The tobacco industry’s challenge to the United Kingdom’s standardised packaging legislation – global lessons for tobacco control policy?

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Abstract

In 2015, legislation imposing a standardised packaging regime for tobacco products was passed by the United Kingdom Parliament. The Standardised Packaging of Tobacco Products Regulations 2015 came fully into effect from 21 May 2017 and was contested vigorously by the tobacco industry, both through the legislative consultation process and in the courts. This article focuses on R on the application of British American Tobacco Limited v The Secretary of State for Health, the claim for judicial review brought by the industry against the Regulations in the United Kingdom. In this claim, the introduction of standardised packaging was challenged on a number of grounds – including proportionality, compatibility with the right of property and with international and European Union rules on the protection of intellectual property. All these arguments were rejected in forceful terms by Green J in the High Court and, again on appeal, by the Court of Appeal. This article sets out the industry’s claims in detail and explores the grounds on which the legislation was upheld. It also outlines the European Union legal context within which the legislation operates, including the important judgment of the Court of Justice of the European Union in (C-547/14) Philip Morris Brands SARL and Others v Secretary of State for Health. It is suggested here that the reasoning in these judgments may prove instructive well beyond the borders of the United Kingdom.

Introduction

In the United Kingdom, smoking kills over 100,000 people every year. Deaths from smoking are more numerous than the next six most common causes of preventable death combined. At the same time, large numbers of young people continue to take up the habit. It is estimated that over 200,000 children between 11 and 15 begin smoking each year. In

* In its description of the legislative process leading up to the Standardised Packaging of Tobacco Products Regulations 2015 and of the content of those Regulations (section 1 below), this article reuses some material published in J Griffiths, “On the back of a cigarette packet – standardised packaging legislation and the tobacco industry’s right to (intellectual) property” [2014] IPQ 343.

1 R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for Health [2016] EWHC 1169 (Admin) [61]-[67]

response to this public health problem, a number of important tobacco control measures have been introduced. These include compulsory standardised packaging for tobacco products, required under the Standardised Packaging of Tobacco Products Regulations 2015 (“the Regulations”). The Regulations came into force on 20 May 2016 and, with effect from 21 May 2017, require all cigarettes and hand-rolling tobacco to be sold in standardised packaging. The United Kingdom was the second country in the world (after Australia) to introduce such legislation. However, its progress onto the statute book was far from smooth. Tobacco companies fought the measure vigorously, both through the consultation process and in the courts.

This article focuses on the legal challenge brought against the Regulations by the tobacco industry. It had two prongs. In the first, which was ultimately referred to the Court of Justice of the European Union for a preliminary ruling in (C-547/14) Philip Morris Brands SARL and Others v Secretary of State for Health, the companies challenged the legality of a provision of the Tobacco Products Directive that permits individual member states to go beyond the packaging controls contained in the Directive by introducing more rigorous measures, including standardised packaging, at domestic level. The second challenge, R on the application of British American Tobacco Limited v The Secretary of State for Health, more wide-ranging and more direct, was brought by means of an application for judicial review of the legality of the Regulations in the High Court of England & Wales.

In this article, I aim to explain in detail the industry’s objections to the United Kingdom’s standardised packaging legislation in British American Tobacco and to outline the legal system’s response to. This may, at first sight, appear a relatively modest goal. However, the range and scale of the challenges brought to the Regulations makes it a worthwhile one. The range of arguments raised by the tobacco company claimants was exceptionally wide (involving, for example, the law of evidence, domestic and European constitutional law, human rights law, European and international intellectual property rules and the rules of the internal market) and it is hoped that this exploration of the industry’s attempt to derail standardised packaging legislation may prove valuable and instructive well beyond the borders of the United Kingdom.

1 Standardised packaging legislation – the European Union and the United Kingdom framework

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3 SI 2015/829.
4 [2016] 3 WLR 973.
5 Under the Directive, specified text and image health warnings must be carried on the outside packaging of tobacco products. Such warnings must cover 65% of the main surfaces of the unit packet of a tobacco product (see Directive 2014/40 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, Art 10)
6 s 24(2), see below.
7 R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for Health [2016] EWHC 1169 (Admin); [2016] EWCA Civ 1182.
Before looking in more detail at British American Tobacco, it is necessary to outline the relevant legislative framework at European and domestic levels. As a member of the European Union, the United Kingdom has enacted tobacco control measures within a framework deriving from Union law. The Tobacco Products Directive (Directive 2014/40/EU) ("TPD2") is designed to implement the Union's obligations under the Framework Convention on Tobacco Control ("FCTC") and to replace and update a previous Directive in the area ("TPD1"). TPD2 requires the implementation of extensive restrictions on the labelling and packaging of tobacco products. In particular, it increases the percentage of the space on the outer faces of a tobacco pack which must be taken up with health warnings and imposes a series of further prohibitions on different aspects of product presentation and appearance. TPD2 does not oblige member states to introduce a full standardised packaging regime. However, the option to do so at national level is explicitly left open to member states by Art 24(2) of the Directive, which states that:

“This Directive shall not affect the right of a Member State to maintain or introduce further requirements, applicable to all products placed on its market, in relation to the standardisation of the packaging of tobacco products, where it is justified on grounds of public health, taking into account the high level of protection of human health achieved through this Directive. Such measures shall be proportionate and may not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States...”

8 Following a referendum held on 23rd June 2016, the UK Government has commenced the formal process of bringing membership of the EU to an end. At the time of writing, it is not possible to state precisely how this change in Treaty relations will affect the status of EU rules currently forming part of UK law. The Government’s current intention is to “domesticate” secondary legislation implementing Directives wherever possible. If this intention is fulfilled, the vast majority of rules deriving from directives in the area of copyright law will be retained in existing form at the time of formal departure from the Union. See Department for Exiting the European Union, Legislating for the United Kingdom’s Withdrawal from the European Union, Cm 9446, March 2017.


10 2001/37/EC

11 It also places further regulatory controls on the marketing of tobacco products (including e-cigarettes) and introduces a prohibition on the marketing of tobacco products with “characterising flavours” (including menthol cigarettes).

