CLAIM NO. TBA

IN THE HIGH COURT OF JUSTICE

ADMINISTRATIVE COURT

BETWEEN

THE QUEEN

On the application of

PILLBOX 38 (UK) LIMITED (Trading as "Totally Wicked")

Claimant

-and-

THE SECRETARY OF STATE FOR HEALTH

Defendant

STATEMENT OF FACTS AND GROUNDS

References to pages in the accompanying application bundle are given as [AB/Volume/Tab/Page].

The essential reading for this application is:

1. The Tobacco Products Directive 2014 *[AB/2/7.1/1]*;
2. The witness statement of Fraser Cropper dated 4 July 2014 *[AB/1/6/1]*;
3. The Commission Impact Assessment at pages 15 to 18, 52 to 53 and 77 to 84 *[AB/2/7.5/135]*;
4. A letter from a group of scientific experts to the Commission dated 16 January 2014 *[AB/3/8.11/138]*;
5. Study by Dr Maciej Goniewicz of the Department of Health Behaviour at the Roswell Park Cancer Centre Institute in Buffalo, New York, USA *[AB/3/8.5/67]*;
6. Paper produced by the National Centre for Smoking Cessation and Training *[AB/3/8.8/108]*;
7. A report from Public Health England, May 2014 *[AB/3/8.7/78]*.

The time estimate for this reading is four hours.

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A. Introduction

1. The Claimant is Pillbox 38 (UK) Limited. It is an electronic cigarette wholesaler and retailer, trading under the name "Totally Wicked".

2. The Defendant is the Secretary of State for Health. The Department of Health is the designated department responsible for the implementation of Directive 2014/40/EU – the Tobacco Products Directive 2014 ('the TPD 2014').[1] The TPD 2014 substantially modifies the EU regime governing the sale of tobacco products, formerly found in Directive 2001/37/EC ('the TPD 2001').[2] In addition, it brings within its regulatory scope tobacco related products, which are defined to include "electronic cigarettes" even though these products contain no tobacco.

3. The Claimant contends that Article 20 of the TPD 2014 is invalid, on the basis that it represents a disproportionate impediment to the free movement of goods and/or the free provision of services. Further or alternatively, Article 20 distorts the nature of competition in the relevant markets for electronic cigarettes and tobacco products and fails to comply with the general EU principle of equality. Since Article 20 of the TPD 2014 infringes Union law and is invalid, the Secretary of State is precluded from implementing its provisions into domestic law (as he is presently required to do by 20 May 2016 in accordance with Article 29(1) of the Directive).

4. For the reasons set out below, it is not open to this Court to make a declaration that Article 20 of the TPD 2014 is incompatible with EU law without a reference for a preliminary ruling from the Court of Justice of the European Union ('ECJ') pursuant to Article 267 of the Treaty on the Functioning of the European Union ('TFEU'). The Claimant accordingly requests that such a reference be made to seek a ruling from the

[1] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, OJ [2014] L No 127, 29.4.2014, p. 1.

[2] Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products, OJ [2001] L No. 194, 18.7.2001, p. 26.

ECJ declaring Article 20 of the TPD 2014 to be invalid. Proposed questions for the reference are set out in Annex 1 to this Statement of Facts and Grounds.

5. In the circumstances, the Claimant seeks the following relief:

   5.1. Permission to apply for judicial review of the UK's obligation to implement the TPD 2014;
   5.2. The determination of appropriate questions for a reference to the ECJ under Article 267 TFEU;
   5.3. A stay of these proceedings pending the issue of the validity of Article 20 of the TPD 2014 being referred to the ECJ;
   5.4. Appropriate declaratory or other relief in the light of such ruling as the ECJ may in due course give, together with costs;
   5.5. In the light of the likely duration of a reference to the ECJ, the Claimant also seeks expedition to enable the question of validity to be fully addressed by the ECJ prior to the entry into effect of the Directive on 20 May 2016.

6. The Claimant has set out some draft reference questions in an annex to this Statement of Facts and Grounds.

B. The factual background

7. The Claimant's business, trading under the name Totally Wicked, was established in 2008. It is one of the founding companies in the UK electronic cigarette market. Since that time it has become a leading UK-based manufacturer and retailer of electronic cigarettes (also known as "e-cigarettes"), liquid nicotine refills (known as "e-liquid"), and related products.

8. The witness statement of Fraser Cropper, managing director of the Claimant, dated 10 July 2014, describes its business, products and customers in detail. He also outlines the potential impact that compliance with the requirements of the TPD 2014 could have on his business, other electronic cigarette manufacturers and retailers and/or on consumers more generally.

9. Further details of the Claimant's business and the developing market for e-cigarettes are given at paragraphs 19 to 31 of Mr. Cropper's witness statement.

10. Electronic cigarettes usually have three main elements:

10.1. A cartridge or "tank". This is the part of the device that contains the nicotine fluid (also known as 'e-liquid'), although the Claimant also markets "nicotine-free" e-liquids.

10.2. An atomizer. This is the functional part of the device. It heats the fluid to a sufficient temperature so that when air is drawn through it, the fluid is transformed into a fine vapour that can be inhaled. There are many different types of atomizer, but they all deliver this basic function, to change the fluid into an inhalable vapour.

10.3. A battery. E-cigarettes use lithium ion batteries which typically supply 3.7 volts (a higher voltage than normal 1.5v household batteries, due to the power requirements of the device). The battery powers the atomizer.

11. There are many different variants of e-cigarettes. Some attempt to look like conventional tobacco cigarettes. Others look nothing like a conventional cigarette. But they each work along the same principles with the same primary component parts.

12. On or about 24 September 2010, the EU Commission (through the Directorate General for Health and Consumers – DG SANCO) initiated a consultation procedure in which it sought views from interested parties on the need for revisions to be made to the TPD 2001. A copy of the consultation document is at *[AB/2/7.2/39]*.[3] The Consultation Document noted that one of the definitional issues for tobacco related products concerned the introduction into the markets of the Member States of "electronic cigarettes." At p. 4, the Commission stated:

> "The Directive does not cover electronic nicotine delivery systems (ENDS), such as electronic cigarettes. Yet they are generally marketed as alternatives to smoking. Some Member States classify electronic cigarettes that contain nicotine as pharmaceutical products. This means they cannot be put on the market unless they have proven efficacy, safety and quality. However, in many Member States electronic cigarettes (with and

[3] http://ec.europa.eu/health/tobacco/docs/tobacco_consultation_en.pdf

without nicotine) are marketed as consumer products with no prior authorisation or safety checks. This results in a legal uncertainty."

13. The Commission outlined a potential option for revised legislation (Option 2) in the following terms:

"An extension of the scope of the Directive could be envisaged to include novel forms of oral tobacco, herbal cigarettes, and electronic nicotine delivery systems, insofar as they are not already covered by other EU legislation (food, pharmaceutical). Specific safety and quality requirements would be developed for ENDS."

14. Following the receipt and analysis of a large number of consultation responses (around 85,000), the Commission published a report summarising the reaction to its Consultation Document. A copy is at *[AB/2/7.3/50]*.[4] Member States were divided on the issue as to whether electronic cigarettes should be included within the scope of a revised TPD. The Consultation Report at p. 9 stated:

"As regards the future regulation of 'electronic cigarettes' in tobacco legislation, Member States seemed to be more divided, with some presenting arguments for regulating the product as a pharmaceutical or medical device, and others arguing for the inclusion of electronic cigarettes in the Tobacco Products Directive."

15. With the exception of a category of respondents described as "public health organisations" and the pharmaceutical industry, the remaining respondents were either against including ENDS in the definition of tobacco related products or thought that regulation should await scientific evidence of actual risks to human health.

16. On 19 December 2012, the EU Commission published a proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products. A copy of the Explanatory Memorandum and the draft Directive proposed by the Commission is at *[AB/2/7.4/72]*.[5]

17. Paragraph 3.7 of the Explanatory Memorandum addressed Nicotine-Containing Products ('NCP'). It stated:

[4] http://ec.europa.eu/health/tobacco/docs/consultation_report_en.pdf
[5] COM(2012) 788 final

"NCP fall outside the scope of Directive 2001/37/EC and Member States have so far taken different regulatory approaches to address these products, including regulating them as medicinal products, applying certain provisions that are used for tobacco products or having no specific legislation.
The proposal stipulates that NCP that either have a nicotine level exceeding 2 mg, a nicotine concentration exceeding 4 mg per ml or whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng per ml may be placed on the market only if they have been authorised as medicinal products on the basis of their quality, safety and efficacy, and with a positive risk/benefit balance. NCP with nicotine levels below this threshold can be sold as consumer products provided they feature an adapted health warning. The nicotine threshold identified in this proposal has been established by considering the nicotine content of medicinal products (Nicotine Replacement Therapies, NRTs) for smoking cessation which have already received a market authorisation under the medicinal products' legislation.
The proposal removes current legislative divergence between Member States and the differential treatment between Nicotine Replacement Therapies and Nicotine Containing Products, increases legal certainty and consolidates the on-going development in Member States. It also encourages research and innovation in smoking cessation with the aim of maximising health gains. Given the novelty and rapid increase of the NCP market as well as their addictive and toxic character there is an urgency to act, before more people – unaware of the content and effects of these products – inadvertently develop a nicotine addiction.
The labelling requirement set out in this proposal for NCP containing nicotine below the identified threshold will better inform consumers about the health risks associated with the products."

18. Article 18 of the draft Directive then provided for NCPs with a certain level of nicotine content to be assimilated with medicines and regulated under the Medicinal Products Directive, Directive 2001/83/EC. Article 18(1) read as follows:

"The following nicotine-containing products may only be placed on the market if they were authorised pursuant to Directive 2001/83/EC:
(a) products with a nicotine level exceeding 2 mg per unit, or
(b) products with a nicotine concentration exceeding 4 mg per ml or
(c) products whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng of nicotine per ml."

19. Article 18(3) to (5) provided for certain warnings to be provided in the marketing for electronic cigarettes:

"3. Each unit packet and any outside packaging of nicotine-containing products below the thresholds set out in paragraph 1 shall carry the following health warning:

This product contains nicotine and can damage your health.

