Totally Wicked legal challenge to the Tobacco Products Directive e-cigarette measures

written by Clive Bates | 26 September 2015



Where the hubris and ignorance of European Union legislators is brought painfully to account

This page explains the Totally Wicked legal action against the European Union Tobacco Products Directive, Article 20 – the section that deal with e-cigarettes.

Update. The Totally Wicked case was dismissed on 4th May 2016. No appeal is possible.

Final Update: predictably on 4 May 2016, the judgement was announced and Totally Wicked's case rejected in full. See judgement in case C-477/14. No appeal is possible. The basic problem is that the law depends on the science, bad science makes bad law, and the Commission and members states drew on bad science to defend this completely counterproductive law. The court did add any value or interrogate the science. The court has defended the status quo and the cigarette trade and shaped the e-cigarette market for the convenience of the tobacco companies. See Totally Wicked press statement. The court also settled the cases brought by the tobacco companies and Poland in favour of the directive.

The Court's press release is available here and links to each judgment are provided below:

- C-547/14 – Philip Morris Brands and Others – Tobacco Products Directive
- C-477/14 – Pillbox 38 – Electronic cigarettes – Article 20 Tobacco Products Directive
- C-358/14 – Poland v Parliament and Council – Ban on characterising flavours

Update 23 December 2015: Advocate General issues her opinion declaring the directive to be sound. This is to inform the judges who will make the final decision. Her reasoning is based on poor science and I provide a critique here: Totally Wicked case: Advocate General's flawed reasoning would protect the cigarette trade

Update 1st Oct 2015: Totally Wicked's arguments are heard in court, along with objections from UK, France, Spain and the EU institutions – i.e formidable opposition. Totally Wicked provides a guide to the process in the case.

Update 29 Sept 2015: Petition handed to Department of Health with 71,095 signatures. My speech:

Update 26 Sept 2015: read the English High Court's *very positive assessment* of the merits of the case, in its referral to the European Court (especially para 12-44), written by Mr Justice Green.

Update 25 Sept 2015: Totally Wicked Press statement – European Court update – in advance of the hearing, provides an overview of the damage this legislation will do.

Update 10 Sept 2015: Court hearing for Totally Wicked case C-477/14 will be 1st October 2015 and is expected to last one day. PMI/BAT case C-547-14 will be heard on the same day, and the Polish case C-358/14 the day before, 30th Sept.

Background: TPD Article 20 text and related provisions > What's wrong the EU tobacco directive for e-cigarettes > Tobacco Product Directive – what next and what can be done

Update: support the Totally Wicked case here. Over 60,000 supporters at 26 Sept. Petition to be submitted 29 Sept 2016.

In October 2014, a legal challenge by Totally Wicked, an e-cigarette vendor, to Article 20 (electronic cigarettes) of the EU Tobacco Products Directive was referred from the English High Court of Justice – Administrative Court to the Court of Justice of the European Union (CJEU). The English Court cannot overturn EU legislation, so it seeks guidance from the European Court, which rules on the lawfulness of EU legislation under the EU treaties. The EU treaties act like a constitution and place constraints on what the EU institutions can do.

It's a good moment to look at what the case involves – so here is a briefing for the non-lawyer.

Key documents

I have obtained two key documents from the case in which you can read the case in detail (**warning**: quite hard going). This briefing is the easier way into it…

1. Totally Wicked's Statement of Facts and Grounds. This contains the meat of the complaint, and case to have the issues heard at the ECJ (45 pages – 4.5mb scanned PDF).
2. The Secretary of State's Summary Grounds for Contesting the Complaint. This is mostly procedural – it doesn't actually give the government's substantive response, just says that it does contest the complaint.

See legal documentation on Totally Wicked's dedicated site.

Update 26 Sept 2015. The English High Court's referral to the European Court provides a very good summary of the legal argument.

Background

The rule of law. Firstly, no-one should be surprised or scandalised about this case or think of it as somehow sinister 'industry tactics'. The argument that the TPD legislation and the process of making it were unlawful has been pretty compelling from October 2013 onwards: see for example *Flawed Science, Irregular Procedure, Unlawful Measures* and *Making Bad Law: legal vulnerabilities in the tobacco directive*. Any firm or citizen has the right to expect governments and legislators to uphold the 'rule of law' and this applies to

the laws governing law-making in the EU. It means that the EU legislature cannot just do what it likes when it agrees a directive. It has to comply with the European Union's main 'constitutional treaties' and conventions – just as the US Congress cannot make laws that breach the Constitution. In this case, the relevant European treaties are:

- Treaty on European Union (TEU)
- Treaty on the Functioning of the European Union (TFEU)
- Charter of Fundamental Rights of the European Union (CFR)

These establish a number of principles that can be used to test whether specific measures included in a directive are compatible with European treaties. The principles themselves are quite broad and high level, so the court also relies on case law to apply precedents that have been set in previous cases.