12 An amendment requiring the inclusion of a full, standardised packaging regime within the Directive was proposed, and rejected, during the legislative process, see A Alemanno & A Garde, “Legal opinion on the compatibility of the UK proposals to introduce standardised packaging on tobacco products with the EU Tobacco Products Directive”, provided for Action on Smoking & Health (ASH), 2014, 22-3.

13 “…[P]rovided that those provisions are compatible with the TFEU, with WTO obligations and do not affect the full application of this Directive” (Recital 53).
Some member states, including the United Kingdom, have already taken advantage of the option presented by this provision or have indicated that they will do so in future.\footnote{14}

In (C-547/14), \textit{Philip Morris Brands SARL}, tobacco companies challenged the legality of Art 24(2).\footnote{15} The case originated in judicial review proceedings in the High Court of England & Wales, in which the companies objected to the TPD2 on a variety of grounds (the claim was described as a “kind of general onslaught” by Advocate General Kokott).\footnote{16} A number of issues were referred to the Court of Justice for a preliminary ruling. Amongst the claims, the tobacco companies argued that Art 114 TFEU\footnote{17} did not provide a suitable legislative basis for Art 24(2) because it envisaged the introduction of more stringent controls on tobacco packaging in some member states and could not, accordingly, be regarded as having an internal market objective. The Court held that Art 24(2) was not to be interpreted as permitting the introduction of further requirements in relation to any aspect of the packaging of tobacco products, including those harmonised under the TPD2. Rather, it was to be interpreted as permitting member states to implement the further standardisation of tobacco product packaging in respect of aspects of packaging which were not harmonised under TPD2. TPD2 was held only partially to harmonise the packaging of tobacco products within the Union and, as a result, it did not preclude member states from introducing more stringent controls on the colour and presentation of packaging in areas that had not been harmonised. Interpreted in that way, Art 24(2) was held to be consistent with Art 114. While partial harmonisation measures do not eliminate all obstacles to trade, they eliminate some and, accordingly, assist in the establishment of the internal market.\footnote{18}

The Court’s confirmation of Art 24(2)’s legality effectively gave the green light to member states contemplating the introduction of standardised packaging legislation. These included the United Kingdom, where the Regulations had already been adopted when \textit{Philip Morris} was handed down. The legislative process leading to the Regulations had been protracted. Following an initial consultation in 2012,\footnote{19} a provision was inserted into the Children and Families Act 2014 authorising the Secretary of State for Health to make regulations concerning the retail packaging of tobacco products if he or she considers that such

\begin{footnotesize}
\footnote{14} Both Ireland and France have also instigated standardised packaging rules.
\footnote{15} \textit{Philip Morris} was one of three references to the Court of Justice on the interpretation and legality of the TPD2 to be heard at the same time, although it is the only one that is directly relevant to the issue of standardised packaging. In (C-358/14) \textit{Republic of Poland v Parliament & Council}, Poland sought annulment of the Union-wide prohibition on menthol cigarettes. In (C-477/14) \textit{Pillbox 38 (UK) Ltd} questions were referred in an another application for judicial review concerning the domestic implementation of the Directive’s rules concerning e-cigarettes.
\footnote{16} [2016] 3 WLR 973, Opinion of AG Kokott [2].
\footnote{17} “Article 114(1) TFEU establishes that the Parliament and the Council are to adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.” \textit{Philip Morris} [2016] 3 WLR 973 [57].
\footnote{18} Ibid, [85]-[95].
\footnote{19} Department of Health, \textit{Consultation on Standardised Packaging of Tobacco Products}, 16\textsuperscript{th} April 2012.
\end{footnotesize}
regulations might contribute at any time to reducing the risk of harm to, or promoting, the health or welfare of people under the age of 18. Following the coming into force of this provision, the government sought an independent review of the scientific evidence on the effectiveness of standardised packaging legislation from the paediatrician, Sir Cyril Chantler. His report concluded that, in conjunction with existing tobacco control measures, such legislation was “very likely to lead to a modest but important reduction over time on the uptake and prevalence of smoking and thus have a positive impact on public health”. Following further consultation in 2014, the Regulations were tabled and received Parliamentary approval through the affirmative resolution procedure on 19th March 2015.

The aims of the Regulations, set out in an accompanying memorandum, are; first, to discourage young people from starting to use tobacco products; secondly, to encourage people to give up using tobacco products; thirdly, to reduce the appeal or attractiveness of tobacco products; fourthly, to reduce the misleading elements of packaging and the potential for packaging to detract from the effectiveness of health warnings and, finally, to alter attitudes, beliefs, intentions and behaviour relating to the reduction in use of tobacco products. The Regulations pursue these goals through a series of stringent controls on the packaging of cigarettes and hand-rolling tobacco. External packaging surfaces must be presented in a specified dull brown colour and internal surfaces must either be white or the same dull brown. With the exception of health warnings and other statutorily prescribed information, the only distinguishing text permitted on the packaging of products covered by the legislation is a brand and variant name. The font and maximum size of this text is specified. Restrictive conditions are imposed on the presentation of cigarettes themselves. Further constraints relating to the required materials, shape and type of packaging for tobacco products are designed to eradicate all other opportunities for product differentiation. These packaging requirements apply to retail packaging only (that is, to packaging intended to be presented for sale to consumers). Breach of the Regulations is a criminal offence and no compensation is payable for those adversely affected by the legislation.

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20 Children and Families Act 2014, s 94.
21 Chantler Report, supra, 6.
23 The Regulations came into force on 20th May 2016, the date of the transposition deadline for the TPD2.
24 Department of Health, Explanatory Memorandum to the Standardised Packaging of Tobacco Products Regulations 2015 (“Explanatory Memorandum”) [7.3].
25 Standardised Packaging of Tobacco Products Regulations 2015, Reg 3 (cigarettes); Reg 7 (hand rolling tobacco). See also Schedules 1-4 for further detail of the text and other markings permitted on the packaging of cigarettes and hand-rolling tobacco.
26 Sch 1 (cigarettes); Sch 3 (hand rolling tobacco).
27 Reg 5.
28 Reg 4 (cigarettes); Reg 8 (hand-rolling tobacco); Regs 10-12; Sch 2.
29 See Explanatory Memorandum, 7.10.
30 Reg 15.
The Regulations do not restrict promotion of tobacco products at wholesale level and include provisions designed to preserve the existence of the intellectual property rights in the Industry’s brand signs, despite the serious controls placed on the use of those signs. Thus, for example, it is provided (i) that trade marks and designs relating to tobacco products may still be registered even though they cannot be applied to tobacco products and (ii) a trade mark proprietor’s inability to use a registered trade mark relating to tobacco products as a result of the Regulations will not result in the revocation of that mark.

