawful circumvention of the scheme of Article 114 TFEU in much the same way as Article 24(2) does.[153]

97. Article 114 only permits Member States to adopt stricter measures on public health grounds if the conditions contained in Article 114(10) are met.[154] Those conditions are not met in the present case because any product bans made under Article 24(3) would be permanent, and not "*provisional*", as required by Article 114(10). Article 24(3) does not therefore comply with Article 114 and is unlawful on that ground alone.

98. Furthermore, the presence of Article 24(3) in the Directive fundamentally undermines and belies any internal market objective that Article 7 of TPD2 could have.

99. In particular, as noted above, the EU Legislature sought to justify the internal market basis for Article 7 of TPD2 on the basis of speculation that some Member States may seek to ban menthol cigarettes in the future. The purported justification for the ban was the need to remove obstacles to the internal market that would be created by some Member States banning menthol while others did not. Yet, this is what Article 24(3) expressly permits in respect of other categories of products. These two provisions are therefore irreconcilable.

100. It follows that the stated objective of Article 7 cannot be achieved while Member States remain free under Article 24(3) of TPD2 to ban yet more categories of tobacco products. For that additional reason, Articles 7 and 24(3) of TPD2 are invalid.

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152 [**Auth/15**].

153 As to which, see paragraphs 61-68 above.

154 See paragraphs 65-66 above.

E. GROUND OF CHALLENGE 2: BREACH OF FUNDAMENTAL RIGHTS/ PROPORTIONALITY

Overview

101. The EU Legislature is legally bound to comply with the principles of fundamental rights contained in the EU Charter. Article 6 of the TEU provides that the rights contained in the Charter have the same legal value as the Treaties. The Charter requires the EU institutions to "*respect the rights, observe the principles and promote the application* [of the Charter] *in accordance with their respective powers*".[155] Indeed, the Commission has stated that its objective, since the entry into force of the Lisbon Treaty, is to ensure that the EU is "*exemplary*" in its respect for fundamental rights.[156]

102. As explained below, the EU Legislature has fallen short of this standard because Article 13 of TPD2 infringes the fundamental right to freedom of expression, and the rights of consumers to receive information guaranteed by Article 11 of the Charter.

Applicable legal principles

103. Article 11(1) of the Charter provides:

> Everyone has the right to freedom of expression. This right shall include freedom to hold opinions and to receive and impart information and ideas without interference by public authority and regardless of frontiers.[157]

104. As the explanations to the Charter confirm,[158] the right of freedom of expression in Article 11 of the Charter corresponds to Article 10 of the European Convention on Human Rights (the "Convention").[159] Pursuant to Article 52(3) of the Charter, therefore, Article 11 of the Charter must provide at least as much protection for freedom of expression as that provided by the jurisprudence of the European Court of Human Rights (the "ECtHR") concerning Article 10 of the Convention.

105. Any interference with Article 11 of the Charter must pursue a legitimate aim

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155 Article 51(1) of the Charter [**Auth/4**].

156 Communication from the Commission: *"Strategy for the effective implementation of the Charter of Fundamental Rights by the European Union"*, 19 October 2010, COM(2010) 573 final, p. 3 [**Auth/51**].

157 [**Auth/4**].

158 When interpreting the provisions of the Charter, courts must have regard to the explanations: Article 6(1) TEU [**Auth/3**].

159 [**Auth/6**].

and respect the principle of proportionality.[160] As Article 52(1) of the Charter states:

> 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.[161]

106. Proportionality is a general principle of EU law pursuant to which "*the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties*".[162] The principle requires the following:[163]

(a) The measure in question must be appropriate and necessary in order to achieve a legitimate aim;

(b) When there is a choice between several appropriate measures, recourse must be had to the least onerous or restrictive measure; and

(c) The disadvantages caused by the measure must not be disproportionate to the aims pursued.

107. The principle of proportionality is applied with varying degrees of intensity depending on the context. A distinction must be drawn, in that regard, between cases in which a fundamental right protected by the Charter is engaged, and, those cases where no fundamental rights are restricted and where the legislative choices made are purely of a political, social or economic nature.

108. It is well established, and a key element of the rule of law, that the Courts will rigorously scrutinise the proportionality of a legislative measure that restricts fundamental rights. Thus, in its recent judgment in Joined Cases C-293/12 and C-594/12 *Digital Rights Ireland*, [164] in which it declared Directive 2006/24/EC[165] to be invalid, the CJEU held that:

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160 See Case C-112/00 *Schmidberger v Austria* [2003] ECR I-5659 at [80] [**Auth/27**].

161 [**Auth/4**].

162 Article 5(4) TEU [**Auth/3**].

163 See, for example, Case 331/88 *R v Minister of Agriculture, Fisheries and Food, ex parte FEDESA* [1990] ECR I-4023 at [13] [**Auth/20**]. See also Case C-157/96 *R v Minister of Agriculture Fisheries and Food ex p. National farmers' Union and others* [1998] ECR I-2211 at [60] [**Auth/23**], and Case C-343/09 *Afton Chemical Ltd v Secretary of State for Transport* [2010] ECR I-7027 at [45] [**Auth/34**].

164 Cases C-293/12 and C-594/12 *Digital Rights Ireland Ltd v Minister for Communications, Marine and Natural Resources*, (not yet published), judgment of 8 April 2014, at [47] [**Auth/40**].

165 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 [2006] OJ L 105/54 [**Auth/13**].

> ... where interferences with fundamental rights are at issue, the extent of the EU legislature's discretion may prove to be limited depending on a number of factors, including, in particular, the area concerned, the nature of the right at issue guaranteed by the Charter, the nature and seriousness of the interferences and the object pursued by the interference.

109. That situation can be contrasted with those cases where no fundamental rights are engaged and the EU Legislature is making the types of political, economic or social choices as to which the Treaties give it a wide discretion.

110. As explained below, Article 13 of TPD2 significantly restricts an important right, that of manufacturers to impart true and non-misleading information and of consumers to receive it. A heightened level of scrutiny therefore applies. However, even if the CJEU were to accord a greater margin of appreciation to the EU Legislature, Article 13 would still be disproportionate.

The importance of the Impact Assessment

111. The Commission's impact assessments are critical to assessing the proportionality of EU legislation and to protecting the fundamental rights contained in the Charter.

112. The Commission's Impact Assessment Guidelines state that an impact assessment "*is a process that prepares evidence for political decision-makers on the advantages and disadvantages of policy options by assessing their potential impacts*".[166] The Guidelines emphasise that an impact assessment "*helps to ensure … consistency with Treaty objectives such as respect for Fundamental Rights*".[167] An impact assessment provides the basis upon which the CJEU can assess whether the EU Legislature adequately ensured that fundamental rights are respected. The Commission's operational guidance for taking account of fundamental rights emphasises the importance of "[p]*roperly assessing any impact on fundamental rights in the preparatory stages of new legislation*".[168]

113. It is notable that TPD2's Impact Assessment contained only a single, cursory paragraph on the topic of fundamental rights. That lone paragraph acknowledged that the proposed Directive would restrict various fundamental rights but tersely stated that the Directive's impact on those rights was proportionate.[169] The Impact Assessment's assessment of the proportionality

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166 Impact Assessment Guidelines SEC(2009)92 at [1.1] [**Auth/49**].