Process. The Totally Wicked (TW) case uses a particular route to access the ECJ.

- TW initiated judicial review proceedings against the Secretary of State for Health in England, arguing that it would be unlawful for the government to bring in implementing regulations for the directive (as required under Article 29 TPD), because the provisions of Article 20 are unlawful under the EU treaties. TW knows that this cannot be settled in the High Court in London, so asks for the key issues to be referred to the ECJ under process described in Article 267 TFEU.
- The Department of Health has accepted that there is a case to answer (though please note it *does not accept* that the directive is unlawful). It was common ground between TW and the Government that the questions should be put to the ECJ – and with a view to getting a clear decision as quickly as possible. Some commentators misread that as 'supporting the case' – in reality the government supports the *process of resolving the case quickly*.
- The government has not made the case for the defence in detail at this stage. The detailed defence will be made in front of the ECJ – and probably by the Commission.
- The ECJ will make a 'preliminary ruling' that will decide on the answers to the questions it has received from the High Court. This will determine the lawfulness of the Directive.
- TW are expecting resolution within 12 months and hoping for nine months

(i.e. mid to late 2015). The main provisions of the directive apply from 20 May 2016.
- The ECJ could strike out all of Article 20 or specific provisions within the article.

Grounds for challenge – principles

The TW case rests on challenge using the following principles:

1. Principle of proportionality in conjunction with principle of legal certainty;

2. Principle of equality (non-discrimination)

3. Principle of subsidiarity

4. Right to property and to run a business under the Charter of Fundamental Rights.

More discussion of these principles is available in: Making bad law – legal vulnerabilities in the tobacco directive. Most of the case rests on demonstrating violations of the principle of proportionality – i.e. that the measures don't contribute to meeting or are more burdensome than necessary to meet the policy objective, namely free movement of goods with a high level of health protection. It is important to understand that the directive is justified under the EU treaties as a measure to *develop the internal market.*

Grounds for challenge – specifics

I'll go through the 'grounds' part of the statement of facts and grounds giving a (non-legal) summary by paragraph number. For reference to the directive, see the text of Article 20 2014/40/EU.

1. Principle of proportionality and legal certainty

51-54 explains that proportionality requires that legislation must be suitable for the purpose of achieving its desired objective and must not go beyond what is necessary to achieve it. Recognises that the ECJ allows some discretion in how this is achieved, but does not absolve the legislature of this responsibility.

55-58 argues that meeting this proportionality requirement necessarily requires an impact assessment, and notes that none was done because the text is a compromise forged in the trilogue process and bears no relation to the options considered in the Commission's original impact assessment. To the extent there is any similarity with the options assessed by the Commission, these options were dismissed.

59-61 demonstrates that e-cigarettes are not medicines and that numerous standard consumer protection, health and safety regulations already apply.

62-71 asserts that the legislature was proceeding with an implicit assumption that e-cigarettes pose an equivalent risk to cigarettes and so should be regulated accordingly. The case then draws on several scientific citations from leading figures to show this is wrong by a large margin.

72-75 draws on the exchanges between 15 expert scientists in this field and the European Commission in January 2014 [letter: Scientific Errors in the Tobacco Products Directive and subsequent exchanges and direct challenge to the Commission by a scientist cited: Please Do Not Distort My Words To Justify Your Policy] to pile further scorn on the scientific underpinning of the directive.

76-77 covers Article 20(2) – the notification regime. Argues that the 6 month notification period serves no useful purpose but is a drag on innovation, and that setting standards should suffice instead. Argues that the notification regime calls for a lot of pointless information, especially in relation to 'dose', 'uptake', 'emissions' and 'addictiveness' – as these all vary markedly depending on the user's behaviour and desired nicotine consumption.

78-86 covers Article 20(3) – technical requirements. It starts (**78-82**) by exposing the fallacious reasoning in setting a nicotine strength limit and highlights the confusion between nicotine content, yields and absorption. Argues that a higher limit (=50mg/ml) is necessary and the 20mg/ml will limit the effectiveness of e-cigarettes as an alternative to smoking – this causing a *negative* public health impact.

83-84 go on to deal with the misplaced attempt to control nicotine toxicity risk by requiring small containers – hence more refilling and potentially greater chocking risk to children, making the point there is no equivalent restriction for cigarettes. Again they draw on the very clear letter from scientists to the Commission

showing that this is pointless bureaucratic harassment.

