CLAIM NO. CO/3234/2014

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

ORDER

UPON THE APPLICATION by the Claimant for reference to the Court of Justice of the European Union for a preliminary ruling on the questions set forth in the Schedule annexed to the Application Notice and for a stay of proceedings pending such preliminary ruling;

And upon hearing Counsel for the Claimant and for the Defendant;

And upon reading the documents recorded in the Court File as having been read;

It is ordered that the questions set out in the Schedule hereto concerning the validity of Article 20 of Directive 2014/40/EU ("the Tobacco Products Directive 2014") and its compatibility with EU law be referred to the said Court of Justice for a preliminary ruling in accordance with Article 267 of the Treaty on the Functioning of the European Union;

And it is ordered that all further proceedings in the above-named matter be stayed until the said Court of Justice has given its ruling on the questions or until further order;

And it is ordered that this Order be communicated to the said Court of Justice forthwith, without waiting for any period for appeal to expire.

Dated this 6th day of October 2014

The Honourable Mr Justice Green

By the Court

SCHEDULE

REQUEST FOR PRELIMINARY RULING OF THE COURT OF JUSTICE OF THE EUROPEAN UNION

A. INTRODUCTION

1. The Claimant, Pillbox 38 (UK) Limited, is a company established under English law. It trades under the name "Totally Wicked" ('TW'). TW is a manufacturer and retailer of "electronic cigarettes". This reference for a preliminary ruling is made in the context of TW's contention that Article 20 of the Tobacco Products Directive 2014[1] ('the TPD 2014') is invalid, on the basis that it:

    a) First, represents a disproportionate impediment to the free movement of goods and/or the free provision of services;
    b) Secondly, 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.
    c) Thirdly, infringes the principle of subsidiarity, contrary to Article 5 TEU;
    d) Fourthly, infringes Articles 16 and 17 of the Charter of Fundamental Rights.

2. 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. The TPD 2014 requires Member States to bring into effect transposing legislation which will impose restrictions on the manufacture,

[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.

presentation and sale of tobacco and tobacco related products, including electronic cigarettes. Member States must apply domestic provisions transposing the TPD 2014 from 20 May 2016.

3. Various restrictions on the marketing and advertising of electronic cigarettes are found in Article 20 of the TPD 2014, which also cross-refers to certain provisions in Article 18. The TPD 2014 in its entirety is attached at **Annex 1**.

4. The Defendant is the United Kingdom's Secretary of State for Health ('the Secretary of State'). He has overall responsibility for the Department of Health, which is the department responsible for the implementation of the TPD 2014 in the UK.

B. RELEVANT FACTUAL BACKGROUND

5. TW is a leading manufacturer and retailer of electronic cigarettes (also known as "e-cigarettes"), liquid nicotine refills (known as "e-liquid"), and related products.[3]

6. Between 2010 and 2012, the EU Commission consulted on the potential revision of the TPD 2001. This included whether e-cigarettes, recently introduced to the markets of Member States, should be included within its scope and be subject to product specific regulation, and if so, what form such regulation should take.[4] The consultation examined whether e-cigarettes should be regulated as "medicinal products or devices."

7. On 19 December 2012, the EU Commission published a proposed draft Directive, together with an Explanatory Memorandum (at **Annex 4**). Article 18 of the draft Directive provided for "nicotine containing products" ('NCPs') with a certain level of nicotine content to be assimilated with medicines and regulated under the Medicinal Products Directive, Directive 2001/83/EC. The Commission concluded that this would remove current legislative divergence between Member States and the

[3] An extract from Totally Wicked's website describing the product and its components is at **Annex 2**
[4] A copy of the relevant consultation document is at **Annex 3**.

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."[5]

8. 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 Treaty on the Functioning of the European Union ('TFEU').[6] An insufficient number of objections were received from Member States to trigger a review pursuant to Article 7 of the Protocol. The Council subsequently agreed to the general approach of the proposed revisions on 21 June 2013. Thereafter, the legislative text was examined by a series of Committees established by the European Parliament ('EP').