167 *Ibid.*, at [1.2]. See also Commission Staff Working Paper, *Operational Guidance on taking account of Fundamental Rights in Commission Impact Assessments* SEC(2011) 567, p. 3 [**Auth/52**].

168 Commission Staff Working Paper, *Operational guidance for taking account of fundamental rights in Commission Impact Assessments* SEC (2011) 567 final, p. 3 [**Auth/52**].

169 Impact Assessment, p. 43 [**KD/25/113**].

of those restrictions was even more telling: it merely noted that the CJEU generally grants the EU Legislature a "***broad discretion***" to make policy choices and only strikes down legislation where it is "***manifestly inappropriate***".[170] The EU Legislature appears to have taken this margin of appreciation as a licence to legislate without testing the proportionality of its legislation for itself. This perfunctory approach to assessing the compliance of a measure with fundamental rights is inconsistent with the procedural standards that the CJEU demands of the EU Legislature. As will be explained below, the Impact Assessment in this case provides no basis to conclude that Article 13 of TPD2 complies with fundamental rights.

Article 13 infringes the right to freedom of expression enshrined in Article 11 of the Charter

114. Article 13 of TPD2 is an extraordinary provision. It appears to prohibit cigarette manufacturers from providing consumers with true and non-misleading statements about their products on their packaging and thereby prevents consumers from receiving such information.

115. Article 13(1) provides:

> 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 a 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 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 cosmetic product;
>
> (e) suggests that a certain tobacco product has improved biodegradability or other environmental advantages.[171]

116. It appears from recital 27 to TPD2 that the rationale of Article 13(1) is to prevent labelling or packaging that "*could mislead consumers*".[172] However, on its face, Article 13(1) appears to go far beyond that objective in that it

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170 Impact Assessment, p. 46 [**KD/25/116**]. No emphasis added.

171 [**Auth/15**].

172 *Ibid.*

seems to prohibit a wide range of statements that are not misleading. If that is correct, then Article 13(1) is disproportionate and an unlawful infringement of Article 11 of the Charter.

117. It is instructive to compare Article 13(1)(a) with Article 13(1)(b)-(e). Article 13(1)(a) is concerned with features of labelling or packaging that promote a tobacco product by creating an erroneous impression about its characteristics, health effects, risks or emissions or that encourages the consumption of a product by creating an erroneous impression in relation to the same factors. The prohibitions set out in Article 13(1)(b)-(e), however, are not qualified in that manner and therefore appear to prohibit statements that fall within their scope whether or not they are misleading.

118. Article 13(1)(b) would, for example, appear to prohibit a manufacturer such as PMI from including true and non-misleading statements on the packaging of their products, even though that information may well be helpful, and indeed, of utmost interest and importance to consumers. In this regard, it should be noted that PMI has devoted and continues to devote substantial resources to developing reduced-risk tobacco products. Mr Azinovic describes what those products are and how close PMI is to bringing them to market.[173] However, even if PMI were to provide conclusive scientific evidence on these points, Article 13 would appear to prohibit PMI from communicating that information to consumers on the product packaging. Article 13 would thus prevent consumers from identifying products that have reduced health risk, and discourage tobacco manufacturers from developing such products in the first place.

119. As Mr Azinovic has explained, PMI's contention that information of this kind is of critical importance for consumers is confirmed by consumers themselves.[174] PMI commissioned the Ipsos Group to conduct a poll of consumers in 14 Member States to measure the level of consumer support for tobacco companies to develop reduced-risk products and to provide information about those products to consumers via the product packaging. The overwhelming majority of consumers were in favour of both. Indeed, 87% of respondents (and 92% of smokers) were in favour of tobacco companies bringing reduced-risk products to market and 90% of respondents (and 95% of smokers) believed that smokers had a right to access information about reduced harm on the product's packaging.[175]

120. Furthermore, Article 13(1)(c) appears to prohibit cigarette manufacturers from informing consumers (truthfully and without misleading) that a product contains, for example, a blend of tobacco leaves that produces a distinctive flavour or aroma. Remarkably, Article 13(1)(e) of TPD2 appears to prohibit cigarette manufacturers from (truthfully and without misleading) informing

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173 See [45-48] [**CB/3/77-78**].

174 *Ibid.*, at [51] [**CB/3/78-79**].

175 *Ibid.*

consumers that their products are more environmentally friendly than other products on the market.

121. Thus, a manufacturer that has developed or purchased, for example, cigarette filters with a faster rate of biodegradation than the filters used by other manufacturers, is not permitted to inform customers of that fact on the packaging. This position conflicts with other EU legislative measures in which the EU Legislature has expressly stated that "*consumers play a key role in the management of packaging and packaging waste and thus have to be adequately informed in order to adapt their behavior and attitudes*".[176] It is illogical that tobacco manufacturers should be *prohibited* from providing consumers with information that the EU Legislature itself considers essential for the protection of the environment.

122. Article 13(1) of TPD2 restricts the freedom of tobacco manufacturers to communicate true and non-misleading statements to consumers via their product packaging. Article 13(1) also impedes the right of consumers to receive such information. The right to freedom of expression includes (as Article 11 of the Charter expressly confirms) the right to receive information and ideas that others are willing to communicate.[177] The right of freedom of expression guaranteed by the Charter includes the right to engage in and receive "*commercial*" speech,[178] which is essential for the functioning of any competitive market and is also based upon the values of autonomy and human dignity.[179] The restriction of that right resulting from Article 13(1) of TPD2 assumes particular significance given that, as a result of the ban on tobacco advertising,[180] packaging is a key channel of communication between cigarette manufacturers and consumers.

123. The CJEU must, therefore, examine whether any restriction on commercial speech is proportionate to a legitimate aim. That is particularly so if the restricted speech serves to promote public health or protect the environment (as would some of the information prohibited by Article 13(1) of TPD2). It is also particularly important if the measure in question constitutes, like Article 13(1), a "*prior restraint*", thus warranting "*the most careful scrutiny on the part of the court*".[181] Very cogent reasons must be advanced in order to justify a ban on true and non-misleading speech as it is difficult to see that such a ban could be justified other than in the most exceptional circumstances.

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176 Directive 94/62 of 20 December 1994 on packaging and packaging waste, recital 30 [**Auth/9**].

177 See, for example, *Leander v Sweden* (1987) 9 E.H.R.R. 433 at [74] [**Auth/41**].

178 See, for example, *Remuszko v Poland* (ECtHR judgment of 16 July 2013) at [59] [**Auth/45**]; *Casado Coca v Spain* (1994) 18 E.H.R.R. 1 at [35-37] [**Auth/44**]; *Markt Intern GmbH v Germany* (1989) 11 E.H.R.R. 161 at [26] [**Auth/42**]. See also the *First Tobacco Advertising* case at [AG153-AG154], per AG Fennelly [**Auth/24**], and the *Second Tobacco Advertising* case at [155] [**Auth/30**].

179 See the *First Tobacco Advertising* case at [AG154], per AG Fennelly [**Auth/24**].

180 See Directive 2003/33/EC [**Auth/12**].

181 *Observer v United Kingdom* (1992) 14 E.H.R.R. 153 at [60] [**Auth/43**].