2  R on the application of British American Tobacco Limited v The Secretary of State for Health

Unsurprisingly, tobacco companies brought a wide-ranging legal challenge to the Regulations. Indeed, Green J, who heard the judicial review of the Regulations in the Queen’s Bench Division of the High Court noted that “no even remotely or marginally arguable stone has been left unturned” by the companies. Ultimately, he upheld the legality of the Regulations against all challenges in a judgment that extended to precisely 1000 paragraphs. On appeal, the Court of Appeal occasionally differed from the judge’s approach to specific aspects of the challenge but, overall, confirmed his conclusions in the clearest of terms.

British American Tobacco was concerned with the legality of a specific measure in a single state. Nevertheless, it can justifiably be suggested to have broader significance. A number of the arguments advanced by the companies in this case seem likely to be rehearsed elsewhere in one form or another in future. This will be the case, for example, for the claims relating to (i) the treatment of the company’s evidence, (ii) the proportionality of standardised packaging legislation, (iii) the alleged interference with the companies’ fundamental right of property, (iv) the relationship between standardised packaging legislation and European Union trade mark law and (v) the legislative competence of member states to introduce standardised packaging legislation, with particular reference to the TRIPS Agreement. The UK courts’ analysis of, and conclusions on, these subjects will be of interest in other jurisdictions in which the industry has challenged tobacco control measures, or seems likely to do so in future. Each of these important categories of claim is examined further below. However, before considering them each in turn, it is first necessary to pause briefly to note a number of further, less fundamental arguments that were also raised in British American Tobacco.

31  Regs 13(1)-(3) (trade marks); 14 (designs).
32  Reg 13(4)-(8).
33  R (on the application of British American Tobacco (UK Limited) v The Secretary of State for Health [2016] EWHC 1169 (Admin); [50].
34  The Court of Appeal was critical of the extreme length of Green J’s judgment, see R (on the application of British American Tobacco (UK Limited) v The Secretary of State for Health [2016] EWCA Civ 1182 [2].
The companies challenged the Regulations on the ground that Art 114 did not provide a suitable foundation for Art 24(2) of the TPD2 and, therefore, that the Regulations were unlawful. However, by the time that Green J handed down his judgment in *British American Tobacco*, the Court of Justice had already decided *Philip Morris* and, as a result, it was clear that this challenge was unsustainable. The argument that the Secretary of State should have awaited the Judgment in *Philip Morris* before proceeding with the Regulations, and that the consultation exercise had been a sham, were also held to be without merit.

In a further claim related to the legislative basis for the Regulations, the companies argued that the Secretary of State had failed to give adequate weight to the fact that a decision to introduce standardised packaging legislation at national level could only be justified where the “high level of protection of human health” already achieved through the TPD2 was taken into account. The companies argued that such legislation could therefore only be introduced if there was clear evidence that it would achieve a higher level of health protection than that achieved by TPD2. In rejecting this reading of the provision, Green J held that the Secretary of State had taken adequate steps to assess the desirability of standardised packaging controls within a legislative exercise that was “precautionary, predictive and related to public health”. The Court of Appeal upheld this conclusion, finding that Art 24(2) did not require a direct comparative exercise based on specific evidence addressing the relative health benefits of TPD2 packaging and standardised packaging.

A parallel claim for judicial review was brought by producers of “tipping paper”, the paper which encases the filter tips of cigarettes, and was joined to the companies’ challenge to the Regulations. The producers argued that the Regulations’ restrictions on the presentation of the paper surrounding cigarettes were *ultra vires*, firstly because they were not permitted under Art 24(2) because they did not relate to “packaging” and, secondly, because they were disproportionate. On the first of these arguments, Green J held (i) that, read purposively, and in the light of the FCTC, tipping paper fell within the definition of “packaging”; (ii) that, in any event, member states were free to introduce extra restrictions on the branding of tobacco products in order to secure the *effet utile* of the packaging restrictions in the Regulations and (iii) even if those arguments were wrong, the TPD2 was a partial harmonisation measure which did not prevent member states from introducing further public health restrictions on the presentation of tobacco products. On proportionality, the producers argued that there was no evidence that the controls on the presentation of the paper surrounding cigarettes would serve a useful public health purpose. However, Green J considered that the Secretary of State had acted proportionately

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35 *R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for Health* [2016] EWHC 1169 (Admin) [266].
36 Ibid [935]-[948].
37 Ibid [919]-[932].
38 Ibid [895].
39 *R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for Health* [2016] EWCA Civ 1182 [261]-[262].
40 Regulations, Reg 5.
41 *R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for Health* [2016] EWHC 1169 (Admin) [949]-[979].
in determining that the altered appearance of the tipping paper would have a beneficial impact.\textsuperscript{42} In a relatively rare instance of substantive disagreement with the judge, the Court of Appeal did not accept that “packaging” could be interpreted as encompassing tipping paper. Nevertheless, it upheld his judgment on the ground that the TPD2 was only a measure of partial harmonisation and that the EU legislature had not intended to prevent member states from standardising the presentation of the paper surrounding cigarettes more generally.\textsuperscript{43} On proportionality, the Court of Appeal agreed with the Judge’s conclusion that there were reasonable grounds for believing that the controls on the presentation of tipping paper would be beneficial to public health.\textsuperscript{44}

3 The challenge to the Secretary of State’s treatment of the tobacco companies’ evidence

In a claim that has wide potential relevance, the companies argued that the Secretary of State had acted unlawfully in according limited weight to the evidence they had presented against standardised packaging legislation during the consultation processes. Green J found that no such error had been made, stating that:

“...measured against internationally accepted research and evidence standards, [the companies’] evidence, as a generality, was materially below par”.\textsuperscript{45}