4. The health warning referred to in paragraph 3 shall comply with the requirements specified in Article 10(4). In addition, it shall:
(a) be printed on the two largest surfaces of the unit packet and any outside packaging;
(b) cover 30 % of the external area of the corresponding surface of the unit packet and any outside packaging. That proportion shall be increased to 32 % for Member States with two official languages and 35 % for Member States with three official languages.
5. The Commission shall be empowered to adopt delegated acts in accordance with Article 22 to adapt the requirements in paragraphs 3 and 4 taking into account scientific and market developments and to adopt and adapt the position, format, layout, design and rotation of the health warnings."

20. The Proposal was accompanied by an Impact Assessment that had been conducted by the Commission. *[AB/2/7.5/135]* Pages 15 to 18 gave a summary of the development of NCPs. Pages 52 to 53 set out the different policy options available to address NCPs. The options were as follows:

20.1. Option 0: No change. This would mean that NCPs were not regulated by the revised TPD, but would remain subject to the General Product Safety Directive[6] and other legislation;

20.2. Option 1: This would see NCPs subject to labelling and ingredients requirements under the TPD;

20.3. Option 2: establish a new authorisation procedure for NCP, with a prohibition on marketing unauthorised products;

20.4. Option 3: this envisaged subjecting NCPs over a certain nicotine threshold to the medicinal products' legislation and imposing labelling requirements on the remaining NCPs;

20.5. Option 4: this last option was for all NCPs to be subject to the medicinal products' authorisation procedure, with a ban on marketing products not so authorised.

20.6. The Commission discarded the possibility of setting specific safety requirements under the General Product Safety Directive, on the basis of its conclusion that since nicotine was addictive and toxic, no levels could be set for its safe use.

[6] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ [2002] L No. 11, 15.1.2002, p. 4–17.

21. Pages 77 to 84 contained the actual assessment of the impact of these different policy options. The conclusions and preferred options were then outlined at pages 117 to 123. The Commission concluded at p. 83 that its preferred option was Option 3. It considered that this would remove current legislative divergence between Member States and the differential treatment between nicotine replacement therapies ('NRTs') and NCPs. It would "increase legal certainty and consolidate the on-going development in Member States based on the function of these products. It would encourage research and innovation in smoking cessation with the aim of maximising health gains."

22. The Commission also published an executive summary of the conclusions of the Impact Assessment. *[AB/2/7.6/285]* Page 5 of that Executive Summary contained the following conclusion in relation to NCPs:

> "**Regulating NCP under the TPD** could contribute to improving the safety of these products. However, this option does not correspond to the current regulatory development in Member States, based on the function of these products.
> **Setting up of a separate authorisation scheme for NCP** would imply high administrative costs for national authorities, involve complex considerations in terms determining the criteria to be used in the evaluation and imply a risk of overlap with the pharmaceutical framework.
> **Subjecting those NCP which fall above a predetermined nicotine threshold to the medicinal products' legislation and allowing the remaining NCP to be sold as consumer products provided they feature health warnings is the preferred option.** It would remove the current differential treatment between NCP and Nicotine Replacement Therapies (NRT), increase legal certainty and consolidate the on-going development in Member States based on the function of these products. Authorised products could circulate freely in the EU, others only if their nicotine content is below the identified threshold and they comply with the labelling rules. The option encourages R&D in smoking cessation with the aim of maximising health gains.
> **Subjecting all NCP to medicinal products' legislation** is the most stringent option identified, but this option was rejected for proportionality reasons." [Emphasis in original]

23. A number of national parliaments filed opinions raising concerns about the proportionality of the Commission proposal, pursuant to the so-called 'Yellow Card' procedure under Article 6 of Protocol 2 to the TFEU. *[AB/2/7.7/298]* The Danish Parliament, for example, considered that the Directive should apply only to tobacco products and that NCPs should be regulated under a different measure. The Italian Parliament thought that careful consideration should be given to encouraging the use of products which would help smokers stop smoking, rather than restricting them. The

Portuguese Parliament issued a reasoned opinion that the proposed Directive breached the principle of subsidiarity. As did the Romanian and Swedish Parliaments in reasoned opinions that they issued.

24. The Council nonetheless agreed to the general approach of the proposed revisions to the TPD on 21 June 2013. *[AB/2/7.8/325]*[7] Thereafter, the legislative text was examined by a series of Committees established by the European Parliament ('EP'). On 10 July 2013, the Public Health Committee of the EP published a report recommending the strengthening of certain measures in the proposed Directive, including the provisions on electronic cigarettes.[8] *[AB/2/7.9/327]* The report recommended changes to the drafting so that e-cigarettes could only be placed on the market under existing rules on medicinal products, with no exceptions. But the MEPs who had written the report did recommend that NCPs so authorised should be available for purchase outside pharmacies. The recommendation accordingly suggested an option for NCPs which the Commission impact assessment had expressly dismissed as being disproportionate in its impact.

25. At a plenary session of the EP on 8 October 2013, MEPs voted in favour of yet further changes in the approach to the regulation of electronic cigarettes. They resolved to give Ms Linda McAvan MEP a mandate to negotiate a first-reading agreement with EU ministers in the course of a "trilogue" procedure between the EU institutions. A Press Release from the EP dated 8 October 2013[9] *[AB/2/7.10/325]* set out the measures which the EP were hoping to secure from the legislative process:

> "E-cigarettes should be regulated, but not be subject to the same rules as medicinal products unless they are presented as having curative or preventive properties. Those for which no such claims are made should contain no more than 30mg/ml of nicotine, should carry health warnings and should not be sold to anyone under 18 years old. Manufacturers and importers would also have to supply the competent authorities with a list of all the ingredients that they contain. Finally, e-cigarettes would be subject to the same advertising restrictions as tobacco products."

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[7] http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/en/lsa/137571.pdf

[8] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+IM-PRESS+20130708IPR16824+0+DOC+XML+V0//EN&language=EN

[9] http://www.europarl.europa.eu/news/en/news-room/content/20131004IPR21539/html/Tobacco-larger-warnings-flavours-banned-e-cigarettes-regulated

26. This amounted to an entirely new approach to the question of the regulation of electronic cigarettes. It was a variant of Option 2 proposed by the Commission, which had nonetheless been rejected by the Commission as being unduly complex, giving rise to a lack of certainty between two different regimes, raising costs for national governments and producing uncertain health benefits.

27. The draft proposal from the Commission was essentially rejected by the EP through the vote of MEPs on 8 October 2013. There then followed a series of exchanges between the EP and the Council while a draft text of the Directive was scrutinised. A completely new compromise text was finally agreed between those two institutions on 18 December 2013. This new text and approach had not featured in the Commission's impact assessment as such and was not subject to any consultation with interested parties, such as the electronic cigarette industry. A Council Press Release of the same date[10] *[AB/2/7.11/331]* confirmed what had been agreed for the regulation of e-cigarettes:

> "The scope of the Directive is extended to electronic cigarettes which will be subject of a number of safeguards (e.g. maximum concentration of nicotine of 20 mg/ml, maximum single use cartridge size of 2 ml). As regards refillable electronic cigarettes, the Commission will have to report on their potential risk to public health at the latest two years after the entry into force of the directive. If for justified reasons related to a serious risk to human health at least three member states have banned refillable electronic cigarettes the Commission is allowed to extend the ban to all member states. Member states may authorise electronic cigarettes under the rules for pharmaceuticals if they meet the provisions of the pharmaceutical legislation. The agreement is aimed at helping smokers to quit while preventing any incentive for young people to start smoking."

28. An EP Press Release confirmed that changes to the legislation had been suggested by MEPs, rather than the EU Commission. An EP Press Release dated 18 December 2013 gave a summary of the legislative proposals now on the table for e-cigarettes *[AB/2/7.12/333]*:[11]

> "As proposed by MEPs, e-cigarettes should be regulated either as medicinal products, if they are presented as having curative or preventive properties, or alternatively as tobacco products. In the latter case, they should not contain nicotine in a concentration of more than 20 mg/ml. Refillable cartridges would be allowed, albeit with a clause enabling the

[10] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/EN/genaff/140146.pdf

[11] http://www.europarl.europa.eu/news/en/news-room/content/20131216IPR31001/html/Tobacco-directive-MEPs-reach-agreement-with-Council-of-Ministers

Commission to extend the ban if such cartridges are prohibited in at least three member states.
A single cartridge should contain the equivalent in nicotine of a pack of cigarettes. Electronic cigarettes should be childproof and should carry health warnings. They would be subject to the same advertising restrictions as tobacco products."

29. The EP formally approved a revised version of the Directive on 26 February 2014. Commissioner Borg welcomed the approval in a statement.[12] *[AB/2/7.13/335]* The Commission also issued a memo with questions and answers concerning the new provisions *[AB/2/7.14/337]*.[13] That memo gave the following justification for the decision to introduce new rules for e-cigarettes in the proposed TPD 2014:

"E-cigarettes are a relatively new product category and their market share is growing. While they may have a role to play in smoking cessation or reduction, their long-term effects on public health are not yet known. As nicotine is an addictive and toxic substance, safety and quality requirements for nicotine-containing e-cigarettes are necessary. Reporting obligations are also needed so that public authorities can monitor and learn more about these products. A number of decisions on e-cigarettes will be left to the Member States, e.g. the regulation of flavours, advertising without cross border effects, and age limits.
The new rules will not apply to medicinal e-cigarettes (as set out in Directive 2001/83/EC) or medical devices (Directive 93/42/EEC), but will cover all consumer electronic cigarettes placed on the EU market."

30. The Council formally approved the TPD 2014 on 14 March 2014. It was published in the Official Journal on 29 April 2014 and entered into force on 19 May 2014. It will be brought into effect from 20 May 2016.

C. The contested Directive

31. The TPD 2014, from the date of its entry into effect, will govern the manufacture, presentation and sale of tobacco and tobacco related products. Pursuant to Article 29(1) of the TPD 2014, Member States shall apply their domestic provisions transposing the Directive from 20 May 2016. Article 30 also confers a discretion on the Member States to permit the continued marketing of products on their domestic markets until 20 May 2017 in so far as the have been released for free circulation before 20 November 2016.