124. In order for the CJEU properly to carry out its function in this respect, it was therefore incumbent on the EU Legislature to provide robust and coherent evidence that Article 13(1) would be effective in achieving an internal market or public health objective and that a less restrictive measures would not have been equally as effective. The EU Legislature failed to do this. Indeed, as noted above, the Commission's Impact Assessment failed to provide any justification for the ban on true and non-misleading statements in Article 13(1).

What is the legitimate objective of Article 13(1) of TPD2?

125. Article 13(1) does not appear to pursue any internal market objective, and the EU Legislature has failed to identify any basis to justify the measure under Article 114 TFEU.

126. It follows that the proportionality of the measure must be assessed in relation to the public health objective that it purports to achieve. However, the EU Legislature has failed to demonstrate that the ban on true and non-misleading statements can be justified on public health grounds.

Article 13(1)(b), (c) and (e) is not an appropriate means of achieving a high level of public health protection

127. The Commission stated that TPD2 was intended to secure a high level of health protection and that it "*focuses on initiation of tobacco consumption, in particular by young people*".[182] The Commission appears to believe that prohibiting cigarette manufacturers from providing consumers with true and non-misleading statements about their products on packaging is an appropriate means of achieving that objective. There is, however, no proper evidential basis for concluding that the prohibitions in Article 13(1)(b), (c) and (e) satisfy the first limb of the proportionality test.

128. The section of the Impact Assessment entitled "*Problem Identification*" dealing, in particular, with packaging/labelling[183] contains no reference at all to any problems, whether related to public health or the internal market, arising from the inclusion on tobacco packaging of true and non-misleading statements about those products, whether in relation to health risks, the environment or flavour or aroma. The justification for Article 13 contained in recital 27 is concerned with "*misleading elements*" on packaging and contains no justification for banning elements that are not misleading. The failure to identify a problem to which Article 13 is a solution means in itself that the EU Legislature has failed to demonstrate the proportionality of the measure. Moreover, read literally, Article 13(1)(c), which prohibits true and non-misleading statements about flavour or aroma, appears to suggest that, even during the period within which it remains lawful for tobacco companies to manufacture and market menthol cigarettes, they will be prohibited from making any reference on the packaging to the fact that the cigarettes are

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182 Impact Assessment, p. 2 [**KD/25/72**].

183 *Ibid.*, pp. 29-33 [**KD/25/99-103**].

menthol-flavoured. That bizarre consequence would inevitably cause consumer confusion and cannot have been intended. Yet it appears that the EU Legislature failed to correct the wording of Article 13(1)(c) to clarify that issue.

129. In fact, the Commission appears to have had no evidence at all to suggest that these particular measures would improve public health. There was not even a clear assertion to that effect in the Impact Assessment. Nor did the Commission attempt to: (i) quantify any purported reduction in smoking prevalence as a result of Article 13(1); or (ii) take into account the chilling effect the measures would have on the development of reduced-risk products and the impact of that on public health.[184]

130. In short, there is no adequate evidential record establishing that Article 13(1)(b), (c) and (e) are appropriate measures to improve public health.

Less restrictive alternatives and the disadvantages of Article 13(1)(b), (c) and (e) of TPD2

131. Article 13(1)(b), (c) and (e) of TPD2 also fail to satisfy the second and third limbs of the proportionality test. Even if these measures were capable of achieving the EU's public health objectives, they would not be the least onerous measures that could be used.[185] The relevant objective is to prevent consumers from being given a false impression as to the health risks of using tobacco products. The provisions, however, are not confined to false or misleading information. They are accordingly disproportionate on that ground.

132. Furthermore, the EU Legislature failed to consider whether Article 13(1)(b) may harm public health by chilling the development of reduced-risk products. The EU Legislature should have considered those disadvantages and considered whether they rendered the measure disproportionate. It failed, however, to carry out such an assessment.

133. PMI expressly brought this issue to the Commission's attention during the legislative process. As Mr Doms explains, PMI requested a meeting in March 2012 at which it informed the Commission that PMI would be in a position to develop, substantiate and introduce these products "*in the near term*".[186] Moreover, PMI specifically stressed the need for TPD2 to "*permit manufacturers to make accurate and scientifically substantiated claims of reduced risk*".[187] Yet the Commission did not consider these points at all in its

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184 The Commission merely asserted that the packaging and labelling proposals would reduce smoking prevalence by 1-1.5% (the Impact Assessment, p .114 [**KD/25/184**]), but that forecast related mostly to the expected effect of larger health warnings and minimum packet sizes (measures that, unlike the prohibition on true and non-misleading statements, the Impact Assessment discussed in detail).

185 This is also true of Article 13(1)(b) if it applies to true and non-misleading statements. The record does not show that Article 13(1)(e) promotes a high level of public health.

186 See [45] [**CB/4/94**].

187 *Ibid.*, at [46] [**CB/4/94**].

Impact Assessment.

134. Following the Impact Assessment, as explained by Mr Doms, António Vitorino made the same point in his submission of 21 March 2013.[188] The European Economic and Social Committee also recognised the need for consumers to be informed about reduced-risk products, but no amendments were made to TPD2 to make that possible.[189]

135. It follows that the EU Legislature has failed to establish that Article 13(1)(b), (c) and (e) satisfy the third limb of the proportionality test.

Conclusion

136. The EU Legislature did not provide a proper justification for Article 13(1)(b), (c) and (e). As the recitals to TPD2 and the Impact Assessment reveal, the purported public health justification for these measures (such as it was) was anchored in the need to avoid misleading consumers. No justification whatsoever has been provided for prohibiting true and non-misleading statements and Article 13 is, on that basis alone, disproportionate. Furthermore, the EU Legislature failed to recognise and assess the public health disadvantages caused by the impact of the measure on the development of reduced-risk products. This constitutes a further ground for concluding that Article 13 is disproportionate. It follows that the prohibitions in Article 13(1)(b), (c) and (e) are unlawful because they infringe Article 11 of the Charter.

F. GROUND OF CHALLENGE 3: UNLAWFUL DELEGATION

Overview

137. PMI's third ground of challenge is that the EU Legislature has, in several instances, unlawfully conferred powers on the Commission to regulate tobacco products further. Although those powers are purported to have been conferred under the rubric of "*delegated*" or "*implementing*" acts under Articles 290 and 291 TFEU respectively, the acts in question go much further than is permitted by those provisions.

138. As such, these "*delegated*" and "*implementing*" acts amount to an unlawful circumvention of the constitutional procedures of checks and balances set out in the EU's "*ordinary legislative procedure*". Under the ordinary legislative procedure, important questions of EU policy fall to be determined through the combined efforts and scrutiny of the Commission (the EU's executive arm), the Council (representatives of the Member State Governments) and the

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188 *Ibid.*, at [47] [**CB/4/95**].

189 See [4.4] [**KD/46/132**].

European Parliament (the only directly elected element of the EU legislative system). Moreover, legislative proposals are subjected to review by national parliaments for compliance with the principle of subsidiarity (as to which, see below). Instead, under TPD2, important policy questions are delegated to the Commission to decide, with significantly less oversight by the other institutions of the EU, and without any oversight at all by the national parliaments.