9. At a plenary session of the EP on 8 October 2013, MEPs voted in favour of changes in the approach to the regulation of electronic cigarettes. They resolved to negotiate a first-reading agreement with EU ministers in the course of a "Trilogue" procedure between the EU institutions.

10. There then followed a series of exchanges between the EP and the Council while a draft text of the Directive was scrutinised. An amended compromise text was agreed between those two institutions on 18 December 2013.

11. The EP formally approved a revised version of the Directive on 26 February 2014. 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.

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[5] See **Annex 4** at para 3.7.
[6] Some examples of the opinions filed by national Parliaments can be found at **Annex 5**.

C. RELEVANT DOMESTIC LAW

12. A number of legislative provisions (other than the TPD 2014) are relevant to the marketing and sale of electronic cigarettes within the UK, derived in large part either from EU Directives or from directly applicable EU Regulations. These include[7]:

a) The General Product Safety Directive 2001/95/EC;[8]
b) The Dangerous Substances Directive 67/548/EEC;[9]
c) The Dangerous Preparations Directive 99/45/EC;[10]
d) The Classification, Labelling and Packaging of Substances and Mixtures Regulation (EU) No 1272/2008, which applies from 2015;[11]
e) The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) 1907/2006;[12]
f) The Low Voltage Directive 2006/95/EC;[13]
g) The Electro-Magnetic Compatibility Directive 2004/108/EC;[14]
h) The Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU (where appropriate);[15]

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[7] See also the 2013 position paper by the Health and Safety Executive summarising the relevant classification, labelling and packaging at **Annex 6.**

[8] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, as amended.

[9] 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.

[10] 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.

[11] 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.

[12] 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.

[13] 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.

[14] 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.

i) The Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU;[16]

j) The Batteries Directive 2006/66/EC;[17]

k) The Making-up by weight or by volume of certain pre-packaged products – Directive 76/211/EEC;[18]

l) The Nominal Quantities for Pre-packed Products Directive 2007/45/EC;[19]

m) The Distance Selling Directive 97/7/EC;[20]

n) Directive on Electronic Commerce 2000/31/EC;[21]

o) The Misleading and Comparative Advertising Directive 2006/114/EC;[22]

p) The Unfair Commercial Practices Directive 2005/29/EC.[23]

D. RELEVANT UNION LAW

13. The individual provisions of the TPD 2014 whose validity is challenged by TW are identified below at paragraphs 26 to 37.

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[15] 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.

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

[17] 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.

[18] 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.

[19] 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.

[20] 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.

[21] 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.

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

[23] 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, 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.

E. SUBMISSIONS OF THE PARTIES

(1) Submissions from the Secretary of State

14. The Secretary of State maintains that Article 20 is valid. However, he has agreed that a preliminary reference would be appropriate because the EU institutions are best placed to explain why Article 20 is lawful. The Secretary of State does not have all the necessary information to put forward a complete explanation in this regard. As a result, the Secretary of State was not required by the national court to produce submissions or evidence relating to the substance of the claim. The submissions of TW are summarised below so as to inform all persons who may wish to submit observations on the content of TW's challenge to the TPD 2014. For the same reason, the evidence upon which TW relies is annexed to this Schedule.

(2) Submissions from TW

15. TW contends that the terms of Article 20 generally, and the particular provisions in Article 20 of the TPD 2014 identified below, are invalid as they infringe the following principles of EU law:
    a) The principle of proportionality, read in conjunction with the principle of legal certainty;
    b) The principle of equality and the distortion to the competitive market structure for tobacco related products;
    c) The principle of subsidiarity; and/or
    d) 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').

16. TW's case is more fully set out in its Statement of Facts and Grounds **Annex 25** and the Witness Statement of Fraser Brunel Nicholas Cropper dated 10 July 2014 **Annex 26**.