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[12] http://www.europarl.europa.eu/news/en/news-room/content/20131216IPR31001/html/Tobacco-directive-MEPs-reach-agreement-with-Council-of-Ministers
[13] http://europa.eu/rapid/press-release_MEMO-14-134_en.htm

32. Recitals (36) to (40) provide the reasons which the EU legislature has given for the adoption of regulatory measures governing the sale and marketing of electronic cigarettes.

"(36) Electronic cigarettes and refill containers should be regulated by this Directive, unless they are - due to their presentation or function - subject to Directive 2001/83/EC of the European Parliament and of the Council or to Council Directive 93/42/EEC, Diverging legislation and practices as regards these products, including on safety requirements, exist between Member States, hence, action at Union level is required to improve the smooth functioning of the internal market. A high level of public health protection should be taken into account when regulating these products. In order to enable Member States to carry out their surveillance and control tasks, manufacturers and importers of electronic cigarettes and refill containers should be required to submit a notification of the relevant products before they are placed on the market.

(37) Member States should ensure that electronic cigarettes and refill containers comply with the requirements of this Directive. Where the manufacturer of the relevant product is not established in the Union, the importer of that product should bear the responsibilities relating to the compliance of those products with this Directive.

(38) Nicotine-containing liquid should only be allowed to be placed on the market under this Directive, where the nicotine concentration does not exceed 20 mg/ml. This concentration allows for a delivery of nicotine that is comparable to the permitted dose of nicotine derived from a standard cigarette during the time needed to smoke such a cigarette. In order to limit the risks associated with nicotine, maximum sizes for refill containers, tanks and cartridges should be set.

(39) Only electronic cigarettes that deliver nicotine doses at consistent levels should be allowed to be placed on the market under this Directive. Delivery of nicotine doses at consistent levels under normal conditions of use is necessary for health protection, safety and quality purposes, including to avoid the risk of accidental consumption of high doses.

(40) Electronic cigarettes and refill containers could create a health risk when in the hands of children. Therefore, it is necessary to ensure that such products are child- and tamperproof, including by means of child-proof labelling, fastenings and opening mechanisms."

33. The rationale for imposing specific restrictions on the marketing and sale of electronic cigarettes is then set out in recitals (41) to (43), as follows:

"(41) In view of the fact that nicotine is a toxic substance and considering the potential health and safety risks, including to persons for whom the product is not intended, nicotine-containing liquid should only be placed on the market in electronic cigarettes or in refill containers that meet certain safety and quality requirements. It is important to ensure that electronic cigarettes do not break or leak during use and refill.

(42) The labelling and packaging of these products should display sufficient and appropriate information on their safe use, in order to protect human health and safety,

should carry appropriate health warnings and should not include any misleading elements or features.

(43) Disparities between national laws and practices on advertising and sponsorship concerning electronic cigarettes present an obstacle to the free movement of goods and the freedom to provide services and create an appreciable risk of distortion of competition. Without further action at Union level, those disparities are likely to increase over the coming years, also taking into account the growing market for electronic cigarettes and refill containers. Therefore, it is necessary to approximate the national provisions on advertising and sponsorship of those products having cross-border effects, taking as a base a high level of protection of human health. Electronic cigarettes can develop into a gateway to nicotine addiction and ultimately traditional tobacco consumption, as they mimic and normalize the action of smoking. For this reason, it is appropriate to adopt a restrictive approach to advertising electronic cigarettes and refill containers."

34. Recital (47) confirmed that the TPD 2014 does not harmonise all aspects of electronic cigarettes or refill containers. So the Member States still retain competence to address matters such as the use of flavouring in the products.

35. Article 1(f) of the Directive establishes that the objective of the legislation includes the approximation of the laws of the Member States in relation to "the placing on the market and the labelling of certain products which are related to tobacco products, namely electronic cigarettes and refill containers . . ."

36. An electronic cigarette is defined in Article 2(16) as follows:

"(16) 'electronic cigarette' means a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges."

37. A "refill container" is defined as "a receptacle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette." See Article 2(17).

38. Article 2(34) defines "cross-border distance sales" in the following terms:

". . . distance sales to consumers where, at the time the consumer orders the product from a retail outlet, the consumer is located in a Member State other than the Member State or

the third country where that retail outlet is established; a retail outlet is deemed to be established in a Member State:
(a) in the case of a natural person: if he or she has his or her place of business in that Member State;
(b) in other cases: if the retail outlet has its statutory seat, central administration or place of business, including a branch, agency or any other establishment, in that Member State."

39. The act of placing goods on the market is also given a definition by Article 2(40) as the act of making the products available to consumers located in the Union.

40. The restrictions on the marketing and advertising of electronic cigarettes are found in one article of the Directive – Article 20. Although it is a lengthy article, it is here set out in full for convenience.

"1. The Member States shall ensure that electronic cigarettes and refill containers are only placed on the market if they comply with this Directive and with all other relevant Union legislation.
This Directive does not apply to electronic cigarettes and refill containers that are subject to an authorisation requirement under Directive 2001/83/EC or to the requirements set out in Directive 93/42/EEC.

2. Manufacturers and importers of electronic cigarettes and refill containers shall submit a notification to the competent authorities of the Member States of any such products which they intend to place on the market. The notification shall be submitted in electronic form six months before the intended placing on the market. For electronic cigarettes and refill containers already placed on the market on 20 May 2016, the notification shall be submitted within six months of that date. A new notification shall be submitted for each substantial modification of the product.

The notification shall, depending on whether the product is an electronic cigarette or a refill container, contain the following information:

(a) the name and contact details of the manufacturer, a responsible legal or natural person within the Union, and, if applicable, the importer into the Union;
(b) a list of all ingredients contained in, and emissions resulting from the use of, the product, by brand name and type, including quantities thereof;
(c) toxicological data regarding the product's ingredients and emissions, including when heated, referring in particular to their effects on the health of consumers when inhaled and taking into account, inter alia, any addictive effect;
(d) information on the nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions;
(e) a description of the components of the product; including, where applicable, the opening and refill mechanism of the electronic cigarette or refill containers;

(f) a description of the production process, including whether it involves series production, and a declaration that the production process ensures conformity with the requirements of this Article;
(g) a declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions.

Where Member States consider that the information submitted is incomplete, they shall be entitled to request the completion of the information concerned.

Member States may charge manufacturers and importers proportionate fees for receiving, storing, handling and analysing the information submitted to them.

3. Member States shall ensure that:

(a) nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml, in disposable electronic cigarettes or in single use cartridges and that the cartridges or tanks do not exceed a volume of 2 ml;
(b) the nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml;
(c) the nicotine-containing liquid does not contain additives listed in Article 7(6);
(d) only ingredients of high purity are used in the manufacture of the nicotine-containing liquid. Substances other than the ingredients referred to in point (b) of the second subparagraph of paragraph 2 of this Article are only present in the nicotine-containing liquid in trace levels, if such traces are technically unavoidable during manufacture;
(e) except for nicotine, only ingredients are used in the nicotine-containing liquid that do not pose a risk to human health in heated or unheated form;
(f) electronic cigarettes deliver the nicotine doses at consistent levels under normal conditions of use;
(g) electronic cigarettes and refill containers are child- and tamper-proof, are protected against breakage and leakage and have a mechanism that ensures refilling without leakage.

4. Member States shall ensure that:
(a) unit packets of electronic cigarettes and refill containers include a leaflet with information on:
    (i) instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers;
    (ii) contra-indications;
    (iii) warnings for specific risk groups;
    (iv) possible adverse effects;
    (v) addictiveness and toxicity; and
    (vi) contact details of the manufacturer or importer and a legal or natural contact person within the Union;

(b) unit packets and any outside packaging of electronic cigarettes and refill containers:
    (i) include a list of all ingredients contained in the product in descending order of the weight, and an indication of the nicotine content of the product and the delivery per dose, the batch number and a recommendation to keep the product out of reach of children;

(ii) without prejudice to point (i) of this point, do not include elements or features referred to in Article 13, with the exception of Article 13(1)(a) and (c) concerning information on the nicotine content and on flavourings; and
(iii) carry one of the following health warnings:

'This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers'.
Or
'This product contains nicotine which is a highly addictive substance.'

Member States shall determine which of these health warnings is to be used;

(c) health warnings comply with the requirements specified in Article 12(2).

5. Member States shall ensure that:
(a) commercial communications in Information Society services, in the press and other printed publications, with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers are prohibited, except for publications that are intended exclusively for professionals in the trade of electronic cigarettes or refill containers and for publications which are printed and published in third countries, where those publications are not principally intended for the Union market;
(b) commercial communications on the radio, with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers, are prohibited;
(c) any form of public or private contribution to radio programmes with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers is prohibited;
(d) any form of public or private contribution to any event, activity or individual person with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers and involving or taking place in several Member States or otherwise having cross-border effects is prohibited;
(e) audiovisual commercial communications to which Directive 2010/13/EU of the European Parliament and of the Council applies, are prohibited for electronic cigarettes and refill containers.

6. Article 18 of this Directive shall apply to cross-border distance sales of electronic cigarettes and refill containers.

7. Member States shall require manufacturers and importers of electronic cigarettes and refill containers to submit, annually, to the competent authorities:
(i) comprehensive data on sales volumes, by brand name and type of the product;
(ii) information on the preferences of various consumer groups, including young people, non-smokers and the main types of current users;
(iii) the mode of sale of the products; and
(iv) executive summaries of any market surveys carried out in respect of the above, including an English translation thereof.

Member States shall monitor the market developments concerning electronic cigarettes and refill containers, including any evidence that their use is a gateway to nicotine addiction and ultimately traditional tobacco consumption among young people and non-smokers.

8. Member States shall ensure that the information received pursuant to paragraph 2 is made publicly available on a website. The Member States shall take the need to protect trade secrets duly into account when making that information publicly available.

Member States shall, upon request, make all information received pursuant to this Article available to the Commission and other Member States. The Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.