Accordingly, to the extent that limited weight had been placed on the companies’ evidence, it had been entirely appropriate for the Secretary of State to do so. The judge also held that, even if insufficient weight had been placed on the industry’s evidence, there was no reason to believe that such failure had affected the decision making process leading to Parliament’s approval of the Regulations.\textsuperscript{46} In concluding thus, the judge approved the best practice guidelines on scientific evidence applied by the Secretary of State at the pre-legislative stage. He took into account the FCTC and WHO guidelines on tobacco industry evidence, and critical academic studies of the companies’ submissions to the standardised packaging consultation. He also referred to the judgment in the District Court in the District of Columbia in Tobacco-Free Kids Action Fund v Philip Morris USA Inc, in which the industry’s systematic failure to provide honest evidence had been exposed.\textsuperscript{47}

The judge’s conclusions on the industry’s practices on research and evidence were strongly worded. He noted, for example, that:

“Uniquely in this case there is an international consensus from within the WHO and across the world that tobacco companies are set on subverting national health

\textsuperscript{42} Ibid [980]-[1000].
\textsuperscript{43} R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for Health [2016] EWCA Civ 1182 [280].
\textsuperscript{44} Ibid [288].
\textsuperscript{45} Ibid [404].
\textsuperscript{46} Ibid [376].
\textsuperscript{47} Ibid [276]-[376].
policies antithetical to their financial interests. This is, in part, due to experiences in the US courts and the sharp conflict between public utterances and private analysis. There is in such circumstances a real premium upon full observance with the principles laid down in the [Civil Procedure Rules] (in so far as there is day light) with best and transparent research and publication practices generally. It is in this way that the tobacco companies can persuade a systemically sceptical world that their research is valid and worthy of the great probative weight they claim for it."

There were a number of significant ways in which the companies’ evidence was held to fall below best scientific practice. It was not peer-reviewed, or based on peer-reviewed material, and it was not transparent, in that it was not benchmarked against the the companies’ own internal documents. The evidence, according to the judge, was “virtually devoid of any reference to the internal documents of the tobacco companies themselves”. The evidence presented was often unverifiable and ignored the broader literature on the subjects at issue. At an individual level, the Judge was scathing in his criticism of the evidence of some of the witnesses who appeared on behalf of the companies.

On appeal, the Court of Appeal held that Green J had been entitled to refer to the FCTC and its Guidelines and to the judgment in Tobacco-Free Kids Action Fund, even though the latter, in particular, had not been extensively canvassed by the parties at the hearing at first instance. The Court of Appeal also held that the judge had not applied different standards to the expert evidence relied on by the Secretary of State from those applied to the companies’ experts. Overall, the Court of Appeal held that the judge had not disregarded or marginalised the companies’ evidence by applying a “sui generis rule which singles out the tobacco companies for particular and adverse treatment”. It was clear that he had reviewed all the expert evidence in the case in the light of best scientific methodological practice. Any doubts about his approach could not undermine his overall conclusions on this issue.

4 Proportionality

The tobacco companies argued that the Regulations violate the principle of proportionality because (i) they are not suitable and appropriate to meet the objective of improving public health, (ii) they are not “necessary”, in that other less onerous measures could have been adopted just as effectively, and (iii) they do not strike a fair balance between the public interest and the interests of the companies (“proportionality stricto sensu ”). Proportionality was relevant to a number of the arguments advanced by the companies, including those

48 Ibid [318].
49 Ibid [292].

50 See, for example, ibid [314]-[315].

51 R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for Health [2016] EWCA Civ 1182 [178].
relating to an alleged violation of the right of property and incompatibility with the principle of free movement of goods. It was also raised as a free-standing challenge considered in its own right by both Green J and the Court of Appeal. Their findings on this issue lie close to the core of the dispute. Ultimately, it is absolutely clear that the judge and the Court of Appeal were clearly convinced that the Regulations represented an entirely proportionate response to a serious health problem.

Nevertheless, the framework within which a UK court is obliged to assess the proportionality of measures within the scope of EU law is complex and it was therefore necessary for both Green J and the Court of Appeal to consider the applicable principles in some detail. The Judgment of the Supreme Court in R (Lumsdon) v Legal Studies Board (“Lumsdon”) and that of the Court of Justice in (C-333/14) Scotch Whisky Association v Lord Advocate (“Scotch Whisky”) were particularly significant in this respect. In Scotch Whisky, the Court had emphasised that a member state derogating from the freedom of movement of goods in order to protect human life and health was obliged to provide appropriate evidence of the proportionality of the measures adopted. However, member states were not required to prove that “no other conceivable measure could enable the legitimate objective pursued to be attained under the same conditions”. Any court assessing the proportionality of such a derogation must “examine objectively whether it may reasonably be concluded from the evidence submitted by the member state concerned that the means chosen are appropriate for the attainment of the objectives pursued and whether it is possible to attain those objectives by measures that are less restrictive of the free movement of goods.” In doing so, the court was entitled to take account of scientific uncertainty.

On these foundations, Green J set out a number of principles relevant to the proportionality analysis. He held that the concept of proportionality under the ECHR and the Human Rights Act 1998 was fundamentally the same as that applied in EU law. He also noted that certain factors, such as the “precautionary” nature of a national intervention in an area of scientific uncertainty might provide a “margin of appreciation” for a decision-maker and that the intensity of the court’s review was fact and context sensitive. Drawing on Lumsdon, he pointed to a number of factors which could affect the intensity of judicial review for proportionality. These included:

“(i) the nature and importance of the “private interest” being derogated or departed from...(ii) the importance of the public interest being prayed in aid to justify the departure from the competing private right; (iii) the need in an EU case to prevent unnecessary barriers to free movement and market integration...; (iv) the extent to which the alleged derogation itself furthered a recognised social policy of the EU...; (v) the extent to which the national measure derogated from free movement in an

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52 See discussion below in section 5.
54 [2016] 1 WLR 2283.
55 Ibid [55].
56 Ibid [56].
57 Ibid [57].
area where the EU had not legislated but where it was said that the derogating measure furthered an important consumer protection policy in the Member State...” 58

Having traced these important basic principles, he considered their application in British American Tobacco itself.