Legal framework

139. The EU constitutional framework for secondary legislation is set out in Articles 290 and 291 TFEU, which distinguish between "*delegated*" acts and "*implementing*" acts. Those provisions are as follows.

140. Article 290 TFEU states:

> 1. A legislative act may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act.
>
> The objectives, content, scope and duration of the delegation of power shall be explicitly defined in the legislative acts. The essential elements of an area shall be reserved for the legislative act and accordingly shall not be the subject of a delegation of power.
>
> 2. Legislative acts shall explicitly lay down the conditions to which the delegation is subject; these conditions may be as follows:
>
> (a) the European Parliament or the Council may decide to revoke the delegation;
>
> (b) the delegated act may enter into force only if no objection has been expressed by the European Parliament or the Council within a period set by the legislative act.
>
> For the purposes of (a) and (b), the European Parliament shall act by a majority of its component members, and the Council by a qualified majority.
>
> 3. The adjective 'delegated' shall be inserted in the title of delegated acts.[190]

141. Article 291 TFEU states:

> 1. Member States shall adopt all measures of national law necessary to implement legally binding Union acts.

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190 [**Auth/1**].

> 2. Where uniform conditions for implementing legally binding Union acts are needed, those acts shall confer implementing powers on the Commission, or, in duly justified specific cases … on the Council.
>
> 3. For the purposes of paragraph 2, the European Parliament and the Council, acting by means of regulations in accordance with the ordinary legislative procedure, shall lay down in advance the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.
>
> 4. The word 'implementing' shall be inserted in the title of implementing acts.[191]

142. Several points emerge from those provisions.

143. First, the distinction between delegated and implementing acts is an objective one that depends on the function of the secondary legislation:[192]

(a) A delegated act is one that supplements or amends the primary legislation. The Commission has explained that amending means changing the text of, and supplementing means specifically adding new non-essential rules that change the framework of the legislative act; and[193]

(b) An implementing act is one that implements the primary legislation, in the same way as Member States implement directives in their own national law. That is, unlike a delegated act, an implementing act gives effect to the existing rules set out in the primary legislation by providing further details of them, but without amending those rules or adding new ones.[194]

144. Second, the TFEU specifies the substantive conditions according to which delegated or implementing powers can be conferred on the Commission:

(a) Delegated powers can only be conferred in relation to "*non-essential elements*" of the primary legislation. Moreover, the Commission's discretion is narrowly circumscribed by the primary legislation. In particular, the "*objectives, content, scope and duration of the delegation of power shall be explicitly defined*" by the primary legislation.[195] The concept of "*essential elements*" of legislation derives from a long line of CJEU decisions under the Pre-Lisbon Treaties. In those decisions, the CJEU has stated that "*essential*"

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191 *Ibid.*

192 See the Commission's Communication to the European Parliament and the Council concerning the Implementation of Article 290 TFEU (COM(2009) 673), at p. 3 [**Auth/50**].

193 *Ibid.*, at p. 4.

194 *Ibid.*

195 Article 290(1) TFEU [**Auth/1**].

elements entail "*political choices falling within the responsibilities of the European Union legislature, in that* [they require] *the conflicting interests at issue to be weighed up on the basis of a number of assessments*".[196] The CJEU has also characterised as "*essential*" legislation that can "*mean that the fundamental rights of the persons concerned may be interfered with to such an extent that the involvement of the European Union legislature is required*"; and[197]

(b) Implementing powers can only be conferred on the Commission "[w]*here uniform conditions for implementing legally binding Union acts are needed*".[198] That limitation on the EU Legislature's ability to confer power on the Commission reflects the important EU constitutional concept of subsidiarity (discussed below in PMI's fourth ground of challenge). It is only when uniform implementation is "*needed*" that implementing acts can be put in place.

145. Third, the TFEU sets out the different checks and balances that apply to delegated and implementing acts:

(a) Primary legislation that confers delegated powers can provide the Council and Parliament with veto rights over the Commission's delegated acts and with the right to revoke the power of delegation. Importantly, however, neither the Council nor the Parliament can ever be empowered to amend the Commission's delegated acts; and

(b) Implementing powers are exercised by the Commission subject to the control of the committee procedures that the EU Legislature has created pursuant to Article 291(3) TFEU. Regulation 182/2011 of the Parliament and of the Council sets forth the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.[199] Essentially, the procedure involves scrutiny by committees made up of technical experts appointed by the Member States. The committees either follow an "*advisory procedure*", pursuant to which the Commission must take the committee's opinion into account when making its implementing acts, or an "*examination procedure*", pursuant to which the committee has a veto right over the Commission's draft implementing acts. Neither the Council nor the Parliament has rights of veto. Rather, Article 11 of Regulation 182/2011 provides that the Parliament and Council can express a view that the draft act exceeds the Commission's powers, in which case the Commission must take that view into account.

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196 Case C-355/10 *Parliament v Council* (judgment of 5 September 2012) (the "*SBC* case") at [76] [**Auth/35**].

197 *Ibid.*, at [77].

198 Article 291(2) TFEU [**Auth/1**]

199 [2011] OJ L 55/13 [**Auth/16**].

146. Although, as noted above, there must be an objectively verifiable boundary between permissible and impermissible delegations under Articles 290 and 291 TFEU, the CJEU is yet to clarify precisely where that boundary lies. The CJEU has only been called upon to apply Articles 290 and 291 TFEU (as opposed to the Pre-Lisbon provisions that they replaced) in two cases, both of which were decided earlier this year.[200] Neither judgment needed to consider the boundary between essential and non-essential elements that is at issue in the present case. The Opinions of the Advocates General (Jääskinen and Cruz Villalón respectively) did address that issue, but reached different conclusions. Advocate General Cruz Villalón expressed caution about drawing too heavily from Pre-Lisbon case-law when interpreting Articles 290 and 291 TFEU.[201] Advocate General Jääskinen, by contrast, specifically endorsed the analysis of the CJEU in the *SBC* case (discussed above) as to the distinction between "*essential*" and "*non-essential*" acts.[202] On that issue, Advocate General Cruz Villalón appeared to suggest that, if anything, the scope for delegation might be narrower under Article 290 TFEU than it was in the Pre-Lisbon environment.[203]

147. In light of the absence of clear authority on the EU constitutional principles at stake, PMI respectfully submits that it is essential that a reference to the CJEU should be made.

The TPD2 legislative process leading to the incorporation of delegated and implementing acts

148. As noted above, an important part of the EU legislative process is scrutiny by the various committees of the European Parliament. A particularly important committee, from the perspective of compliance with the constitutional rules in the Treaties, is the Legal Affairs Committee. That committee expressed serious concerns about the constitutionality of TPD2 that the EU Legislature has never addressed adequately (if at all).

149. In relation to the various conferrals of powers to make delegated and implementing acts, the Legal Affairs Committee gave a special, detailed opinion on 10 July 2013, which was in addition to the more general opinion of 20 June 2013 (discussed above in the context of legal basis).[204] In its opinion, the Legal Affairs Committee noted that there was an "*absence of any case law from the Court of Justice on the question of the demarcation between*

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200 See Case C-270/12 *UK v Council and Parliament* (judgment of 22 January 2014) [**Auth/38**] and Case C-427/12 *Commission v Parliament and Council* (judgment of 18 March 2014) [**Auth/39**].