9. Member States shall require manufacturers, importers and distributers of electronic cigarettes and refill containers to establish and maintain a system for collecting information about all of the suspected adverse effects on human health of these products.

Should any of these economic operators consider or have reason to believe that electronic cigarettes or refill containers, which are in their possession and are intended to be placed on the market or are placed on the market, are not safe or are not of good quality or are otherwise not in conformity with this Directive, that economic operator shall immediately take the corrective action necessary to bring the product concerned into conformity with this Directive, to withdraw or to recall it, as appropriate. In such cases the economic operator shall also be required to immediately inform the market surveillance authorities of the Member States in which the product is made available or is intended to be made available, giving details, in particular, of the risk to human health and safety and of any corrective action taken, and of the results ofsuch corrective action.

Member States may also request additional information from the economic operators, for example on the safety and quality aspects or any adverse effects of electronic cigarettes or refill containers.

10. The Commission shall submit a report to the European Parliament and the Council on the potential risks to public health associated with the use of refillable electronic cigarettes by 20 May 2016 and whenever appropriate thereafter.

11. In the case of electronic cigarettes and refill containers that comply with the requirements of this Article, where a competent authority ascertains or has reasonable grounds to believe that specific electronic cigarettes or refill containers, or a type of electronic cigarette or refill container, could present a serious risk to human health, it may take appropriate provisional measures. It shall immediately inform the Commission and the competent authorities of other Member States of the measures taken and shall communicate any supporting data. The Commission shall determine, as soon as possible after having received that information, whether the provisional measure is justified. The Commission shall inform the Member State concerned of its conclusions to enable the Member State to take appropriate follow-up measures.

Where, in application of the first subparagraph of this paragraph, the placing on the market of specific electronic cigarettes or refill containers, or a type of electronic cigarette or refill container has been prohibited on duly justified grounds in at least three Member States, the Commission shall be empowered to adopt delegated acts in accordance with Article 27 to extend such a prohibition to all Member States, if such an extension is justified and proportionate.

12. The Commission shall be empowered to adopt delegated acts in accordance with Article 27 to adapt the wording of the health warning in paragraph 4(b) of this Article. When adapting that health warning, the Commission shall ensure that it is factual.

13. The Commission shall, by means of an implementing act, lay down a common format for the notification provided for in paragraph 2 and technical standards for the refill mechanism provided for in paragraph 3(g).

These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2)."

41. The cross reference to Article 18 brings into play the following provisions at the option of the Member States:

"**Article 18**
Cross-border distance sales of tobacco products

1 Member States may prohibit cross-border distance sales of tobacco products to consumers. Member States shall cooperate to prevent such sales. Retail outlets engaging in cross-border distance sales of tobacco products may not supply such products to consumers in Member States where such sales have been prohibited. Member States which do not prohibit such sales shall require retail outlets intending to engage in cross-border distance sales to consumers located in the Union to register with the competent authorities in the Member State, where the retail outlet is established, and in the Member State, where the actual or potential consumers are located. Retail outlets established outside the Union shall be required to register with the competent authorities in the Member State where the actual or potential consumers are located. All retail outlets intending to engage in cross-border distance sales shall submit at least the following information to the competent authorities when registering:
(a) name or corporate name and permanent address of the place of activity from where the tobacco products will be supplied;
(b) the starting date of the activity of offering tobacco products for cross-border distance sales to consumers by means of Information Society services, as defined in point 2 of Article 1 of Directive 98/34/EC;
(c) the address of the website or websites used for that purpose and all relevant information necessary to identify the website."

42. There are consequential provisions set out in Articles 18(2) to 18(5), with requirements for certain data to be disclosed to the competent authorities of the Member States, subject to compliance with the Data Protection Directive, Directive 95/46/EC.

43. Article 23(2) requires Member States to take steps to ensure that tobacco related products which do not comply with the TPD 2014 are not placed on the market. Member States are required by Article 23(3) to establish a penalty regime for non-compliance. Article 26

requires Member States to designate the competent authorities responsible for the implementation and enforcement of the obligations provided by the TPD 2014.

D. Other relevant legal provisions

44. In Case 314/85 Firma Foto-Frost v Hauptzollamt Lubeck-Ost [1987] E.C.R. 4199, the ECJ held that national courts were entitled to examine the validity of a Union act, and, if they were of the opinion that the arguments challenging its validity were unfounded, they might conclude the act was valid. However, such courts were not entitled to declare acts of EU Institutions invalid. For the coherence and unity of the Union legal order it was for the ECJ alone to declare that any acts of the EU institutions were invalid. That reasoning was endorsed by the ECJ in Case C-344/04 IATA and European Low Fares Airline Association [2006] ECR I-403, ECJ at [29] and [30]. If this Court does not find that the Claimant's challenge is unfounded, then it is appropriate for a reference to be made to the ECJ under Article 267 TFEU to enable the validity of the Directive to be assessed by the ECJ itself.

45. The test for a national court has been expressed by Mitting J in R (Telefonica O2 Europe Plc) v Secretary of State for Business Enterprise and Regulatory Reform [2007] EWHC 3018 (Admin) at [4]:

> "The underlying question therefore is the validity or otherwise of the Roaming Regulation. There is no doubt that it has a significant direct and indirect effect on the business activities of the claimants. If satisfied that the challenge to its validity is reasonably arguable or, put negatively, not unfounded, I should refer the issue to the European Court and grant permission for the domestic challenge to the UK regulations."

46. The Claimant does not have standing to bring a direct challenge to the TPD 2014 before the EU Courts. In Joined Cases T-172/98 and T-175/98 to T-177/98 Salamander AG v. Parliament and Council [2000] ECR II-2487, the General Court of the European Union ('GCEU') held at [54]:

> "It must be recalled here that a directive cannot of itself impose obligations on an individual and may therefore not be relied on as such against him (*Marshall*, paragraph 48, Case 80/86 *Kolpinghuis Nijmegen* [1987] ECR 3969, paragraph 9, *Faccini Dori*, paragraph 25, and Case C-192/94 *El Corte Inglés* v *Blázquez Rivero* [1996] ECR I-1281, paragraph 15). It follows that a directive which, as in the present case, requires the

Member States to impose obligations on economic operators is not of itself, before the adoption of the national transposition measures and independently of them, such as to affect directly the legal situation of those economic operators within the meaning of the fourth paragraph of Article 173 of the Treaty."

47. Accordingly the Claimant's only route for challenging the validity of the TPD 2014 is to apply to this Court for a reference for a preliminary ruling under Article 267 TFEU.

48. A reference was also made from this Court in similar circumstances in Case C-74/99 Imperial Tobacco and others v. Secretary of State for Health and others [2000] ECR I-8599, ECJ. The ECJ entertained a reference from the English High Court challenging the validity of Directive 98/43/EC of the European Parliament and of the Council of 6 July 1998 on the approximation of laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products.[14] The ECJ did not ultimately rule on the challenge itself, since the Tobacco Advertising Directive was annulled by the Court in Case C-376/98 Germany v. Parliament and Council [2000] ECR I-2247, on the ground that the Treaty legal base chosen for the measure was inadequate.

E. The Grounds of Challenge

49. The Claimant seeks declaratory relief in relation to the obligation imposed on the UK Government by Articles 29 and 23 of the TPD 2014 to implement and then enforce domestic legislation to give effect to Article 20 of the TPD 2014.[15] The Claimant contends that the terms of Article 20 generally, alternatively the particular provisions in Article 20 of the TPD 2014 identified below, are invalid as they infringe the following principles of EU law:

49.1. The principle of proportionality, read in conjunction with the principle of legal certainty;

49.2. The principle of equality;

[14] OJ [1998] L No. 213, p. 9.

[15] In Case C-491/01 R v. Secretary of State for Health, ex p. British American Tobacco [2002] ECR I-11453, the High Court again referred to the ECJ certain questions, this time concerning the validity of replacement Directive 2001/37/EC. The High Court was prepared to make a reference to the ECJ concerning the validity of the Directive. That reference was made in the course of judicial review proceedings in which the Claimants challenged the intention and/or obligation of the UK Government to transpose the Directive into UK law.

49.3. The principle of subsidiarity; and/or

49.4. The Claimant's right to property and to run a business, as protected by Articles 16 and 17 of the Charter of Fundamental Rights ('CFR').

50. These four grounds of challenge are addressed in turn.

(1) The contested provisions in Article 20 TPD 2014 infringe the principle of proportionality, read in conjunction with the principle of legal certainty

51. The contested provisions of Article 20 impose a series of restrictions on the ability of the Claimant to market and sell its products or to make or receive advertising and marketing services. Those restrictions have an actual or potential impact on cross-border trade. Indeed, part of Article 20 is specifically aimed at cross-border supplies of NCPs. Those provisions accordingly engage the fundamental Treaty freedoms concerning the free movement of goods, as found in Articles 34 and 35 TFEU; and the free provision of services, as now found win Article 56 TFEU. In the circumstances, the EU legislature will be required to justify the restrictions of EU fundamental freedoms on public interest grounds. In so doing, the EU legislature will be required to comply with the general EU law principle of proportionality.

52. Further or alternatively, under Article 5(1) TEU, the EU competences are limited by the principles of proportionality and subsidiarity. The appropriate test for a proportionality challenge to an EU measure has been set out in Case C-84/94 UK v. Council [1996] ECR I-5755, ECJ at [57]; and Case C-426/93 Germany v Council [1995] ECR I-3723, ECJ at [42]; and Case C-293/12 Digital Rights Ireland [2014] ECR I-0000, ECJ at [46]. In short, it must be ascertained whether the means which the EU legislation employs are suitable for the purpose of achieving the desired objective and whether they do not go beyond what is necessary to achieve it. See also the judgment of the ECJ in Case C-491/01 R v. Secretary of State for Health, ex p. British American Tobacco [2002] ECR I-11453 at [122].