On appropriateness and suitability, the companies argued that the Regulations would not improve public health. They suggested that the evidence from Australia, following the introduction of standardised packaging legislation, supported this contention and claimed that the introduction of the Regulations would lead customers to “downtrade” to lower-priced products and, as a result, to increase their use of tobacco. Green J did not accept this argument, holding that the Secretary of State’s evidence established a prima facie basis for demonstrating the suitability and appropriateness of the Regulations. In this respect, his assessment of the relative merits of the evidence presented by the parties (as discussed above) was significant. He noted that, while it was necessary to consider the factual foundation and reasoning underlying the proportionality of the impugned measure at an appropriate level of detail, a decision-maker such as the Secretary of State benefited from a “relatively broad margin of appreciation” in a case such as this. This margin arose as a result of:

“(a) the fact that the Regulations are public health measures where both the precautionary principle applies and where the scientific evidence is predictive and not fully mature or robust; (b) the fact that there exist scheduled reviews at points in time when it can be expected that the evidence will have developed and matured; (c) the fact that the decision maker was Parliament and that the process of promulgation of the Regulations was supervised by the EU Commission; (d) the fact that the adoption of standardised packaging measures is endorsed at the highest level of international consensus; and (e) the fact that this is an area of shared competence between the EU and the Member States in which the Member States must take a high level of protection of health as their starting point.” 59

Great importance was to be attached to legislative activity in the spheres of health and consumer protection. Also militating in favour of a broad margin of appreciation were the facts that (i) this was an area where harmonisation is partial; (ii) the decision to introduce the legislation required a complex evaluation involving political, economic or social choices; (iii) the Regulations were passed by affirmative resolution and (iv) the operation of the Regulations was to be reviewed after a period of 5 years. 60

The judge’s conclusion that the Regulations were appropriate and suitable was challenged on appeal. In particular, the companies challenged the “margin of appreciation” accorded to the Secretary of State. The Court of Appeal doubted the utility of this concept in domestic

58 R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for Health [2016] EWHC 1169 (Admin) [434].
59 Ibid [629].
60 Ibid [438]-[472].
law but concluded nevertheless that any error in the judge’s approach had not been
determinative because, regardless of any margin of appreciation applied, he had
independently concluded, after careful examination, that the companies’ evidence was
adequate to establish the suitability and appropriateness of the Regulations. He had not
adopted an erroneous “manifest inappropriateness” standard. The companies also disputed
Green J’s reference to the precautionary principle, suggesting that it should only apply
where there is uncertainty as to the existence of a risk. The Court of Appeal held (i) that an
assessment of the proportionality of a measure made at first instance should not be
reversed unless vitiated by error of law and (ii) that the precautionary principle could extend
to situations, such as that at issue in these proceedings, in which it is uncertain whether
action against a known public health risk would be effective. In any event, even if the judge
had erred in relying on the precautionary principle, this error had not vitiated his judgment
because he had had other reasons for deciding that the Secretary of State benefited from a
relatively broad margin of appreciation and had, quite independently, reached a prima
facie conclusion that the Secretary of State’s evidence was sufficient to demonstrate the
appropriateness of the Regulations without reference to any margin of appreciation.61

On necessity, the judge held that Parliament acted reasonably in concluding that there was
no equally effective, less restrictive, measure that would have met the aims of the
Regulations. Relying again on Scotch Whisky and Lumsdon, he stated that the Secretary of
State was not required to prove “positively that no other conceivable measure could enable
the legitimate objective pursued to be attained under the same conditions”62 and that,
while all the circumstances bearing on the question of necessity were to be taken into
account, a reviewing court would be “heavily reliant on the submissions of the parties for an
explanation of the factual and policy context.”63 Because it was uncertain whether a margin
of appreciation was available to a decision-maker on this issue after Scotch Whisky, Green J
applied a test of “objective reasonableness”. On this basis, he accepted that Parliament had
acted reasonably in concluding that there was no less onerous, but equally effective,
alternative to the Regulations.64 On appeal, the companies argued that this step of the
proportionality review had been emptied of all substance by the judge. However, while the
Court of Appeal accepted that some aspects of the judge’s reasoning on this issue might be
open to criticism, his application of the “objective reasonableness” test drawn from Scotch
Whisky was correct and, on this basis, he had been entitled to reach the conclusion that the
Regulations were necessary.65

As a matter of legal principle, prior to British American Tobacco, there has also been some
uncertainty as to whether or not the proportionality test under EU law also encompasses a

61 R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for
Health [2016] EWCA Civ 1182 [223]-[230].
62 R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for
Health [2016] EWHC 1169 (Admin) [660].
63 Ibid [665].
64 Ibid [676].
65 R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for
Health [2016] EWCA Civ 1182 [236]-[241].
third component under which a court is obliged to balance the rights and interests of the parties (proportionality *stricto sensu*) in a case such as this. Green J held that it does and that this element of the test was the same as the “fair balance” enquiry conducted by the European Court of Human Rights when it considers situations in which competing rights conflict. In applying this test, he noted that tobacco control was a public interest of the first order and that the competing interest of the companies was “profit”. These two interests were said to “collide in the most irreconcilable of ways” and the balance between them overwhelmingly favoured the state. The companies’ appeal on this point was rejected.

5 The fundamental right of property

The companies also challenged the legality of the Regulations on the ground that they violated their property rights, most notably their trade marks, under Art 1, Protocol 1 of the ECHR, Art 17 of the Charter of Fundamental Rights of the EU and at common law. In essence, they claimed that the restrictions imposed on the use of trade marks relating to tobacco products under the Regulations were tantamount to an expropriation of those marks and, more broadly, of their brands. They argued that such an interference with property rights could only be lawful on payment of compensation. Green J considered Art 1, Protocol 1 of the ECHR first, noting that the companies’ intellectual property rights were undoubtedly “possessions” for the purpose of this provision. Having established that the marks were *covered* by the ECHR’s property guarantee, he went on to determine whether the Regulations were to classified as a “deprivation” of the companies’ marks or as a less restrictive “control” on their use. This distinction is significant because states have greater leeway in relation to the latter than the former. Indeed, generally, in the Strasbourg jurisprudence, there is an assumption that “deprivation” of possessions is only lawful where compensation is paid. Having considered the relevant case-law in detail, the judge concluded that the Regulations were a control on the use of the companies’ marks rather than an expropriation/deprivation. Trade mark law establishes *negative* rights and, while the Regulations severely curtailed the companies’ ability to use their marks, those marks could still be used on communications at a wholesale level (subject to pre-existing controls on tobacco marketing) and enforced against third party infringers. Accordingly, they