85-86 address the requirement of Article 20(3)(f) for consistent dosing of nicotine arguing that this is pointless burden as users control their dosing, and that the requirement in the directive is so poorly specified that the requirement is unclear. Note also, that no such dosing consistency is required of cigarettes.

87 covers Article 20(4) on warnings, leaflets etc. Points out that the information required on a leaflet is redundant or based on misconceptions and that no equivalent leaflet is required in cigarette packs. [Note: I think there is also a case to challenge the size and design of the tobacco-style warnings required on e-cigarette and e-liquid packs – these seem disproportionate to risk to me].

88-91 covers Article 20(5) on advertising, sponsorship etc. Argues that this is applying the EU tobacco advertising legislation (2003/33/EC) indiscriminately to e-cigarettes – even though the market for e-cigarettes is far less developed and that the prohibitions will also potentially damage internet based businesses – by banning or limiting presence on websites, social media etc. TW is not a big direct advertiser, so it has focussed primarily on impositions on its own business model. [Note: here I am surprised that they did not draw on the argument that tobacco advertising is banned because of the harm smoking does: recital 3 of the tobacco advertising directive 2003/33/EC asserts that the directive is: *intended to protect public health by regulating the promotion of tobacco, an addictive product responsible for over half a million deaths in the Community annually, thereby avoiding a situation where young people begin smoking at an early age as a result of promotion and become addicted*.]

92-94 covers Article 20(6) which extends Article 18 on cross border distance sales of tobacco products to e-cigarettes. The EU legislature provided no justification for allowing member states to ban cross border sales (recalling that this is a single market directive designed to promote free movement of goods) and further maintains there is no evidence to justify it anyway – specifically that this allows young people to access these products with greater ease, noting that e-cigarettes are hardly used by young people, and to the extent they are it is mostly be existing smokers. TW recommends an alternative 'proof of age' system at the point of sale backed by law prohibiting sales to under-18s.

95-96 covers Article 20(7) on submission of sales and other commercial data. No

equivalent obligations are imposed on cigarette makers and the requirements are too vaguely specified to be meaningful and may clash with data protection legislation. Argues that overall market surveillance is best conducted by the regulator or other public body – as in other fields.

2. Principle of equality or non-discrimination

97-100 states that in some circumstances the directive is *more* burdensome than for tobacco (97-8), but also states that given the large difference in public health impact they should not be treated as comparable (99) and gives six examples of where the TPD imposes burdens not faced by tobacco vendors (100).

101. Draws this together as a distortion of competition and violation of the free trade principles.

Note: I think there would be a strong case even if the restrictions were identical to tobacco – and they ought to lean more heavily on their statement at para 99 – tobacco and e-cigarettes simply are not comparable. The best exposition of the equality principle is Case 304/01 Sept 2004 Spain v European Commission para 31

> *… the principle of equal treatment or non-discrimination requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified.*

3. Principle of subsidiarity

102-103 the case for harmonisation through single market legislation is weak and not adequately justified, and that the only justification made related to the different treatment of e-cigarettes as medicines – which is not relevant under the finalised TPD.

[Note: I don't think this is a particularly strong rationale in practice, even if it works in law – in many ways the directive allows *too much* member state discretion – e.g. on banning flavours, distance selling, and arbitrary classification of e-cigarettes as medicines etc – they are right however that no adequate justification has been made under subsidiarity principle for the EU assuming the

competence to impose these harmonising measures]

4. Charter of Fundamental Rights

104-108 deal with the directive's impact on rights to property and to run a business guaranteed under Article 17 and 16 of the CFR respectively. These paragraphs show how the restrictions criticised as disproportionate above affect the proper exploitation of the claimant's commercial property. This section is probably 'belt and braces' showing another basis on which the TPD infringes established principles of the European Union.

Questions referred to the ECJ

> *1. Is Article 20 of [the Tobacco Products Directive 2014/40/EU] invalid, either in whole or in a relevant part, for one or more of the following reasons:*
>
> > *1.1. It imposes either as a whole or in relevant parts a series of obligations on electronic cigarette manufacturers and/or retailers which infringe the principle of proportionality?*
> >
> > *1.2. For equivalent or similar reasons, it fails to comply with the principle of equality?*
> >
> > *1.3. It distorts competition in the relevant markets for electronic cigarettes and traditional tobacco cigarettes?*
> >
> > *1.4. It fails to comply with the principle of legal certainty?*
> >
> > *1.5. It fails to comply with the principle of subsidiarity?*
> >
> > *1.6. It infringes the rights of electronic cigarette manufacturers or retailers under Articles 16 and/or 17 of the Charter of Fundamental Rights?*

Will it work?