(a) TW's first plea: Proportionality and legal certainty

17. The contested provisions restrict TW's ability to market and sell its products or to make or receive advertising and marketing services. The restrictions have an actual or potential impact on cross-border trade. Indeed, part of Article 20 is specifically aimed at cross-border supplies. The 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 in Article 56 TFEU. Further or alternatively, under Article 5(1) TEU, the EU competences are limited by the principles of proportionality and subsidiarity.

18. TW contends that the means the EU legislation has employed are not suitable for the purpose of achieving the desired objective; and go beyond what is necessary to achieve it.[24] The measures in question were in fact formulated as a compromise text during the "Trilogue" procedure. The Commission's Impact Assessment accordingly contained no analysis of the legislative regime ultimately adopted.[25] The regime adopted was not subject to any impact assessment by the Commission or other EU institution.[26] The EU legislature, faced with a choice between several appropriate measures (as reflected in the Commission's impact assessment), did not have recourse to the least onerous. Disadvantages caused must not be disproportionate to the aims pursued. Furthermore where the 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.[27]

19. TW contends that the EU legislature adopted a disproportionate approach by putting in place an "authorisation scheme" for electronic cigarettes. TW's electronic

[24] 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-491/01 R v. Secretary of State for Health, ex p. British American Tobacco [2002] ECR I-11453 at [122].
[25] See **Annex 7**. See also Case C-310/04 Spain v. Council [2006] ECR I-7285, at [97] and [122].
[26] Unlike in Case C-58/08 Vodafone [2010] ECR I-4999, ECJ. See the judgment at [55].
[27] See Case C-293/12 Digital Rights Ireland [2014] ECR I-0000, ECJ at [46]-[48].

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 subject to a parallel authorisation scheme akin to that found in the Medicinal Products Directive 2001. TW further contends that, 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. In fact, while e-cigarettes have been characterised in the TPD 2014 as tobacco related products, they contain no tobacco.

20. It is not correct that the marketing and sale of electronic cigarettes will otherwise be unregulated. A large number of existing measures at EU level and domestically already regulate the safety and marketing of electronic cigarettes, including strict requirements on the classification, labelling and packaging of e-cigarettes and e-liquids. Details are given in section C above.

21. While it is true that e-cigarettes are used by some consumers as a replacement for cigarettes, the EU legislature appears to have proceeded under an implicit assumption that they pose an equivalent risk to public health. 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 contain only a fraction of the 7,000 chemicals 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.[28]

22. The EU legislature has erred in regulating electronic cigarettes in the same manner as conventional tobacco, when the public health justification for doing so cannot be substantiated. Independent scientific evidence has shown that the number of potentially toxic compounds in e-cigarette vapour is substantially lower (in one study found to between 9 and 450 times lower)[29] than in conventional tobacco cigarettes.

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[28] Examples of relevant medical reports on the subject are found at **[Annex 8 - 13]**; see also ASH April 2014 at **Annex 20** and STS Toolkit at **Annex 22**.

[29] See **Annex 14** (see page 6 of the Report)

This supports the proposition that vapour from e-cigarettes is less injurious to public health than smoke from cigarettes. There are comparative benefits to public health from conventional smokers switching to electronic cigarettes, because nicotine is not a significant health hazard, does not cause serious adverse health effects such as acute cardiac events, coronary heart disease or cerebrovascular disease, and is not carcinogenic. Studies show that the "doses" of nicotine delivered by electronic cigarettes are extremely unlikely to cause significant short or long-term adverse effects.[30] At worst, any health risks from e-cigarettes are likely to be only a small fraction of the risks of smoking tobacco, because electronic cigarettes do not contain the combustion chemicals which cause lung and heart disease and cancer.[31]

23. The only justification advanced for seeking to implement an authorisation regime for electronic cigarettes is that nicotine is addictive and toxic in high doses. However, caffeine has a mildly addictive effect, and that is not a regulated substance. Alcohol is toxic (indeed fatal) in high doses, but that is not subject to an authorisation regime either. Article 20 also imposes conditions on the sale and marketing of electronic cigarettes which are in fact *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.