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66 *R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for Health* [2016] EWHC 1169 (Admin) [432].
67 Ibid [683].
68 *R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for Health* [2016] EWCA Civ 1182 [244]-[245]

69 The companies also sought to argue that there had been an infringement of their right to conduct a business under Art 16. However, it was held that this “heavily circumscribed” right added nothing to the claim based upon the right of property. *R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for Health* [2016] EWHC 1169 (Admin) [858]-[864].
70 Ibid [731].
retained their core function, that of indicating the origin of goods. As a result, there was no deprivation of property.\(^71\)

Having determined the nature of the interference with the companies’ possessions, Green J considered whether compensation was necessary. He noted that, under the case-law of the Strasbourg Court, a “fair balance” test was applied. This was the same as the balancing test previously considered in relation to proportionality and, therefore, clearly came out in the Secretary of State’s favour. According to the judge, it was important to appreciate the context of the dispute:

“The Claimants seek compensation for the loss of the ability to promote a product that is internationally recognised as pernicious and which leads to a health “epidemic”. It is as such unlike any other case in which the Courts have granted compensation...The Claimants could not identify a case where compensation had been paid for the suppression or control of a private activity that pursued an end or objective recognised as a public vice.”\(^72\)

Even if the Regulations had been defined as a deprivation of property, rather than as a control on use, compensation would not have been payable. Under the Strasbourg case-law, compensation generally had to be paid for deprivations of property unless “exceptional circumstances” prevailed. Green J believed that such circumstances existed here:

“The reason why there is no breach of A1P1 if compensation is not paid is due to (a) the undeniable and all pervasive harm caused by the product; (b) the fact that the trade marks are used causally to further that harm by promoting the product to consumers; and (c) the fact that they thereby impose on the State clear up and remedial costs of a staggering large scale...It is hard to avoid the conclusion that the suppression of rights which promote a health epidemic and impose huge costs on the taxpayer is precisely the sort of circumstance where exceptionality does apply.”\(^73\)

The Court of Appeal upheld his conclusion on this point.\(^74\)

The rights under the EU’s Charter of Fundamental Rights are closely aligned with those under the ECHR. Nevertheless, the companies argued that, even if there was no violation of Art 1, Protocol 1, there could still be a breach of Art 17 of the Charter because Art 17 encompassed an absolute prohibition on interferences with the right of property which fail to respect the “essence” of that right. On this basis, even if the Regulations were held to be proportionate, they would still fall foul of Art 17. The judge held that this interpretation of the requirements of the Charter would lead to absurd outcomes and could not be

\(^{71}\) Ibid [732]-[784].
\(^{72}\) Ibid [794].
\(^{73}\) Ibid [802].

\(^{74}\) R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for Health [2016] EWCA Civ 1182 [91]-[115].
supported by the jurisprudence of the Court of Justice. Nevertheless, because the issue was not completely free from doubt, he considered the companies’ claim on the assumption that Art 17 did, in fact, encompass such an absolute prohibition on the impairment of the “essence” of protected rights. On this basis, he held that the Regulations did not impair the “essence” of the companies’ trade mark rights because those trade mark rights primarily provided a cause of action against infringing third parties. Green J’s strong overall conclusion on this issue is worth quoting at length:

At base this point boils down to the correctness of the [companies’] proposition that the essence or substance of their trade marks allows them to facilitate a health epidemic...and that since they are prevented from using their property rights to do this by the Regulations those measures are unlawful, even if they are otherwise proportionate. In my judgment this is an unsustainable proposition. Nothing in international or EU law could or would tolerate this proposition; it runs counter to almost every sensible notion of how and why fundamental rights are to be defined and it assumes that the tobacco companies’ shareholders have a greater hold on fundamental rights than do (say) the 600 children a day who start smoking in the UK and whose long term health prospects and life expectancy are threatened by the [companies’] product and who can also assert a (fundamental) right to protection of their health. In short and even assuming that nothing can impair the essence of a fundamental right, the very concept of “the essence” is flexible and it responds to and is governed by overriding public interest considerations. In the present case the fact that the Regulations intrude upon trade mark usage is simply a reflection of the fact that the essence of the rights yields to and is defined by superior health interests; the essence of the right is not impaired or disrespected as a result.

The Court of Appeal upheld this conclusion on Art 17, holding that the essence of the companies’ rights was the ability to employ their trade marks as negative rights against third parties and that those rights were retained under the Regulations. Furthermore, the jurisprudence of the Court of Justice clearly demonstrated that the right of property under the Charter is not absolute but can be regulated so far as is necessary in the general interest and is to be viewed in relation to its social function. The various rights protected under the Charter sometimes come into conflict and the resolution of such conflicts inevitably involves an analysis of proportionality. However, this would be impossible if the companies’ claim that the essence of a right could not be interfered with in any circumstances were to be upheld. This consequence underlined the absurdity of the companies’ submission on this point.

It was also argued that, at common law, the property in trade marks could not be interfered with without the clearly expressed will of Parliament and, even then, only if compensation

75 British American Tobacco (UK) Limited) v The Secretary of State for Health [2016] EWHC 1169 (Admin) [825]-[830].
76 Ibid [831]-[843].
77 Ibid [837].
78 R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for Health [2016] EWCA Civ 1182 [116]-[124].
were paid. Green J held that Parliament had not ousted the right of property at common law in adopting the Regulations because there was no clear wording to that effect in the legislation. However, he held that a common law right of property must inevitably contain similar limitations to those included in Art 1, Protocol 1 and Art 17. As a result, the common law right neither prohibited the Regulations nor required the payment of compensation. On appeal, the Court of Appeal upheld this conclusion but employed slightly different reasoning in reaching it, holding that the right of property at common law applied to deprivations of property only and not to controls on the use of property such as that at issue in these proceedings.