53. The Claimant of course recognises that the EU institutions will be afforded a margin of discretion in this area. In British American Tobacco at [123], the ECJ stated:

"With regard to judicial review of the conditions referred to in the previous paragraph, the Community legislature must be allowed a broad discretion in an area such as that involved in the present case, which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments. Consequently, the legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate having regard to the objective which the competent institution is seeking to pursue (see, to that effect, Case C-84/94 *United Kingdom* v *Council* [1996] ECR I-5755, paragraph 58; Case C-233/94 *Germany* v *Parliament and Council* [1997] ECR I-2405, paragraphs 55 and 56, and Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraph 61)."

54. While the test for intervention by the ECJ respects the broad discretion that is conferred on the EU legislature, the substantive requirements of the general principle nonetheless maintain that acts adopted by EU institutions should not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives of the legislation in question: Case C-310/04 Spain v. Council [2006] ECR I-7285, at [97]. Where there is a choice between several appropriate measures, recourse must be had to the least onerous. Disadvantages caused must not be disproportionate to the aims pursued. Furthermore, at [122] the Court added: "However, even though such judicial review is of limited scope, it requires that the Community institutions which have adopted the act in question must be able to show before the Court that in adopting the act they actually exercised their discretion, which presupposes the taking into consideration of all the relevant factors and circumstances of the situation the act was intended to regulate."[16]

55. Furthermore where, as here, the EU measure imposes limitations on fundamental rights recognised by the CFR, such as Articles 16 (the right to conduct a business) and 17 (the right to property), the proportionality assessment is conducted with greater stringency: see Case C-293/12 Digital Rights Ireland (*supra*) at [45] to [48].[17] Moreover, in Case C-58/08 Vodafone [2010] ECR I-4999, the ECJ at [55], when examining the proportionality of the contested provisions, expressly recalled that "before it drafted the proposal for the regulation, the Commission carried out an exhaustive study, the result of which is summarised in the impact assessment mentioned in paragraph 5 of this judgment. It follows that the Commission examined various options . . ."

[16] Thus while there is no formal requirement for the EU legislature to abide by the terms of an impact assessment conducted by the Commission (see Case C-343/09 Afton Chemical [2010] ECR I-7027, ECJ at [30]), that does not mean that relevant findings contained in an impact assessment can simply be ignored without good reason. See [34].

[17] See also the Opinion of Advocate General Cruz-Villalón in Case C-293/12, Opinion dated 12 December 2013, at [89] and [133].

56. Here, however, the fact that the measures in question were only specifically formulated as a compromise text during the course of the Trilogue procedure means they have not benefitted from any impact assessment conducted at EU level. A similar argument was advanced by the Slovak Government in Case C-176/09 Luxembourg v. Parliament and Council (Airport charges) [2011] ECR I-3727, ECJ at [57]. The response of the ECJ, having noted the width of the power given to the institutions, was that:

"63. However, even though it has such a power, the European Union legislature must base its choice on objective criteria. Furthermore, in assessing the burdens associated with various possible measures, it must examine whether objectives pursued by the measure chosen are such as to justify even substantial negative economic consequences for certain operators (*Arcelor Atlantique et Lorraine and Others*, paragraph 58, and *Vodafone and Others*, paragraph 53 and the case-law cited).

57. In rejecting the proportionality challenge, the ECJ noted in [65] that:

"65. In that regard, it must be borne in mind that, before preparing the Proposal for a Directive, the Commission carried out an impact assessment, the options studied also being summarised in that proposal. It is apparent therefrom that it examined various options for that field, including, inter alia, the drafting and adoption by air operators of voluntary self-regulation measures, the adoption of a legal framework requiring compliance with common principles for the establishment of airport charges at national level and the introduction of a legal framework requiring receipt and fixing of the charges on the basis of a single method of calculation."

58. In the present case, it is noteworthy that the Commission did conduct an Impact Assessment. But only in relation to the legislative options which were then under consideration. The terms of Article 20 go substantially beyond the draft legislation proposed by the Commission. The regulatory regime in Article 20 was first enunciated by the EP. It was not then subject to any further impact assessment by the Commission. The preferred Option 3 selected by the Commission would only have placed labelling requirements on manufacturers of electronic cigarettes. Instead, the EP's amendments have essentially put in place a variant of the dual authorisation arrangement, the broad outline of which was considered by the Commission as Option 2, but dismissed. Furthermore, the actual text adopted goes far beyond what was envisaged by the Commission in Option 2. The Commission identified the following difficulties with such an arrangement at p. 78 of its Impact Assessment:

"Option 2 would result in two parallel authorisation schemes for NCP: one scheme which would apply if the product falls under the medicinal products' legislation by presentation or by function and another one for consumer products. Competition between these two categories cannot be excluded. Some of the current legal uncertainty would persist under this policy option due to this dual approach which means that similar (or even identical) products could be subject to different schemes. Such uncertainty does not favour the functioning of the internal market. It raises also the question of equal treatment with existing nicotine replacement therapies (NRT), which are subject to medicinal products' authorisations."

59. The EU legislature has adopted a disproportionate approach by putting in place an authorisation scheme for electronic cigarettes. The Claimant's electronic cigarettes do not make claims to be medicinal in nature or effect. They are not marketed as a NRT. There is accordingly no requirement for them to be authorised as medicinal products for human use. While electronic cigarettes are substantially less harmful to human health than ordinary cigarettes, they are not medicinal in nature, any more than ordinary tobacco is medicinal.

60. Nonetheless, this does not mean that a parallel authorisation scheme to that found in the Medicinal Products Directive 2001 could permissibly be introduced. Nor would the marketing and sale of electronic cigarettes otherwise be unregulated. A large number of existing measures at EU level and domestically already regulate the safety and marketing of electronic cigarettes. These measures include:

60.1. The General Product Safety Directive 2001/95/EC;[18]

60.2. The Dangerous Substances Directive 67/548/EEC;[19]

60.3. The Dangerous Preparations Directive 99/45/EC;[20]

60.4. The Classification, Labelling and Packaging of Substances and Mixtures Regulation (EU) No 1272/2008, which applies from 2015;[21]

[18] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, as amended.
[19] Directive 67/548/EC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, as amended from time to time.
[20] Directive 99/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, as amended.
[21] Regulation (EC) No 1272/2008 of the EP and the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

60.5. The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) 1907/2006;[22]

60.6. The Low Voltage Directive 2006/95/EC;[23]

60.7. The Electro-Magnetic Compatibility Directive 2004/108/EC;[24]

60.8. The Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU (where appropriate);[25]

60.9. The Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU;[26]

60.10. The Batteries Directive 2006/66/EC;[27]

60.11. The Making-up by weight or by volume of certain pre-packaged products – Directive 76/211/EEC;[28]

60.12. The Nominal Quantities for Pre-packed Products Directive 2007/45/EC;[29]

60.13. The Distance Selling Directive 97/7/EC;[30]

60.14. Directive on Electronic Commerce 2000/31/EC;[31]

60.15. The Misleading and Comparative Advertising Directive 2006/114/EC;[32]

60.16. The Unfair Commercial Practices Directive 2005/29/EC.[33]

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[22] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

[23] Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits.

[24] Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility and repealing Directive 89/336/EEC.

[25] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

[26] Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE).

[27] Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC.

[28] Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain pre-packaged products.

[29] Directive 2007/45/EC Of the European Parliament and of the Council of 5 September 2007 laying down rules on nominal quantities for pre-packed products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC.

[30] Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts, as amended.

[31] Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market.

[32] Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising, as amended.

[33] Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC,

61. A position paper produced by the Health and Safety Executive in May 2013 for a consultation by the Medicines and Healthcare Regulatory Products Authority ("MHRA") (an executive agency of the Department of Health) into the possible regulation of e-cigarettes as medicinal products set out a detailed summary of the regime which e-cigarettes have to comply with in respect of classification, labelling and packaging the regulations that already govern the manufacture and sale of e-cigarettes. *[AB/3/8.27/314]* This detailed paper gives an overview of the requirements the Claimant must satisfy for each bottle of e-liquid, cartridge and refill it sells (including e-cigarettes already containing e-liquid cartridges).

62. While it is true that e-cigarettes are used as a replacement to cigarettes, the EU legislature appears to have proceeded under an implicit assumption that they pose an equivalent risk to public health and should therefore be regulated. This assumption is significantly flawed. E-cigarettes deliver to the consumer "clean" nicotine, which does not contain the tar, carbon monoxide, and volatile hot gases of tobacco cigarettes. E-cigarettes also have only a fraction of the 7,000 chemicals contained in ordinary tobacco cigarettes. They greatly reduce risk and produce an obvious benefit to public health, whilst also satisfying a user need for nicotine and any "behavioural" aspects of smoking.

63. Article 20 of the TPD 2014 wrongly imposes conditions on the sale and marketing of electronic cigarettes which are more rigorous than the restrictions imposed on tobacco cigarettes, despite the public health detriment posed by e-cigarettes being: (a) unproven; and (b) on any view significantly lower than the risk posed by ordinary tobacco.

64. The Commission memo cited at paragraph 29 above expressly recognised (as recently as February 2014) that the long-term effects of electronic cigarettes on public health are not yet known. The most recent leading study into the composition of e-cigarettes was undertaken in 2013 by Dr Maciej Goniewicz of the Department of Health Behaviour at the Roswell Park Cancer Centre Institute in Buffalo, New York, USA in conjunction with colleagues at institutions including Queen Mary University of London. Dr Goniewicz and his colleagues screened e-cigarette vapour for content in order to assess the claims made

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Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council.

by e-cigarette designers that they delivered nicotine without toxicants and were therefore a safer alternative to cigarettes.

65. In the study, Dr Goniewicz concluded that whilst e-cigarette vapour does contain "potentially toxic compounds", these were between 9 and 450 times lower than the number found in conventional tobacco cigarettes, and "in many cases comparable with the trace amounts present in pharmaceutical preparations." *[AB/3/8.5/7 (page 6)]* His conclusion was that the findings "support the proposition that the vapour from e-cigarettes is less injurious than the smoke from cigarettes. Thus one would expect that if a person switched from conventional cigarettes to e-cigarettes the exposure to toxic chemicals and related adverse health effects would be reduced," although he recognised that confirmation of this hypothesis required further study.