201 See the Opinion of AG Cruz Villalón in Case C-427/12 *Commission v Parliament and Council* (Opinion of 19 December 2013) at [AG33]-[AG34] [**Auth/39**].

202 See the Opinion of AG Jääskinen in Case C-270/12 *UK v Council and Parliament* (Opinion of 12 September 2013) at footnote 102 [**Auth/38**].

203 Case C-427/12 *Commission v Parliament and Council* (Opinion of 19 December 2013) at [AG75] [**Auth/39**].

204 [**KD/41/200-217**].

delegated and implementing acts".[205] It therefore applied first principles, and concluded as follows:

> … the Committee on Legal Affairs should take the view that with the exception of [four particular provisions] none of the suggested provisions on delegated acts should be accepted by Parliament.
>
> All other suggested provisions providing for the adoption of delegated acts should be deleted and the substantive content included in the basic act. In certain cases, delegated acts could be used to make determinations or implementing acts to provide uniform implementing conditions, but only where the criteria are further specified in the basic act. Alternatively, the Commission could be required to draw up a report within a certain time-span to the co-legislators, with possible accompanying proposals for amending legislative acts, as in [a previous directive].[206]

150. The Legal Affairs Committee's concerns went unheeded by the Parliament, which negotiated the final text of TPD2 with the Council and Commission in the trilogue procedure. Although the original Commission proposals considered by the Legal Affairs Committee were amended during that procedure, no reasons have been published to explain how those amendments address the Legal Affairs Committee's concerns, and, as explained below, they fail to do so.

The unlawful delegated and implementing acts in TPD2

151. The Legal Affairs Committee's opinion identified three categories of unlawful conferrals of powers to make delegated and implementing acts:

(a) Powers in relation to emissions levels (Articles 3 and 4);

(b) Powers in relation to ingredients (Article 7); and

(c) Powers in relation to labelling (Articles 9, 10 and 12).

152. Those conferrals of power are considered in turn below.

<u>The delegations concerning emissions levels (Articles 3 and 4) are unlawful</u>

153. Article 3 states in relevant part:

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205 See pp. 4/18 and 5/18 of the Committee's opinion [**KD/41/203 and 204**]. This opinion pre-dated the judgments of the CJEU discussed above, but as noted above, neither judgment sheds much light on the issues raised by the Committee's opinion.

206 [**KD/41/205**].

> 1. The emission levels from cigarettes placed on the market or manufactured in the Member States ('maximum emission levels') shall not be greater than:
>
> a) 10 mg of tar per cigarette,
>
> b) 1 mg of nicotine per cigarette,
>
> c) 10 mg of carbon monoxide per cigarette.
>
> 2. The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to decrease the maximum emission levels laid down in paragraph 1, where this is necessary based on internationally agreed standards.
>
> …
>
> 4. The Commission shall adopt delegated acts in accordance with Article 27 to integrate standards agreed by the parties to the FCTC or by the WHO relating to maximum emission levels from cigarettes other than the emissions referred to in paragraph 1 and for emissions from tobacco products other than cigarettes into Union law.[207]

154. Article 3 therefore confers on the Commission two forms of delegated powers: the power to decrease the cigarette emission levels laid down in Article 3(1), and the power to specify new maximum emission levels for other substances (*i.e.* other than TNCO) or for other products (*i.e.* other than cigarettes).

155. The rationale for those provisions is set out in recitals 10 and 12 to the Directive:

> (10) [TPD1] established maximum limits for tar, nicotine and carbon monoxide yields of cigarettes … Those maximum limits and that approach remain valid.
>
> …
>
> (12) As regards establishing maximum emission levels, it could be necessary and appropriate at a later date to reduce the emission levels for tar, nicotine and carbon monoxide or to establish maximum levels for other emissions from tobacco products, taking into consideration their toxicity or addictiveness.[208]

156. The constitutional question, however, is which institutions are authorised to set new maximum emission levels. The current levels were set by the EU Legislature, presumably with all of the constitutional checks and balances entailed in the ordinary legislative procedure. With TPD1 and TPD2, the

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207 [**Auth/15**].

208 *Ibid.*

Commission made its proposals, Parliament and the Council had the opportunity to propose amendments, and all three institutions of the EU were required to approve the final text. In contrast, Article 3(2) of TPD2 purports to empower the Commission to bypass those checks and balances, and decide on new maximum emission levels subject only to veto rights by the Council and Parliament.

157. TPD2 also sets no limits on how low the Commission could set maximum emission levels using its delegated powers. Article 2(22) defines "*maximum emission level*" to mean "*the maximum ... emission, including zero, of a substance in a tobacco product measured in milligrams*".[209] Accordingly, the Commission could, in theory, exercise its powers under Article 3(2) or (4) of TPD2 to prohibit the sale of tobacco products throughout the EU. As the Legal Affairs Committee put it:

> In view of the public health aim, the question of level of harmful substances touches upon essential elements. The scope of potential prohibition is unlimited.[210]

158. The Legal Affairs Committee was correct. To paraphrase the passages in the CJEU's judgment in the *SBC* case cited above and apply them to the facts of this case, the setting of maximum emissions levels entails political choices falling within the responsibilities of the EU Legislature (assuming that the EU has competence to act at all), in that it requires the conflicting interests at issue to be weighed up on the basis of a number of assessments. Moreover, the regulation of tobacco emissions (and even more so, a complete prohibition) would engage fundamental rights to such an extent that the involvement of the EU Legislature is required. For that reason, this delegation cannot be regarded as a "*non-essential*" element of the legislative act as required by Article 290(1) TFEU.

159. Indeed, one way of testing that point is to consider the fact that there was once a directive that did nothing other than set maximum tar levels for cigarettes. Maximum tar levels must therefore have been an essential element of that directive – after all, that directive did nothing else. But if maximum tar levels were an essential element of that directive, then they must also be an essential element of this Directive. The fact that they are now included among a package of other measures in a single directive cannot change the analysis.

160. The only guidance given by TPD2 as to the scope of the Commission's power is that the emission levels laid down in Article 3(1) can only be amended "*where this is necessary based on internationally agreed standards*".[211] But if the EU Legislature cannot delegate responsibility for making decisions of this kind to the Commission, it follows *a fortiori* that the EU Legislature cannot make the delegation of such powers further dependent on action taken by

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209 *Ibid.*

210 [**KD/41/207**].

211 [**Auth/15**].

international organisations either. As the CJEU stated in *Kadi*:

> an international agreement cannot affect the allocation of powers fixed by the Treaties …
>
> the obligations imposed by an international agreement cannot have the effect of prejudicing the constitutional principles of the EC Treaty, which include the principle that all Community acts must respect fundamental rights, that respect constituting a condition of their lawfulness which it is for the Court to review in the framework of the complete system of legal remedies established by the Treaty.[212]

161. Just as the CJEU found in *Kadi* that a UN Security Council resolution made under the UN Charter could not override the constitutional procedures and fundamental rights protected by the Treaties, so the (more amorphous and less significant) "*internationally agreed standards*" referred to in Article 3 of TPD2 cannot override the need for a full, ordinary legislative procedure to modify the emission levels set down in that Article. Indeed, it is entirely unclear as to what is meant by "*internationally agreed standards*" in this context. By way of illustration, the Directive leaves unanswered the question of whether such standards could extend to non-binding guidelines made by international bodies concerned with tobacco control, or even by declarations made exclusively by non-EU States.