24. A number of leading experts in the field have alleged that the Commission and/or the EP misinterpreted or misapplied the conclusions of their scientific reports that have purportedly been relied upon by the EU institutions. For example, the Commission's contention that 60 mg of nicotine is lethal in a human appears to have been based on

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[30] See, for example, **Annex 15**

[31] See **Annex 15** at paragraph 2.3 and **Annex 16**. It is true that the WHO Framework Convention on Tobacco Control, *Electronic nicotine delivery systems*, 21 July 2014 identified concerns about electronic cigarettes **Annex 47**. But that report has been subject to detailed criticism. See the reports at **Annex 48**. The WHO is to consider the matter more fully at a forthcoming conference in October 2014. Since additional material concerning the WHO's position (and the response of the scientific community to it) may become available after this conference, the national Court recognises that further written materials in that regard may need to be attached to the pleadings of the parties during the written procedure.

experiments recorded in a pharmacology textbook from the year 1856 and not confirmed since.[32]

25. The EU legislature has also asserted (see recital (43) to TPD 2014) that electronic cigarettes could be a "gateway" bringing non-smokers to conventional tobacco use. TW contends that this is simply conjecture and that there is no compelling evidence which supports this proposition. Indeed, many studies contradict this assumption.[33]

26. TW says that the following specific provisions in particular impose disproportionate burdens on electronic cigarette manufacturers and distributors:

Article 20(2) - six month advance notification requirement to the competent authorities of a Member State of an intention to place an electronic cigarette on the market

27. Such an 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 to be met by all products – including new products to be released on the market. The requirements go beyond equivalent reporting requirements found for tobacco products under Articles 5 and 6 of the TPD 2014.

28. A number of the matters which must be stipulated are very difficult to achieve in practice, such as "dosage levels" and "uptake" when consumed "under normal conditions." The fundamental difficulty for a manufacturer or distributor is that "dose", "uptake", "emissions" and "addictiveness" of nicotine as delivered by an electronic cigarette vary considerably depending on the nicotine needs of the user and the individual's manner of use. The absence of any clear indication as to exactly what standards should be stated offends the principle of legal certainty, especially in

[32] See **Annex 17, 18 and 19**
[33] See **Annex 15, 17 – 19 and 20 – 22**

circumstances where the TPD 2014 envisages a regime of financial penalties for non-compliance if material facts are stated inaccurately.

Article 20(3) - restrictions in the manner in which electronic cigarettes may be sold

29. TW has various objections to Article 20(3). First, the EU legislature has selected a maximum strength for e-liquid of 20 mg/ml, seemingly on the assumption that this is equivalent to a conventional tobacco cigarette. This assumption is misplaced. It fails to recognise that electronic cigarettes are very different to ordinary cigarettes in their composition and operation. Whilst a packet of tobacco cigarettes will state the "nicotine content" of those cigarettes, this is not the actual "physical" quantity of nicotine contained within that packet or an individual cigarette within it. It is instead 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. E-cigarettes operate differently. It takes longer for the nicotine ingested in vapour form to metabolise into a user's bloodstream. A much higher quantity of nicotine is required in the e-liquid within an e-cigarette to bring about equivalence with, for example, the 2 mg metabolised intake of nicotine from a tobacco cigarette.[34]

30. Scientific study has shown that a maximum e-liquid nicotine strength of 20mg/ml will be insufficient to deliver nicotine at levels similar to tobacco cigarettes unless e-cigarettes are used continuously for a long time.[35] Setting a 20mg/ml maximum might therefore significantly reduce the efficacy of e-cigarettes as a substitute to smoking. Studies have shown that nicotine levels in e-liquid should be closer to 50mg/ml in order to approximate nicotine delivery with tobacco smoking.[36] It is therefore

[34] See **Annex 23**.
[35] See **Annex 23** at page 484.
[36] See **Annex 23** at page 492.

reasonable to conclude that the TPD 2014 cap will reduce the effectiveness of e-cigarettes as a substitute for smoking ordinary tobacco. The consequence of this will be two-fold:

a) First, electronic cigarettes will not be able to deliver as high a nicotine dose as a conventional cigarette.
b) 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.