66. In its May 2014 Report, Public Health England (an executive agency of the Department of Health) also pointed out the comparative benefits to public health which would be derived from conventional smokers switching to electronic cigarettes. The Public Health England report was written by Professor John Britton and Dr Ilze Bogdanovica of the UK Centre for Tobacco and Alcohol Studies at the University of Nottingham. In it, the authors concluded that: *[AB/3/8.7/84]*

> "The principal addictive component of tobacco smoke is nicotine. However, aside from minor and transient adverse effects at the point of absorption, nicotine is not a significant health hazard. Nicotine does not cause serious adverse health effects such as acute cardiac events, coronary heart disease or cerebrovascular disease, and is not carcinogenic. The doses of nicotine delivered by electronic cigarettes are therefore extremely unlikely to cause significant short or long-term adverse events."

67. In a paper produced by the National Centre for Smoking Cessation and Training ('NCSCT'), in partnership with Public Health England, the researcher Professor Hayden McRobbie concludes (with input from Professor Peter Hajek[34], Professor Robert West[35] and from Dr Lynne Dawkins[36]) that:

[34] Director of the Tobacco Dependence Research Unit at Queen Mary University in London.
[35] Professor of Health Psychology and Director of Tobacco Studies at University College London's Department of Epidemiology and Public Health.
[36] Doctor of the School of Psychology, University of East London.

"Low levels of toxicants and carcinogens have been detected in electronic cigarette liquid and vapour although these are much lower than those found in conventional cigarette smoke and are not considered to pose any passive inhalation risk."

68. The paper goes on to recommend (to health practitioners) that:

". . .although some health risks from electronic cigarette use may yet emerge, these are likely to be, at worst, only a small fraction of the risks of smoking. This is because electronic cigarettes do not contain combustion chemicals which cause lung and heart disease and cancer."

69. The NCSCT paper summarises the debate about the safety of nicotine by stating that:

". . . there is good evidence from the use of NRT that nicotine is associated with few health risks in smokers. There is general agreement among experts that it is not nicotine that causes the adverse health effects associated with smoking."

70. The EU legislature has accordingly erred in seeking to regulate electronic cigarettes in the same manner as conventional tobacco, when the public health justification for doing so cannot be substantiated. Furthermore, the only justification advanced for seeking to implement an authorisation regime for electronic cigarettes is that nicotine is addictive and toxic in high doses. But as the witness evidence of Mr. Cropper makes clear (at paragraph 47) *[AB/1/6/9]*, caffeine has a mildly addictive effect, but that is not a regulated substance. Furthermore, alcohol is toxic (and indeed fatal) in high doses, yet that is not subject to an authorisation regime either.

71. Professor Robert West, a leading expert in the field, was involved in the preparation of the NCSCT paper. He was quoted in a report in *The Guardian* on 4 June 2013 as saying: *[AB/3/8.10/135]*

"We have such a massive opportunity here. It would be a shame to let it slip away by being overly cautious. E-cigarettes are about as safe as you can get. We know about the health risks of nicotine. ... Nicotine is not what kills you when you smoke tobacco. E-cigarettes are probably about as safe as drinking coffee."

72. Furthermore, the Commission and the EP have been accused by a number of leading experts in the field of mis-interpreting or mis-applying the conclusions of scientific reports that have purportedly been relied upon by the EU institutions. In a fact-sheet

produced by the Commission in December 2013, *[AB/2/7.15/344]* the Commission purported to cite research conducted by Dr Konstantinos Farsalinos of the Onassis Cardiac Surgery Center in Kallithea, Greece. He is a cardiovascular specialist who has become a leading expert in recent years on the subject of e-cigarettes and their effects. Dr Farsalinos believes that the Commission has misinterpreted or incorrectly relied on his research findings. On 16 January 2014 *[AB/3/8.11/138]*, Dr Farsalinos was one of 15 leading expert scientists and academics who wrote a letter to the EU Commission setting out their views on how the relevant research had been misquoted. The letter was entitled "Scientific Errors in the Tobacco Products Directive." They went on to challenge a number of the assumptions made by the Commission and EP when imposing the regulatory regime on e-cigarettes. The letter states:

> "One justification for limiting nicotine levels in electronic cigarette liquid to 20mg/ml rests on the claim that higher levels would be dangerously toxic. This is not the case. People have ingested doses 60 times higher, which only led to nausea and vomiting and no other adverse effects. The Commission's contention that 60 mg of nicotine is lethal has been traced to dubious self-experiments recorded in a pharmacology textbook of 1856 and not confirmed since then. Poisoning from tobacco, nicotine replacement medications or e-cigarette liquid is extremely rare. There is also no risk of overdosing through inhalation. As with conventional cigarettes, excessive doses cause nausea, so inhalation is stopped long before any overdosing or health damage is possible."

73. The letter also addressed the assertion in recital (43) to the TPD 2014 that electronic cigarettes could be a "gateway" to conventional tobacco use in the following terms:

> "In conclusion, electronic cigarettes have a very good safety profile and are likely to provide a gateway away from rather than into smoking. Users should be allowed to identify a product and dosage that suit them rather than have regulators decide what they must use. Evidence-based and proportionate regulation should be implemented, and all stakeholders should be involved in the regulatory process. If wisely regulated, electronic cigarettes have the potential to obsolete *[sic]* cigarettes and to save millions of lives worldwide. Excessive regulation, on the contrary, will contribute to maintain the existing levels of smoking-related disease, death and health care costs."

74. Dr. Lynne Dawkins also wrote to the Commission asking them not to mis-represent her findings as a justification for the restrictive measures imposed by the TPD 2014. *[AB/3/8.26/312]*

75. Further or alternatively, the Claimant contends that the following provisions in Article 20 in particular impose a disproportionate burden on electronic cigarette manufacturers and distributors established in the Union.

(a) Article 20(2)

76. Article 20(2) of the TPD 2014 imposes a requirement for advance notification (of at least six months' duration) to the competent authorities of a Member State of an intention to place an electronic cigarette on the market. As Mr. Cropper's witness statement indicates at paragraphs160 to 165, the advance notification requirement restricts the scope for innovation and technological development. The perceived benefit of such a measure is wholly unclear. A less restrictive alternative would be to set a series of standards for all products – including new products to be released on the market – to meet. Furthermore, the requirements for notification go beyond equivalent reporting requirements found for tobacco products under Articles 5 and 6 of the TPD 2014.

77. A number of the matters which must be stipulated in the notification are also very difficult to achieve in practice, such as dosage levels and uptake when consumed under normal conditions. See generally the witness evidence of Mr. Cropper at paragraphs 166 to 180. The absence of any clear indication as to exactly what standards should be stated also offends the principle of legal certainty, especially in circumstances where the TPD 2014 envisages a regime of financial penalties for non-compliance if material facts are stated inaccurately.[37] The fundamental difficulty for a manufacturer or distributor is that the "dose", "uptake", "emissions" and "addictiveness" of nicotine as delivered by an electronic cigarette will vary considerably depending on the nicotine needs of the user and the user's manner of use.

(b) Article 20(3)

78. Restrictions on the manner in which electronic cigarettes may be sold are established under Article 20(3). The Claimant currently markets products which use e-fluid which

[37] See Case C-409/04 Teleos plc and others v. The Commissioners of Customs and Excise [2007] ECR I-7797, CJEU at [48]: "As regards, first, the principle of legal certainty, it must be observed all the more strictly in the case of rules liable to entail financial consequences, in order that those concerned may know precisely the extent of the obligations which such rules impose on them."

has a nicotine content varying from 0 mg/ml to 73 mg/ml. Some of its regular customers purchase nicotine in strengths of around 30-40 mg/ml.[38] The EU legislature has selected a maximum strength for the e-fluid of 20 mg/ml, seemingly on the assumption that this is equivalent to a conventional tobacco cigarette. That assumption was misplaced.

79. A packet of conventional tobacco cigarettes will state the "nicotine content" of those cigarettes. But the figure stated on the packet is not the actual "physical" quantity of nicotine contained within that packet of cigarettes or in an individual cigarette within it. The "nicotine content" figure so stated is in fact the nicotine "yield": that is, the amount of metabolised nicotine delivered into the smoker's bloodstream when smoking one of those cigarettes. The actual "physical" quantity of nicotine will be many times higher than the amount stated on the packet. So although the metabolised nicotine yield of a tobacco cigarette might be 2mg (for the sake of argument), the actual nicotine content in that cigarette may be nearer 20 mg. Electronic cigarettes are very different to ordinary cigarettes in their composition and mode of operation. So it takes longer for the nicotine ingested in vapour form to metabolise into the user's bloodstream. This does not mean that e-cigarettes are "ineffective." They just work very differently to conventional tobacco products. A much higher quantity of nicotine is required in the e-liquid contained within an e-cigarette to bring about equivalence with, for example, the 2 mg metabolised intake of nicotine from a tobacco cigarette.

80. In their letter to the Commission dated 16 January 2014, the group of experts identified above pointed out the scientific fallacy in the EU Legislature's approach. This stated:

> "The Commission quotes (1) Dr. Farsalinos' papers (2,3) to justify the claim that 20mg/ml of nicotine matches the average cigarette delivery. Dr. Farsalinos has written to the Commission stating that they have misinterpreted his findings. His research instead shows that 20 mg/ml e-liquid *provides less than one-third of the nicotine* delivered by one tobacco cigarette (4,5). 50mg/ml is needed to roughly match a tobacco cigarette. All other existing studies confirm this (6-9). Some 20 to 30% of electronic cigarette users use liquids above 20mg (8,10). Higher nicotine content liquids are typically used by the most dependent smokers, who have the highest risk of smoking-related damage, and who benefit most from switching to electronic cigarettes. Most such heavy smokers need more than 20mg/ml to switch from smoking to vaping."

[38] See the witness statement of Mr. Cropper at paragraph 85 *[AB/2/7/14]*.