6 Incompatibility with European Union intellectual property rights

The companies also argued that the Regulations violated secondary Union legislation on intellectual property rights. In particular, they claimed that the Regulations were inconsistent with the unitary character of Community trade marks under the Community Trade Mark Regulation (“CTMR”). Art 1(2) of the CTMR provides that:

“A Community trade mark shall have a unitary character. It shall have equal effect throughout the Community: it shall not be registered, transferred or surrendered or be the subject of a decision revoking the rights of the proprietor or declaring it invalid, nor shall its use be prohibited, save in respect of the whole Community. This principle shall apply unless otherwise provided in this Regulation.”

On the basis of this provision, the companies argued that member states are not permitted to derogate from the rights granted under the CTMR. However, under the Regulations, the companies were prohibited from using certain marks on tobacco packaging in the United Kingdom and, as a result, they claimed, their CTMs would not have “equal effect throughout the Community”. As a result, the use of the marks was not prohibited under the Regulations “in respect of the whole Community”, as required under Art 1(2) CTMR (set out above). According to the companies, the Regulations were not saved by Art 110(2), which provides that:

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79 British American Tobacco (UK) Limited) v The Secretary of State for Health [2016] EWHC 1169 (Admin) [844]-[857].
80 R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for Health [2016] EWCA Civ 1182 [125]-[129].
81 The companies also advanced a parallel, and equally unsuccessful claim based upon the unitary nature of Community registered designs. See British American Tobacco (UK) Limited) v The Secretary of State for Health [2016] EWHC 1169 (Admin) [880]-[882].
This Regulation shall, unless otherwise provided for, not affect the right to bring proceedings under the civil, administrative or criminal law of a Member State or under provisions of Community law for the purpose of prohibiting the use of a Community trade mark to the extent that the use of a national trade mark may be prohibited under the law of that Member State or under Community law.”

The companies suggested that this provision did not justify the Regulations, which discriminated between national marks and CTMs.

Green J held that the CTMR was to be construed in the light of superior legal obligations. The Court of Justice’s trade mark jurisprudence demonstrated that, when granted, trade marks were implicitly limited. This was apparent from the case-law on competition and also from judgments in which the Court had distinguished between the “existence” and “exercise” of trade mark rights. Thus, insofar as the TFEU and the TPD2 permitted member states to introduce restrictions such as those in the Regulations, there was no breach of the Community Trade Mark Regulation. In any event, the CTMR itself contains a “carve-out” from the unitary nature of Community Trade Marks under Art 110(2) and the Regulations fell within this provision.

Green J did not accept the companies’ argument that the Regulations discriminated between national marks and CTMs and, as a consequence, were not covered by Art 110(2). The alleged discrimination was said to arise as a result of Reg 13(2)(b), which provides that nothing done in accordance with the Regulations “amounts to an enactment or rule of law which prohibits the use of a trade mark for the purposes of section 3(4) of that Act”. Under this provision, the Regulations do not preclude the registration, or maintenance, of tobacco marks despite the wide-ranging prohibitions on their use. The companies emphasised that Reg 13(2)(b) applied only to national trade marks and not to CTMs and, accordingly, discriminated between the two forms of trade mark. However, according to Green J, any difference in treatment between these two categories of mark could objectively be justified by the limits upon the United Kingdom legislature’s law-making powers. In any event, even if Reg 13(2)(b) were unlawful, the appropriate remedial response would be the severance of that provision from the legislation rather than the quashing of the Regulations as a whole. He noted that it was rather strange that the companies were pressing this point because, from their perspective, Reg 13(2)(b) represented “the only silver lining to [the] otherwise dark cloud” of the Regulations.

The Court of Appeal upheld the judge’s conclusions on the CTMR, holding that the Regulations were exactly the type of provision for which Art 110(2) CTMR was devised. Reg 13(2)(b) of the Regulations did not detract from the prohibitory effect of the Regulations. It served only to make explicit what was implicit in any event (that is, the fact that compliance with the Regulations would constitute “proper reasons” for non-use of the mark). The Court

83 British American Tobacco (UK) Limited) v The Secretary of State for Health [2016] EWHC 1169 (Admin) [869].
84 British American Tobacco (UK) Limited) v The Secretary of State for Health [2016] EWHC 1169 (Admin) [870]-[879].
85 Ibid [879].
of Appeal also noted that, if Reg 13 of the Regulations were unlawful, it could be severed from the Regulations. In such circumstances, the remainder of the Regulations would remain intact and the companies’ position would be worsened, rather than improved.\textsuperscript{86}

7 Parliament’s competence to make the Regulations – the common commercial policy and TRIPS

The final argument summarised here is the claim that the Regulations fall outside the competence of the United Kingdom Parliament because measures relating to the commercial aspects of trade marks are within the common commercial policy of the EU under Art 207(1) TFEU, and therefore fall within the exclusive competence of the EU. In advancing this claim, the companies relied on the Judgment of the Court of Justice in (C-414/11) \textit{Daiichi Sankyo Co. Ltd v DEMO Anonimos Viomikhaniki kai Emporiki Etaireia Farmakon (Daiichi)}.\textsuperscript{87} This ground of challenge was rejected by Green J for a number of reasons. He held that the Regulations, in the framework of the TPD2, overwhelmingly relate to the protection of health. They affect international trade and trade marks only indirectly. This tangential impact was insufficient for them to become a matter of common commercial policy. As the power provided by Art 24(2) relates to the internal market and public health, it falls within the domain of shared competence between the EU and member states.\textsuperscript{88} According to the judge, this conclusion was in line with common sense because if:

“...the trade mark tail were allowed to wag the health dog this would prevent the Member States from adopting any health measures which indirectly affected international trade.”\textsuperscript{89}

He did not accept that the Judgment in \textit{Daiichi} altered this position. Only rules relating to intellectual property with a \textit{specific link} to international trade fall within the concept of “commercial aspects of intellectual property” in Article 207(1) TFEU. The simple fact that legislation has an impact on the use of intellectual property rights does not bring it within the ambit of the common commercial property.\textsuperscript{90}