31. The Article 20(3) volume and dosage requirements for e-liquid containers and cartridges do not attain a public health objective. They may actually be counter-productive from a public health point of view.[37] In any event, they impose more restrictive conditions than are found under the comparable provisions for tobacco cigarettes. There can be no justification for this disproportionate approach given that the public health justification relied upon by the EU 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.

32. Finally, Article 20(3)(f) requires an electronic cigarette to deliver a consistent dose of nicotine under normal conditions of use. In fact, the dosage delivered will vary considerably depending on the nicotine demands of and the manner of use by the consumer. 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. Furthermore, there are no restrictions on the "ordinary" dose of nicotine obtained from a smoker of ordinary cigarettes.

Article 20(4) – requirement to market products with an enclosed leaflet

[37] See **Annex 17**.

33. 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. Indeed external printing is the method TW presently uses in any event to comply with current consumer safety legislation and packaging requirements[38]. A requirement to give the very same information separately in a leaflet is unnecessary and therefore disproportionate. The TPD 2014 does not impose any such obligation on tobacco cigarette manufacturers and retailers as a pre-condition to the marketing of conventional tobacco.

Article 20(5) - blanket prohibition on commercial communications on websites, the printed press, radio and television

34. This seemingly brings the marketing of electronic cigarettes into line with the restrictions applied to tobacco under Directive 2003/33/EC.[39] But 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). It also has a potentially adverse impact on companies such as TW, 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 EU, especially given the ubiquity of the internet as a sales channel.

35. Furthermore, and contrary to the apparent aim of the legislature, to the best of TW's knowledge, no such restrictions are placed on the promotion and/or sale over the

[38] See photographs of product at **Annex 24**

[39] 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.

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. 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. No justification has been given for the detrimental, disparate treatment of electronic cigarettes compared with conventional tobacco products.

Article 20(6) - extends cross-border prohibition/the requirement for a registration scheme on distance sales for tobacco products to electronic cigarettes

36. No justification has been put forward (and there is no evidence from the EU legislature) that cross-border distance sales would present a risk of the TPD 2014 requirements being circumvented, an increased risk to young people securing access to electronic cigarettes, or would present (for example) smuggling problems. The justification advanced by the EU legislature for the prohibition/requirement for a registration scheme 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. If the underlying concern is the possibility of sales to under 18s, a less restrictive alternative 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, for example, introduced a power to prohibit sales to under 18s in the Children and Families Act 2014.

Article 20(7) - requirement to submit annual data to the competent authorities in the Member States

37. This is also a disproportionate interference with TW's business and its supply of goods. No equivalent annual reporting obligations are imposed on tobacco cigarette

manufacturers or retailers. The requirement to provide information relating 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.[40] Since it is unclear what obligations are required by this provision, and unclear 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 could not be the implementation of market research surveys, which are routinely used by regulators in other fields.

(b) TW's second plea: Equality and non-discrimination

38. In so far as the above obligations also treat e-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. They also give rise to an inconsistent treatment of competing products. Since the products are treated by the EU legislature as 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. EU case law states that persons in comparable situations should not be treated differently without an objective justification for doing so.

39. According to the scientific evidence, the public health justifications for the measure suggest that tobacco manufacturers and retailers should bear the higher regulatory burden, given the more detrimental impact on public health of their products. In particular:

[40] See Case C-409/04 Teleos plc and others v. The Commissioners of Customs and Excise [2007] ECR I-7797, CJEU at [48].