162. The delegation set out in Article 3(4) of TPD2 is equally problematic. Like the delegation in Article 3(2), it envisages that the Commission may set new maximum emission levels. However, rather than conferring discretion on the Commission, it compels the Commission to act to implement standards "*agreed*" by the parties to the FCTC or the World Health Organisation (the "WHO"). If giving the Commission a discretion to implement such unspecified standards agreed by such bodies is unlawful, then compelling the Commission to do so must also be unlawful. Moreover, the text of Article 3(4) does not even explain what the term "*agreed*" means in this context.

163. Article 4(5) of TPD2 is unlawful for the same reasons as Article 3(4). Article 4 establishes the methodology for measuring emissions levels for the purposes of the maximum levels stipulated by Article 3. Article 4(5) is unlawful because it compels the Commission to adopt any new methods for measuring emissions that the parties to the FCTC agree or that the WHO stipulates.

The delegations concerning ingredients regulation (Article 7) are unlawful

164. Article 7(1) of TPD2 prohibits "*the placing on the market of tobacco products with a characterising flavour*". The term "*characterising flavour*" is defined by Article 2(25) to mean:

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[212] Cases C-402/05 P and 415/05 P *Kadi v Council* [2008] I-6351 at [282] and [285] [**Auth/32**].

> a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product.[213]

165. Articles 7(2) to 7(5) then create a complex scheme of implementing and delegated acts to give effect to that broad prohibition:

    (a) Article 7(2) empowers the Commission to determine, by implementing act, whether a particular tobacco product falls within the scope of paragraph 1;

    (b) Article 7(3) requires the Commission to adopt implementing acts laying down uniform rules for the procedures for determining whether a tobacco product falls within paragraph 1;

    (c) Article 7(4) provides for the Commission to adopt implementing acts establishing an independent advisory panel to advise Member States and the Commission on the application of Article 7(1); and

    (d) Article 7(5) empowers the Commission to adopt delegated acts setting maximum content levels for additives resulting in characterising flavours where a particular additive has been banned or restricted in at least three Member States.

166. The second set of delegated and implementing acts in Article 7 relates to the prohibition on tobacco products containing additives that increase the toxic or addictive effect, or the carcinogenic, mutagenic or reprotoxic properties of a tobacco product "*to a significant or measurable degree*" (Article 7(9) of TPD2).[214] As with the ban on characterising flavours, TPD2 creates a complex scheme of implementation and delegation:

    (a) Article 7(10) empowers the Commission to determine by implementing act whether a tobacco product falls within the scope of Article 7(9); and

    (b) Article 7(11) provides that, where an additive has been banned in at least three Member States for breach of Article 7(9), the Commission may adopt delegated acts to set maximum content levels for those additives, and that those levels shall be set at the lowest maximum level set by the Member States.

167. The third category of delegated act relates to tobacco products other than cigarettes and roll-your-own tobacco. Article 7(12) TPD2 exempts those products from the prohibitions on flavourings set down in Articles 7(1) and

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213 [**Auth/15**].

214 *Ibid.*

7(7). But it also permits the Commission to withdraw that exemption for a particular product category "*if there is a substantial change of circumstances as established in a Commission report*" as defined in Article 2(28).[215]

168. The common element in each of those three circumstances is that the EU Legislature has failed to complete the task of specifying the essential elements of the Directive. That is most obvious in Article 7(12), where the Commission has *carte blanche* to apply the scheme of flavouring regulation to entirely new categories of products when there has been a change of circumstances within the meaning of Article 2(28). But even in those circumstances, deciding which categories require legislation is a matter for the EU Legislature.

169. The same proposition is true for the implementation of the general ban on characterising flavours and the ban on harmful additives. In both cases, the EU Legislature has failed to specify essential elements of the Directive.

170. There is also no justification for the delegated acts set out in Articles 7(5) and 7(11) (*i.e*. the provisions that empower the Commission to extend a ban in three Member States throughout the Union). Those provisions do not supplement or amend the Directive; they implement it in exactly the same way as Articles 7(2) and 7(10) implement it. In both cases, the Commission is empowered to set limits on the use of additives on the grounds that they result in a characterising flavour or are harmful. But when the Commission comes to exercise those powers, it will simply be applying the general prohibitions in Articles 7(1) and 7(9) to the facts of a particular additive. Such an exercise could not be construed as supplementing or amending the Directive. For that reason, at the very least, those Articles must be struck down.

Labelling (Articles 9, 10 and 12)

171. Articles 9, 10 and 12 of TPD2 put in place a detailed system of health warnings to be included on packages for various tobacco products. In particular:

(a) Article 9 provides for the display of certain specific textual messages such as "*Smoking kills*" and provides details on exactly where on the package they shall be displayed and how large and in what font they should appear;

(b) Article 10 provides for the display of "*combined*" text and photographic health warnings. Again, it provides a list of approved text and it provides for a library of approved photographs to be established by the Commission; and

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215 *Ibid.*

(c) Article 12 provides for the display of the words "*This tobacco product damages your health and is addictive"* on packaging for smokeless tobacco products.[216]

172. In each case in respect of the textual messages, however, having specified the essential elements of the legislation, the EU Legislature then empowered the Commission to change the text warnings in a manner that may be inconsistent with the EU Legislature's specifications (see Articles 9(5), 10(3) and 12(3) of TPD2).[217] The only limitation on the Commission's freedom to changes those warnings is that is provided by Article 8(7): "*the Commission shall ensure that it is factual or that Member States shall have a choice of two warnings, one of which is factual*".[218]

173. In other words, having selected warnings that the EU Legislature considered to be factually accurate and effective, the EU Legislature has also empowered the Commission to select entirely different warnings. The warnings contained in TPD2 were selected pursuant to the legislative process. However, the Commission now has the power to select new warnings that are not subject to the same legislative controls. Moreover, the Commission could, in theory, require warnings that are false or misleading, as one of the two warnings need not be "*factual*". The Commission could therefore completely alter the message that had been selected by the EU Legislature. To use the words of the Legal Affairs Committee, that delegation "*clearly touches upon essential elements*" and is therefore unlawful.[219]

174. In respect of the photographic warnings, the EU Legislature did not even establish the library in the first place. If permitting the Commission to amend a library of warnings is impermissible, it follows *a fortiori* that permitting the Commission to establish such a library and also to amend it subsequently is also impermissible. By way of illustration, the Commission could establish a library of photographic warnings that convey messages that are inconsistent with the text warnings selected by the EU Legislature.

G. GROUND OF CHALLENGE 4: BREACH OF THE PRINCIPLE OF SUBSIDIARITY

Legal Framework

175. TPD2 also fails to comply with the principle of subsidiarity, which limits the exercise of the EU's powers under the Treaties.

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216 *Ibid.*

217 *Ibid.*

218 *Ibid.*

219 [**KD/41/211**].