81. Indeed, the most recent study by Dr Konstantinos Farsalinos and colleagues from the Onassis Cardiac Surgery Center in Kallithea, Greece and the Abich srl Biological and Chemical Toxicology Research Laboratory in Verbania, Italy was published in February 2014. *[AB/3/8.13/162]* It concluded that:

81.1. A maximum e-liquid nicotine strength of 20mg/ml would be insufficient to deliver nicotine at levels similar to tobacco cigarettes unless e-cigarettes are used continuously for a long time;

81.2. Setting a 20mg/ml maximum might significantly reduce the efficacy of e-cigarettes as a substitute to smoking;

81.3. Nicotine levels in e-cigarette liquids should be closer to 50mg/ml in order to approximate nicotine delivery from smoking; and

81.4. It is reasonable to conclude that the TPD 2014 cap "will reduce the effectiveness of e-cigarettes in substituting smoking." This is also borne out by the evidence of Mr. Cropper that the nicotine strength sought by an average to above average smoker to obtain a sufficient "nicotine hit" is 36 mg/ml.[39]

82. The consequence of the Union's error is two-fold. First, electronic cigarettes will not be able to deliver as high a nicotine dose as a conventional cigarette. Secondly, and as a result, fewer people will consider electronic cigarettes to be a genuine substitute to conventional cigarettes. This will then have a knock-on effect on the public health of those smokers who might otherwise have transferred from smoking tobacco to using electronic cigarettes with their substantially reduced risks to human health.

83. The volume and dosage requirements for refill containers and for cartridges or tanks do not attain a public health objective, may actually be counter-productive from a public health point of view and in any event impose more restrictive conditions than are found under the comparable provisions for tobacco cigarettes. Once again the letter from the numerous experts in this field to the Commission dated 16 January 2014 states: *[AB/3/8.11/140]*

"This proposal seems motivated by the concern about e-liquid toxicity, which is misinformed (see above). Electronic cigarettes have an excellent safety record so far

[39] See paragraph 95 of his witness statement *[AB/2/7/15]*.

(16). Worldwide, only one electronic cigarette fatality has been reported caused by a small child drinking electronic cigarette liquid from an open container (17). The Commission's proposal for smaller containers would generate more handling of refill bottles, so a higher choking risk for small children and higher cost to users. The alternative approach used with much more toxic household chemicals such as bleach is for the risk to be mitigated by common sense, warning labels and child-proof containers."

84. There can be no justification for this disproportionate approach given that the public health justification relied upon by the Union militates in favour of fewer restrictions being imposed on electronic cigarettes, in order at the very least to ensure parity of treatment with ordinary, tobacco cigarettes.

85. Article 20(3)(f) also requires an electronic cigarette to deliver a consistent dose of nicotine under normal conditions of use. In fact, as Mr. Cropper's witness evidence makes clear at [168]-[170], the dosage delivered will vary considerably depending on the nicotine demands of the user and the manner of use by the "vaper." Indeed, in their letter to the Commission dated 16 January 2014, the 15 experts pointed out that: *[AB/3/8.11/139]*

"The medicinal concept of 'consistent delivery' is inappropriate for a consumer product used freely. Users of cigarettes, oral tobacco and e-cigarettes spontaneously determine their nicotine intake according to individual and momentary needs. Individual users of the same electronic cigarette differ in their nicotine intake 20-fold (4,5,15). Quality control of individual brands is needed to ensure consistency of nicotine content but ensuring consistent delivery makes little sense. No such demands have been placed on tobacco cigarettes or oral tobacco."

86. This requirement is insufficiently defined to give manufacturers and retailers the clarity needed for a legal obligation. This also offends the general EU law principle of legal certainty, as addressed above. Furthermore, there are no restrictions on the "ordinary" dose of nicotine obtained from a smoker of ordinary cigarettes.

(c) Article 20(4)

87. Article 20(4)(a) requires electronic cigarettes manufacturers and retailers to market their products with an enclosed leaflet. The requirement to provide much of this information appears to be premised on a concern on the part of the EU legislature, expressed at recital (43), that NCPs are a "gateway" to cigarette use. As set out above at paragraph 73, and as

detailed further in Mr. Cropper's witness statement at paragraphs 110 to 119 *[AB/1/6/19]*, the available scientific evidence does not support the Commission's contention. Furthermore, the TPD 2014 has not imposed any obligation on tobacco cigarette manufacturers and retailers to provide an equivalent leaflet setting out comparable information as a pre-condition to the marketing of conventional tobacco. Furthermore, it is unclear why this requirement could not be satisfied through external printing on the packaging of the product, rather than through a separate leaflet. This is the method which the Claimant presently uses in any event to comply with current consumer safety legislation and packaging requirements. The imposition of a requirement to give the very same information separately in a leaflet is unnecessary and therefore disproportionate. See the witness evidence of Mr. Cropper at paragraph 195.

(d) Article 20(5)

88. Under Article 20(5), the EU has put in place a blanket prohibition on commercial communications on websites, the printed press, radio and television. The prohibition on advertising in the printed press, radio and television was seemingly intended to bring the marketing of electronic cigarettes into line with the restrictions applied to tobacco under Directive 2003/33/EC of the European Parliament and the Council of 26 May 2003 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products.[40]

89. Since the electronic cigarette market is not as developed as that for cigarettes, the restriction of (in effect) all forms of commercial advertising has a disproportionate impact on these products than for tobacco (where years of relentless advertising allowed tobacco companies to establish a significant market presence). In addition, while a challenge to the prohibition on certain forms of advertising found in Directive 2003/33/EC was rejected by the ECJ in Case C-380/03 Germany v. Parliament and Council [2003] ECR I-11573, ECJ, that challenge was only to the prohibition on advertising in printed media and by radio and television (albeit Article 3(2) of that Directive imposes a like prohibition on advertising through information society services).

[40] OJ [2003] L No 152, 20.6.2003, p. 16. A challenge to that measure was rejected by the ECJ in Case C-380/03 Germany v. Parliament and Council [2003] ECR I-11573, ECJ.

90. While it is true that the Claimant has not relied heavily on direct advertising to build its business, the prohibition on all forms of direct or indirect promotion of electronic cigarettes has a potentially adverse impact on companies such as the Claimant, which use internet based sales as a significant part of its "route to market." The prohibition is framed broadly enough to capture (at least potentially) not only advertising on websites and on social media, but the very act of selling the product over the internet for delivery to a customer's address. This is an impediment to the free provision of goods lawfully on sale in the Union, especially given the ubiquity of the internet as a sales channel. Furthermore, as Mr. Cropper's witness evidence shows at [148], to the best of the Claimant's knowledge, no such restrictions are placed on the promotion over the internet of conventional tobacco products. Article 3 of Directive 2003/33/EC is framed more narrowly by reference to restrictions on advertising of tobacco products through information society services. That is narrower in scope than a prohibition on all forms of commercial communication.

91. Furthermore, the prohibition in Article 20(5)(d) on any form of public or private contribution to any event with a cross-border effect is significantly wider than the prohibition on sponsorship found in Article 5 of Directive 2003/33/EC. Again no justification has been given for the detrimental, disparate treatment of electronic cigarettes compared with conventional tobacco products.

(e) Article 20(6)

92. The EU legislature has put forward no justification for the extension of the cross-border prohibition on distance sales for tobacco products being extended to electronic cigarettes. There is no evidence adduced by the Commission, for example, that cross-border distance sales of electronic cigarettes present smuggling problems. The justification advanced by the EU legislature for the prohibition in recital (33) relates solely to conventional tobacco products. Furthermore, there is no evidence that recital (33) could be applied *mutatis mutandis* to electronic cigarettes. There is no evidence from the EU legislature that cross-border distance sales would present a risk of the TPD 2014 requirements being circumvented, nor that they would present an increased risk to young people securing access to electronic cigarettes.

93. As Mr. Cropper's witness statement makes clear at paragraphs 120 to 134, research commissioned by ASH in 2013 *[AB/3/8.21/246]* demonstrated that very few young people are using e-cigarettes on a regular basis and that children are not using e-cigarettes at a significant level. The survey found that regular use of e-cigarettes amongst children and young people is rare and is confined almost entirely to those who currently or have previously smoked. These findings were largely supported by the Public Health England Report in May 2014 *[AB/3/8.7/91]*. At paragraph 4.2.1., that Report noted that "to date there is no data supporting [the] claim" that e-cigarettes promote smoking amongst young people and children, basing this conclusion on the findings in the ASH survey referred to above. The Report added that "it is relatively unlikely that availability and use of electronic cigarettes causes or will cause significant additional numbers of young people to become smokers than do at present."

94. Further or alternatively, a less restrictive alternative to the prohibition imposed would be to enact a prohibition on sales to under 18s, enforceable by a requirement for proof of age to be submitted at the point of sale, including electronically in respect of cross-border distance sales. The UK Government has introduced a power to prohibit sales to under 18s in the Children and Families Act 2014.

(f) Article 20(7)

95. The requirement to submit annual data to the competent authorities in the Member States is also a disproportionate interference with the Claimant's business and supply of goods and services. No equivalent annual reporting obligations are imposed on tobacco cigarette manufacturers or retailers.

96. Further or alternatively, the requirement to provide information in relation to the preferences of "various consumer groups" is insufficiently clear as to exactly what is required. It fails to comply with the core requirements of legal certainty, namely foreseeability and predictability of application.[41] While the Claimant does indeed ask for confirmation that its customers are over 18 years' old, it is not known how the Claimant could insist on customers stating whether or not they are smokers. The Claimant could

[41] See, for example, Hentrich v France (App 1316/88) (1994) 18 EHRR 440, ECtHR at [42].

ask for the relevant information to be provided on a voluntary basis, but the routine provision of such personal data might in itself raises issues under the Data Protection Act 1998 (which gives effect to the Data Protection Directive). Since it is unclear what obligations are required by this provision, and unclear as to what practical steps might realistically be taken to comply with it, it fails the test for proportionality. It is also not apparent why a less restrictive alternative for the Commission and/or Member States would not be the implementation of consumer market research surveys, which are routinely used by regulators in other fields.

(2) Infringement of the principle of equality or non-discrimination

97. In so far as the above obligations also treat electronic cigarette manufacturers or retailers less favourably than conventional tobacco cigarette manufacturers or retailers, the contested provisions fail to comply with the general EU principle of equality. The provisions of Article 20 impose a higher regulatory burden on electronic cigarettes than is found for normal tobacco cigarettes, despite being by far and away the safer product. The Claimant repeats *mutatis mutandis* the particulars of its case given above at paragraphs 75 to 96 above.