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

b) The advance notification obligation under Article 20(2) of the likely "dosage" levels is not easy to comply with and is not required for manufacturers of tobacco products;

c) 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;

d) The requirement to provide childproof packaging for electronic cigarettes is not imposed for normal tobacco products;

e) 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;

f) 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.

40. The effect of this disparate treatment, for which no objective justification has been advanced, is 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 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."[41]

(c) TW's third plea: Subsidiarity

41. Article 20 also infringes the principle of subsidiarity, contrary to Article 5 TEU. A number of national Parliaments complained to the EP and the Commission that the need for harmonising measures on a pan-EU basis in TPD 2014 had not been

[41] Case C-49/07 MOTOE [2008] ECR I-4863 at [51].

substantiated.[42] 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.

42. Paragraph 3.7 of the Explanatory Memorandum accompanying the Commission's proposal **Annex 4** 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 from its scope products which should be treated as medicinal products, 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.

(d) TW's fourth plea: Articles 16 and 17 of the CFR

43. The Explanations to the Charter[43] 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.[44]

44. The ECJ has 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. The complete ban on commercial advertising found in Article 20(5) prevents the

[42] See the Opinions under the Yellow Card procedure at **Annex 5**.
[43] See OJ [2007] C No 303, 14.12.2007, p. 28.
[44] See Case C-390/12 Robert Pfleger [2014] ECR I-0000, ECJ at [57] to [59].

proper promotion of the Claimant's business and the dissemination of its trade mark, contrary to Articles 16 and 17 CFR. Furthermore, Article 20 of the TPD 2014 more generally precludes the proper exploitation of TW'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 TW seeks to challenge the validity of Article 20 of the Directive.

F REASONS FOR THE REFERENCE

45. Following Case 314/85 Firma Foto-Frost v Hauptzollamt Lubeck-Ost [1987] E.C.R. 4199, national courts are not entitled to declare acts of EU Institutions invalid. For the coherence and unity of the Union legal order it is for the Court of Justice of the European Union ('ECJ') or the General Court ('GCEU') to declare that any acts of the EU institutions were invalid: Case C-344/04 IATA and European Low Fares Airline Association [2006] ECR I-403, ECJ at [29] and [30].

46. Having received submissions from the parties, the referring Court considers that the Claimant's arguments as to the validity of Article 20 of the TPD 2014 are reasonably arguable. The referring Court further considers that TW does not have standing to bring a direct challenge to the TPD 2014 before the GCEU: Joined Cases T-172/98 and T-175/98 to T-177/98 Salamander AG v. Parliament and Council [2000] ECR II-2487, GCEU at [54]. A reference was also made to the ECJ 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.[45] A reference to the ECJ with the following questions is accordingly considered to be necessary and appropriate in this case.

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

47. The referring Court observes that the contested provisions are due to enter into effect on 20 May 2016. It has considered the matter on an expedited basis to enable this Order for Reference to be made as soon as possible in the hope that the preliminary ruling from the ECJ might be available prior to that date. The referring Court does not formally request expedition under Article 105 of the ECJ's Rules of Procedure. But it does respectfully observe that it would be highly desirable if the validity of the contested measure could be determined in good time prior to its entry into effect.

G. THE QUESTION REFERRED

48. The referring Court accordingly refers the following question to the ECJ for a preliminary ruling under Article 267 TFEU:

"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:

- It imposes either as a whole or in a relevant part a series of obligations on electronic cigarette manufacturers and/or retailers which infringe the principle of proportionality, read in conjunction with the principle of legal certainty?
- For equivalent or similar reasons, it fails to comply with the principle of equality and/or unlawfully distorts competition?
- It fails to comply with the principle of subsidiarity?
- It infringes the rights of electronic cigarette manufacturers or retailers under Articles 16 and/or 17 of the Charter of Fundamental Rights?"

Parliament and Council [2000] ECR I-2247, on the ground that the Treaty legal base chosen for the measure was inadequate.