176. The principle of subsidiarity is set out in Article 5(3) TEU:

> 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.[220]

177. The Protocol on the Application of the Principles of Subsidiarity and Proportionality (the "Protocol"), recently introduced in the Treaty of Lisbon, establishes a procedure pursuant to which national parliaments are empowered to make submissions on the compliance of draft legislation with the principle of subsidiarity. In particular, Article 5 of the Protocol requires the Commission to provide a "*detailed statement making it possible to appraise the compliance* [of draft legislation] *with the principles of subsidiarity and proportionality.*" In that statement "[t]*he reasons for concluding that a Union objective can be better achieved at Union level shall be substantiated by qualitative and, wherever possible, quantitative indicators*". [221]

178. Pursuant to that Protocol, each national parliament is given eight weeks in which to submit a "*reasoned opinion*" under Article 6 of the Protocol "*stating why it considers that the draft in question does not comply with the principle of subsidiarity*".[222] Article 7(2) provides that "[w]*here reasoned opinions on a draft legislative act's non-compliance with the principle of subsidiarity represent at least one third of all the votes allocated to the national Parliaments ... the draft must be reviewed*". [223] Moreover, Article 7(3) provides that "*where reasoned opinions on the non-compliance of a proposal for a legislative act with the principle of subsidiarity represent at least a simple majority of the votes allocated to the national Parliaments ... the proposal must be reviewed* [and] *if* [the Commission] *chooses to maintain the proposal, the Commission will have, in a reasoned opinion, to justify why it considers that the proposal complies with the principle of subsidiarity.*"[224]

179. The principle of subsidiarity is not governed solely by this political process, however. It is a legally binding principle subject to *ex post* judicial review by the EU Courts, which are tasked with the important function of ensuring that the EU Legislature complies with it.

180. Indeed, it is possible that, even if the EU Legislature has competence under Article 114 TFEU, the measure will nevertheless fail to satisfy the principle of subsidiarity:

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220 [**Auth/15**].

221 [**Auth/2**].

222 *Ibid.*

223 *Ibid.*

224 *Ibid.*

(a) First, as noted above, the principle of subsidiarity demands that "*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*".[225] Compliance with Article 114 TFEU might normally be enough to show that Member States on their own could not achieve in full the Union's objectives in making the legislation in question, but it does not answer the question of whether the Union has gone further than necessary to do so; and

(b) Second, because measures under Article 114 TFEU can also pursue secondary objectives, those secondary objectives must also be tested against the principle of subsidiarity. Just as secondary objectives can tilt the balance of a proportionality assessment, so too, as a matter of logic, can they tilt the balance of a subsidiarity assessment. For example, a measure might marginally satisfy the threshold for power to act under Article 114 TFEU (*e.g.* it makes a modest contribution to the internal market), but it might also have major public health (or other policy) implications that each Member State might have strong preferences for addressing in its own way. In those circumstances, subsidiarity might well require the EU to refrain from exercising its power to legislate. Restraint on the part of the EU Legislature would be fully justified by the preservation of Member State freedom to choose how they want to respond to the public policy issues at hand.

181. In summary, the distinction between legal basis and subsidiarity is as follows: legal basis concerns the EU Legislature's power to act, whereas subsidiarity (like proportionality) concerns the manner in which the EU Legislature exercises that power. The power to act does not imply that the exercise of that power will be lawful. Instead, the CJEU must adjudicate not only whether the exercise of power was *intra vires* and proportionate, but also whether, bearing in mind the legislation's objectives, the EU Legislature adequately considered the benefits of allowing Member States the freedom to decide the public policy issues for themselves.

182. The EU Legislature must demonstrate that it complied with the principle of subsidiarity on the basis of objective factors that are capable of judicial review. The CJEU must review whether the EU Legislature has asked itself the right questions and given rational, evidence-based answers. Indeed, the Treaty of Lisbon strengthened judicial review of subsidiarity by increasing the requirements for formal justification during the legislative process and by conferring on national parliaments and the Committee of the Regions the power to bring an action before the CJEU challenging the subsidiarity of EU legislation.[226] Moreover, the Treaty of Lisbon made available new rights to judicial review, thereby signalling that rigorous judicial review is required to ensure compliance with the principle of subsidiarity.

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225 [**Auth/1**]. Emphasis added.

226 Protocol (No 2) on the Application of the Principles of Subsidiarity and Proportionality, Article 8 [**Auth/2**].

The subsidiarity check in this case

183. The subsidiarity check procedure in this case began with the transmission of the Commission's proposal for a Directive to the national parliaments on 3 January 2013. The deadline for submission of reasoned opinions was therefore 4 March 2013. Not surprisingly, given that many (if not all) national parliaments were not in session during at least a substantial part of that period, several parliaments (including both the United Kingdom's House of Commons and the House of Lords) were unable to complete their internal scrutiny processes during the relevant period. Of the 39 parliamentary chambers throughout the EU, only 19 (*i.e.* just under half) managed to complete the process during the time allowed.[227] Ten chambers were unable even to begin the process.

184. However, almost half the number that were able to complete the process submitted reasoned opinions stating that TPD2 failed to respect the principle of subsidiarity. In particular, they criticised the legality of the draft Directive for lacking a valid internal market basis, for violating the principle of proportionality, and for excessive delegations of power to the Commission.

185. Although the nine reasoned opinions fell just short of the number of votes required to bring about a review of the draft Directive,[228] the strong views expressed in those opinions underline the need for careful judicial scrutiny of the legality of the Directive in this case.

The Directive does not respect the principle of subsidiarity

186. As a preliminary matter, if, as PMI contends (and several national parliaments contended), the Directive does not serve any valid internal market objective, it necessarily also infringes the principle of subsidiarity.

187. However, even if the Directive is capable of justification on internal market grounds, the menthol ban effected by Article 7 TPD2 nevertheless infringes the principle of subsidiarity. The menthol ban's internal market objective (if there were one) could equally have been achieved by imposing uniform regulation falling short of a ban across the Union. To give one simple example: Article 7 of TPD could have prohibited all Member States from banning menthol. Equally, TPD2 could have left to the Member States the decision on whether to ban, to regulate, or to permit menthol. The EU Legislature's decision to impose a universal ban therefore requires judicial

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227 IPEX, *National Parliaments' subsidiary check procedure scrutiny status*, http://www.ipex.eu/IPEXL-WEB/dossier/dossier.do?code=COD&year=2012&number=0366&appLng=EN, accessed on 18 June 2014 [**KD/26/1-2**].

228 Each Member State's parliament has two votes. Where a Member State operates a bicameral system, each house has a single vote. The nine reasoned opinions in this case covered 14 votes out of a total of 56. A further two and a half national parliaments would therefore have sufficed to trigger a review.

review to test for compliance with the principle of subsidiarity.

188. The only basis on which the decision to ban rather than permit menthol could conceivably be justified is on public health grounds. Indeed, that is the only justification given in the Impact Assessment for choosing between harmonising options.[229] But, as discussed above, that public health justification calls for a subsidiarity analysis and the CJEU must appraise whether the EU Legislature has asked itself the right subsidiarity questions and has given rational, evidence-based answers.