98. The contested provisions of the TPD 2014 identified above give rise to an inconsistent treatment of competing products. Since the products are treated by the EU legislature as being comparable (so as to justify bringing electronic cigarettes within the scope of regulatory control in the first place), this infringes the principle of "equality" or non-discrimination. Persons in comparable situations should not be treated differently without an objective justification for doing so: see Joined Cases 201 and 202/85 Klensch [1986] ECR 3477, ECJ at [9]-[11].

99. Indeed, as the scientific literature demonstrates, the public health justifications for the measure would suggest that it is the tobacco manufacturers and retailers which should bear the higher regulatory burden, given the more detrimental impact on public health of their products.

100. In particular:

100.1. Article 20(3)(f) requires electronic cigarettes to deliver a consistent dose of nicotine. This is, as set out above, very hard to guarantee in practice and is not required of conventional cigarettes;

100.2. By parity of reasoning, the obligation under Article 20(2) of the TPD 2014 for advance notification to give six months' notice of the likely dosage levels are not easy to comply with and are not required for manufacturers of tobacco products. In their letter dated 16 January 2014, the experts in this field have made the following observation:

> "Bearing in mind the above comments on nicotine delivery, such data would be of no benefit to consumers, but would incur large unnecessary costs. No such data are required from cigarette or tobacco manufacturers, and this, along with other regulatory proposals, would create a market advantage for the much more dangerous tobacco cigarettes."

100.3. The restrictions on the refill containers and cartridges with which electronic cigarettes may be sold under Article 20(3) do not maintain a consistency of approach with the treatment of the sale of tobacco cigarettes;

100.4. The requirement to provide a childproof packaging for electronic cigarettes is not imposed for normal tobacco products;

100.5. The requirement under Article 20(4) to provide a leaflet with each unit package of electronic cigarettes and with each refill container is not applied to ordinary cigarette manufacturers or retailers;

100.6. Greater restrictions are imposed on the commercial communications which are prohibited under Article 20(5) for electronic cigarettes, than are to be found for ordinary cigarettes under Directive 2003/33/EC.

101. The effect of this disparate treatment, for which no objective justification has been advanced by the EU Legislature, is also to create a distortion of competition in the market, contrary to Article 3 TEU read in conjunction with Articles 106, 116 and 119 TFEU and Protocol (No) 27 to the Lisbon Treaty. The ECJ has reiterated in Case C-49/07 MOTOE [2008] ECR I-4863 at [51] that "a system of undistorted competition, such as that provided for by the Treaty, can be guaranteed only if equality of opportunity is secured as between the various economic operators."

(3) Infringement of the principle of subsidiarity

102. Further or alternatively, Article 20 infringes the principle of subsidiarity, contrary to Article 5 TEU. The question of subsidiarity was addressed as a ground of challenge, albeit not found to be a basis for annulling the contested measures, in Case C-376/98 Germany v. Parliament and Council (*supra*) at [179]-[185]; and Joined Cases C-154/04 and 155/04 Alliance for Natural Health [2005] ECR I-6451, CJEU at [99]-[108]. In British American Tobacco, the ECJ accepted that the principle of subsidiarity could be a ground for reviewing the legality of measures adopted on the basis of Article 114 TFEU, but concluded in that case that the relevant internal market objective could not be sufficiently achieved by action from the Member States individually. Indeed, it was precisely because of divergences in Member State practice that an EU-wide measure was justified.

103. In the present case, a large number of national Governments have complained to the EP and the Commission that the need for harmonising measures on a pan-EU basis has not been substantiated. See the factual background set out at paragraph 23 above. Furthermore, the EU legislature has adduced insufficient evidence of a disparate treatment at national level to justify the co-ordinated response to electronic cigarettes dictated by Article 20 of the TPD 2014. Paragraph 3.7 of the Explanatory Memorandum accompanying the Commission's proposal referred only to differential treatment in Member States concerning the classification of electronic cigarettes as medicinal products or as tobacco products. It did not indicate that differing product safety requirements were being applied. Since the TPD 2014 has in fact excluded products which should be treated as medicinal products from the scope of the Directive, differential approaches to the classification of electronic cigarettes as medicinal products cannot be used to justify the harmonisation measures in fact adopted under Article 20 TPD 2014.

(4) Infringement of Articles 16 and 17 of the CFR

104. Article 16 of the CFR states:

> "The freedom to conduct a business in accordance with Union law and national laws and practices is recognised."

105. Article 17 of the CFR provides as follows:

> "1. Everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions. No one may be deprived of his or her possessions, except in the public interest and in the cases and under the conditions provided for by law, subject to fair compensation being paid in good time for their loss. The use of property may be regulated by law in so far as is necessary for the general interest.
>
> 2. Intellectual property shall be protected."

106. The Explanations to the Charter[42] are a persuasive source of guidance for their interpretation.[43] They make clear that the provisions of Article 16 are intended to protect the right to economic and commercial activity, in a system of free competition. Article 17 reflects the terms of Article 1 of the First Protocol to the European Convention on Human Rights, but marks out the protection of intellectual property for special attention because of its growing importance within the Union. An unjustified or disproportionate restriction of the freedom to provide services under Article 56 TFEU is also capable of limiting the freedom to conduct a business and the right to property enshrined in Articles 16 and 17 CFR. See Case C-390/12 Robert Pfleger [2014] ECR I-0000, ECJ at [57] to [59].

107. At [149] of its judgment in British American Tobacco, the ECJ held that EU legislation might lawfully restrict property rights in the public interest, "provided that those restrictions in fact correspond to objectives of general interest pursued by the Community and do not constitute a disproportionate and intolerable interference, impairing the very substance of the rights guaranteed (see, in particular, Case 265/87 *Schräder* [1989] ECR 2237, paragraph 15; Case C-280/93 *Germany* v *Council* [1994] ECR I-4973, paragraph 78, and Case C-293/97 *Standley and Others* [1999] ECR I-2603, paragraph 54)." At [150], the ECJ found that the legislative measure did not prejudice the substance of the trade mark owners' rights, but it is clear from the judgment at [132] and [152] that the legislation still permitted trade mark owners to distinguish their products by using distinctive signs.

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[42] See OJ [2007] C No 303, 14.12.2007, p. 28.

[43] See the third subparagraph of Article 6(1) TEU and Article 52(7) of the CFR, as well as Case C-279/09 DEB Deutsche Energiehandels- und Beratungsgesellschaft mbH v. Germany [2010] ECR I-13849, ECJ at [30]-[33].

108. The complete ban on commercial advertising found in Article 20(5) of the TPD 2014 prevents the proper promotion of the Claimant's business and the dissemination of its trade mark, contrary to Articles 16 and 17 CFR. Furthermore, Article 20 more generally precludes the proper exploitation of the Claimant's commercial property, including its trade mark rights, in ways that are not justified. Since the measures may only be justified under Article 52 CFR if they are necessary and proportionate, this ground of challenge provides another juridical basis on which the Claimant seeks to challenge the validity of Article 20 of the Directive. The Claimant in this regard repeats its submissions on the lack of proportionality of the measure set out in section E(1) above.

F. The request for expedition

109. For the reasons addressed in Mr. Cropper's witness statement dated 4 July 2014, the Claimant also asks for its application for permission to be dealt with on an expedited basis. While the precise impact of the introduction of this new regulatory regime cannot readily be identified at this stage (particularly in the absence of an indication of the likely domestic implementation of the discretionary powers granted to the Member States) the Claimant considers that there is a real risk that its business in its present form will be severely impeded in the event that the TPD 2014 is implemented by the UK Government. The Claimant in particular envisages that it will be large pharmaceutical or cigarette companies, with the capitalisation and resources to support the lengthy and expensive procedure for obtaining a licence under the Medicinal Products Regulations 2012, which will be in the best position to exploit the high demand for NCPs once the new dual authorisation regime enters into effect.

110. The Claimant therefore desires to have the question of the Directive's validity determined by the ECJ before 20 May 2016. Given the expected duration of a reference, the Claimant will, in the event that permission to apply for judicial review is granted, request that further directions for the service of Detailed Grounds and witness evidence on the part of the Defendant are abridged pursuant to CPR Part 3.2(1)(a). Draft directions to that effect have been set out in the Claimant's application for expedition. The Claimant also respectfully requests that the proceedings be allocated to the expedited list within the Administrative Court.

G. Conclusion

111. The Claimant respectfully seeks the following relief from the Court:

111.1. Permission to apply for judicial review of the UK's obligation to implement the TPD 2014;

111.2. The determination of appropriate questions for a reference to the ECJ under Article 267 TFEU;

111.3. A stay of these proceedings pending the issue of the validity of Article 20 of the TPD 2014 being referred to the ECJ;

111.4. Appropriate declaratory or other relief in the light of such ruling as the ECJ may in due course give, together with costs.

112. In the light of the likely duration of a reference to the ECJ, the Claimant also seeks expedition to enable the question of validity to be fully addressed by the ECJ prior to the entry into force of the Directive on 20 May 2016. Draft reference questions are attached hereto, for consideration by the Court and the Defendant.

KIERON BEAL QC

10 July 2014

Blackstone Chambers

ANNEX 1

Draft questions for a reference for a preliminary ruling

1. Is Article 20 of Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, OJ [2014] L No 127, 29.4.2014, p. 1, invalid, either in whole or in a relevant part, for one or more of the following reasons:

    1.1. It imposes either as a whole or in relevant part a series of obligations on electronic cigarette manufacturers and/or retailers which infringe the principle of proportionality?

    1.2. For equivalent or similar reasons, it fails to comply with the principle of equality?

    1.3. It distorts competition in the relevant markets for electronic cigarettes and traditional tobacco cigarettes?

    1.4. It fails to comply with the EU principle of legal certainty?

    1.5. It fails to comply with the principle of subsidiarity?

    1.6. It infringes the rights of electronic cigarette manufacturers or retailers under Articles 16 and/or 17 of the Charter of Fundamental Rights?