Under \textit{Daiichi}, as long as a national measure is consistent with TRIPS, there is no reason to doubt its legality. In this instance, the Regulations appeared to be compatible with TRIPS.\textsuperscript{91}

\begin{itemize}
\item \textsuperscript{86} \textit{R (on the application of British American Tobacco (UK Limited) v The Secretary of State for Health} [2016] EWCA Civ 1182 [130]-[139].
\item \textsuperscript{87} [2014] Bus LR 1.
\item \textsuperscript{88} \textit{British American Tobacco (UK Limited) v The Secretary of State for Health} [2016] EWHC 1169 (Admin) [908]-[911].
\item \textsuperscript{89} Ibid [909].
\item \textsuperscript{90} Ibid [911]-[914].
\item \textsuperscript{91} The compatibility of Australia’s plain packaging legislation with the TRIPS Agreement has been raised before a WTO dispute resolution panel (see \textit{XXX in this special edition}). A confidential leak of a draft of the panel’s report suggests that it will find the legislation to be compatible with TRIPS when it hands down its final report. See, for example, “Tobacco
There were a number of reasons for this conclusion. TRIPS was concerned with the registration of marks and with the right to exclude others from the use of a mark rather than with a right-holder’s own use of a mark. Furthermore, under Art 7 TRIPS, registration and enforcement of trade marks were subject to a requirement to contribute to public welfare. Art 8 of the Agreement explicitly gave permission to contracting parties to adopt measures necessary to protect public health. The Regulations fell within the ambit of both of these provisions. The interpretation of TRIPS for which the companies argued would also be inconsistent with the principles of the Doha Declaration, which stated that the TRIPS Agreement should not prevent states from taking measures to protect public health. Furthermore, the TRIPS Agreement was to be interpreted consistently with the FCTC. It did not incorporate an “immutable and unyielding principle of non-discrimination as between different categories of goods and services” and was not to be construed as preventing the adoption of prohibitions on product-specific trade marks where those marks cause harm to health. Finally, it was to be noted that Art 17 TRIPS itself permitted limited exceptions to rights within the scope of the Agreement. While the companies argued that this provision permitted only limitations that were narrow in scope, the judge noted that the Regulations preserved the right to register a mark for tobacco products and the right to exercise such a mark to exclude others and, as a result, struck a proportionate balance between the interests of right holders and third parties and, accordingly, fell within Art 17.

On appeal, the companies claimed that the judge had erred in concluding that the Regulations fell within an area of competence shared between the EU and its member states but the Court of Appeal upheld the judge on this point. Art 24(2) TPD2 is a partially harmonising measure and the United Kingdom retains competence to legislate in the area covered by Art 24(2) or, more broadly, in areas falling outside the scope of the TPD2. Daiichi did not help the companies. For the reasons given by the judge, the Regulations did not breach TRIPS. In this regard, the Court of Appeal noted, additionally, that (i) Art 19(2), TRIPS which specifically contemplates non-use of a trade mark as a result of “government requirements” relating to goods, does not only apply where the goods concerned have been banned and (ii) Art 20, TRIPS, which prohibits unjustified encumbrances upon the use of trade marks, encompassed a requirement of proportionality. As has been noted above, both the judge and the Court of Appeal had, in any event, held that the Regulations complied with this requirement.

Conclusion

*British American Tobacco* has doctrinal significance within the United Kingdom. For example, it has further confirmed the existence of significant flexibilities in the assessment

\[92\] Ibid [916].
\[93\] Ibid [915]-[916].
\[94\] *R (on the application of British American Tobacco (UK) Limited) v The Secretary of State for Health* [2016] EWCA Civ 1182 [150]-[168].
\[95\] Ibid [140]-[149].
of the proportionality of legislative measures aimed at the protection of health. However, its real impact may be more wide-ranging. The tobacco industry “threw the kitchen sink” at the Regulations and failed spectacularly on all points. The judgments at first instance and on appeal make it absolutely clear that none of the challenges to the legislation advanced by the industry came anywhere near success. Standardised packaging legislation was clearly understood by the courts as a proportionate attempt to protect the public against a grave health threat. Green J’s judgment was unusually outspoken in his condemnation of the companies’ case and in his tracing of the absurd consequences that would have arisen if their challenges to the Regulations were to have been accepted. His exasperation with the litigation is palpable.

The outcome of British American Tobacco, and the reasoning leading to that outcome, seem likely to embolden other states which are contemplating the introduction of standardised packaging legislation but which have been hesitating in the face of threats that the introduction of such measures would violate the industry’s legal rights and would therefore result in massive compensation payments. Some of the conclusions outlined in this article are particularly significant in this respect. For example, the section of Green J’s judgment in which he analyses the weaknesses of the companies’ approach to evidence is likely to prove interesting reading for tobacco control advocates around the world. The conclusions of the academic research on which he drew to support his criticism of the evidence are also highly informative. Similarly, the long list of reasons advanced by Green J and the Court of Appeal for concluding that standardised packaging legislation is compatible with TRIPS suggests that a more direct challenge on this ground is likely to prove unavailing. Although, of course, on this point, we are soon likely to have the benefit of a more definitive view from a dispute resolution panel.96

Perhaps, however, the most interesting aspect of British American Tobacco was the courts’ determination not to let the “trade mark tail wag the health dog”. In lobbying against the legislation, the industry had placed considerable emphasis upon the status of their brand symbols as “intellectual property”. It had been widely suggested that this categorisation of the trading interests at issue provided an enhanced level of protection for the industry against public interest regulation. Thus, for example, in a submission to the first consultation on the Regulations provided on behalf of the industry, the retired Law Lord, Lord Hoffmann, expressed the view that standardised packaging legislation constituted an expropriation of the companies’ intellectual property.97 In its broader lobbying, the industry often reiterated the claim that such an act of expropriation could only be rendered lawful through the payment of “billions” of pounds in compensation. Both the High Court and the Court of Appeal were completely unmoved by these arguments, suggesting that (if necessary) the tobacco companies’ marks could be treated as one composite “brand” rather than as discrete property entitlements and that intellectual property rights must always be subject to implicit normative limitations in the public interest. These conclusions are important, and will come as a surprise to many intellectual property lawyers. They

96 See n 91 above.

demonstrate an understandable unwillingness on the part of the court to allow the legal protection of trading signs to produce entirely unreasonable outcomes in the sphere of public policy.