189. In this case, the EU Legislature has done neither. Neither the recitals to TPD2 nor the Commission's Impact Assessment grapple adequately with, let alone show, that the principle of subsidiarity has been respected. They use boilerplate language that simply asserts compliance with the principle without giving any explanation of the basis for that assertion. In the section of the Impact Assessment that dealt with subsidiarity, the EU Legislature said nothing at all about its public health objective. There was not even an acknowledgement that by banning menthol throughout the EU, the EU Legislature was necessarily preventing Member States from deciding for themselves how to deal with the public health issues (if any) that they might perceive to arise from menthol cigarettes. The EU Legislature therefore failed to show that the deprivation of Member State freedom to act in relation to public health was justified by the (alleged) internal market benefits of the menthol ban.

190. As Mr Azinovic explains, consumer taste for menthol cigarettes varies significantly across the EU.[230] In some markets they are barely sold at all, whereas in others they account for up to a quarter of cigarette sales. Moreover, the risks of illicit trade are likely to vary according to the proximity of a particular Member State to non-EU States in which menthol cigarettes will continue to be available. Even if the EU Legislature were to have concluded that the subsidiarity test was satisfied in respect of the other elements of the Directive, it should have given much more consideration to the question of whether it was satisfied in respect of the menthol ban.

191. Moreover, some of the other choices made by the EU Legislature strongly suggest that if the subsidiarity question had been properly posed in relation to menthol cigarettes, the answer would have been negative:

    (a) As discussed above, the EU Legislature appears to have considered it to be acceptable in internal market terms that Member States should be free to choose to ban additional categories of tobacco products under Article 24(3) of TPD2 because of public health issues specific to that Member States. That raises the question of why the same should not apply in respect of menthol cigarettes; and

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229 Impact Assessment, p. 47 [**KD/25/117**].

230 See [17] at [**CB/3/70**].

(b) The Commission considered, in its Impact Assessment, the possibility of applying different regulatory treatments to smokeless tobacco products according to whether they had been in use for more than 30 years. In the final version of the Directive, such "*traditional use*" smokeless tobacco products were protected from outright prohibition by their "*traditional use*" status (see recital 32). The EU Legislature therefore respected the principle of subsidiarity by showing sensitivity to the "*traditional use*" status of smokeless tobacco products in some Member States. But it gave no reasons whatsoever for failing to show the same sensitivity to the "*traditional use*" status of menthol cigarettes, which have been used for even longer in several Member States. Indeed, no mention is made in the Impact Assessment of the traditional use status of menthol cigarettes.

192. For those reasons, the menthol ban fails to respect the principle of subsidiarity.

H. JURISDICTION, STANDING AND THE NEED FOR A REFERENCE TO THE CJEU

The Court's jurisdiction to entertain a challenge to EU legislation

193. The Court has on several occasions held that it has jurisdiction to entertain an application for judicial review based on the invalidity of EU legislation, provided only that the application is brought by a claimant with standing under domestic law.[231] The CJEU has confirmed that, in order to give effect to the EU law right to effective legal protection, it must be possible for natural and legal persons to challenge before the national courts EU measures of direct application that affect them.[232] The only circumstance in which EU law prevents the Court from entertaining such applications is where the claimant could have brought a direct action before the General Court challenging the EU legislation, but failed to do so.

194. The law governing standing to bring direct actions in the General Court is set out in Article 263 TFEU, which provides that an applicant may have standing where the challenged measure is "*of direct and individual concern*" to the applicant or that it is a "*regulatory act*" that is of "*direct concern*" to the applicant and that does not entail implementing measures.

195. The case-law of the CJEU and General Court has set a high bar for the establishment of "*individual concern*". An applicant will only be individually concerned by a decision that is not addressed to it if it affects the applicant "*by*

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231 See, for example, *R (on the application of ABNA Limited) and others v The Secretary of State for Health and another* [2003] EWHC 2420 (Admin) at [15] [**Auth/46**].

232 See, for example, Case C-50/00 P *Unión de Pequeños Agricultores v Council* [2002] ECR I-6677 at [42] [**Auth/25**].

reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons and by virtue of these factors distinguishes them individually just as in the case of the person addressed".[233] In this case, TPD2 cannot be said to affect a fixed and closed group of persons.[234] In that regard, PMI is in the same position as the tobacco companies that have brought similar challenges in the past to EU legislation by way of judicial review in England, including BAT's challenge to TPD1 discussed above.

196. The position is the same in respect of the provision for standing to challenge "*regulatory acts*". In Case C-583/11 *Inuit Tapririit Kanatami v Parliament* and Council, the CJEU held that "*the concept of 'regulatory act' provided for in the fourth paragraph of Article 263 TFEU does not encompass legislative acts*".[235] TPD2 is a legislative act made in accordance with the ordinary legislative procedure.

197. It follows that PMI would not have had standing to challenge TPD2 in the General Court and a claim for judicial review is the only remedy open to PMI.

Obligation to make preliminary reference to the CJEU

198. Although the Court has jurisdiction to entertain applications based on the invalidity of EU legislation, it does not have the power to declare EU legislation invalid without making a reference to the CJEU under Article 267 TFEU. Consequently, where a substantial doubt is raised as to the validity of an EU measure and where it is clear that a decision on the validity of that measure is necessary for the resolution of the case, the Court is bound to refer the question of the validity of the legislation to the CJEU. The UK Courts have interpreted "*substantial doubt*" to mean essentially the same standard of arguability as the Administrative Court applies at the permission stage of a judicial review.[236]

199. Accordingly, if the Court accepts that the grounds outlined above are arguable, it is bound to grant permission and make a reference.

200. In PMI's letter before action, PMI invited the Defendant to acknowledge that

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233 Case 25/62 *Plaumann & Co v Commission* [1963] ECR 95 at [107] [**Auth/17**].

234 *cf.* Case 11/82 *AE Piraiki-Patraiki v Commission* [1985] ECR 207 [**Auth/18**].

235 Judgment of 3 October 2013 at [61] [**Auth/37**].

236 See Case 314/85 *Foto-Frost* [1987] ECR 4199 per AG Mancini at [AG9(1)] [**Auth/19**]. This test has been applied in Scotland (see *Booker Aquaculture v Secretary of State for Scotland* 2000 SC 9 per Lord Rodger at [27], referring an issue because it was one that "*I cannot with complete confidence resolve myself*") [**Auth/48**] and by the Administrative Court in England (*R (SCPM SA) v Secretary of State for the Environment, Food and Rural Affairs* [2007] EWHC 2610 (Admin), [2008] EuLR 250, per Jackson J, at [23], referring a question to the CJEU because "*I am satisfied that there is a serious issue concerning the validity*" of the relevant provision) [**Auth/47**]. See, generally, Edward and Lane on European Union Law (2013) at [5.140] [**Auth/54**].

the grounds outlined above are arguable and that a reference to the CJEU should therefore be made. The Defendant indicated by reply, however, that it would prefer to reserve its position on that question until it has seen this Detailed Statement of Facts and Grounds, and the evidence on which PMI relies.

PMI's standing before the Court

201. For completeness, in light of the fact that PMI manufactures and markets tobacco products (including cigarettes) throughout the EU, it clearly meets the threshold level of "*sufficient interest*" for the purposes of standing to make an application for judicial review before this Court.

I. RELIEF

202. PMI seeks, by way of relief, following a successful reference to the CJEU, a declaration that TPD2 is invalid and the United Kingdom therefore has no obligation to implement it.

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