Will they win? I think this case is very strong. But we cannot rule out a court taking a political stance on this or somehow considering these products as variants on NRT – and we haven't seen the defence yet. But on its merits this

case should succeed – removing most or all of Article 20. The EU does require genuine public interest justification for overriding the principle of free movement of goods, and does not allow gratuitous distortions of competition without justification – and TW make that case convincingly.

Is there a nightmare scenario? What if they win and strike out Article 20? Would the EU and/or UK simply revert to requiring everything to be regulated as medicines? I really doubt it – the support for that has dwindled as more people have begun to recognise how that would play out in the market, and the highly burdensome, expensive and time consuming process that MHRA has imposed on the one company that has achieved an authorisation. It would immediately be challenged as unlawful – most people have started to understand that e-cigarettes are not medicines in law or common sense.

What should happen if they win? When the European Parliament dumped the proposal to regulate these products as medicines as medicines on 8 October 2014, they should have taken e-cigarettes out of the directive and started again with a new legislative proposal, based on sound science, options appraisal, a decent impact assessment and consultation. If Article 20 is struck down, they should start that again and, given the strength of the case, start working on it now. Alternatively they could leave it to member states for a few more years and return to the issue if and when there is a case for it. At the same time the industry should get its act together and be clear what standards it want to be held to – that work is advancing well. I was particularly pleased with the outcome of the Commission on Advertising Practice which defined the sensible new UK rules on e-cigarette advertising, which could replace the obviously disproportionate near-total ban conceived in the EU.

Legal arguments not deployed so far

The TW case rests primarily on complaining about unlawful measures included in the final text of the directive. However, there are also numerous process requirements coded into the treaties. Violation of these would in themselves by sufficient to challenge Article 20, because of the way it was made in a closed process of European Parliament amendment followed by Trilogue negotiation between Parliament, Council and Commission. These arguments are as follows:

1. The requirement to consult. No consultation was conducted on the actual proposals agreed or anything remotely close to them. Article 11.3 of the Treaty on European Union*: 11.3. The European Commission shall carry out broad consultations with parties concerned in order to ensure that the Union's actions are coherent and transparent.* Article 2 of the Protocol on the Application of the Principle of Sustainability and Proportionality *2. Before proposing legislative acts, the Commission shall consult widely. Such consultations shall, where appropriate, take into account the regional and local dimension of the action envisaged. In cases of exceptional urgency, the Commission shall not conduct such consultations. It shall give reasons for its decision in its proposal.*

2. Requirement to give reasons. The recitals to the Directive make false assertions and do not provide adequate justification for the measures in the directive. Article 296 Treaty on the Functioning of the European Union, establishes the requirement to state reasons: *Legal acts shall state the reasons on which they are based and shall refer to any proposals, initiatives, recommendations, requests or opinions required by the Treaties.* The reasons given should be evidence based and properly justified.

3. Requirement to produce an impact assessment. There is no impact assessment for these proposals – even though they will regulate a multibillion euro industry, thousands of businesses and the choices available to millions of consumers. Article 5 of the Protocol on the Application of the Principle of Sustainability and Proportionality: *Any draft legislative act should contain a detailed statement making it possible to appraise compliance with the principles of subsidiarity and proportionality. … This statement should contain some assessment of the proposal's financial impact and, in the case of a directive, of its implications for the rules to be put in place by Member States, including, where necessary, the regional legislation. The reasons for concluding that a Union objective can be better achieved at Union level shall be substantiated by qualitative and, wherever possible, quantitative indicators.* Article 5.4 of the Treaty on European Union: *4. Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.*

4. Requirement for national parliament scrutiny. The proposals were defined and finalised without adequate time for scrutiny in member states. Article 4 of the Protocol on the Application of the Principle of Sustainability and

Proportionality: *The Commission shall forward its draft legislative acts and its amended drafts to national Parliaments at the same time as to the Union legislator. The European Parliament shall forward its draft legislative acts and its amended drafts to national Parliaments. The Council shall forward draft legislative acts originating from a group of Member States, the Court of Justice, the European Central Bank or the European Investment Bank and amended drafts to national Parliaments*. (emphasis added).

5. Proper legal procedure for a new legislative proposal. There is credible argument that Article 20 is in itself a *new legislative proposal*, and should go through the full ordinary legislative procedure, under Article 294 TFEU. In effect the Parliament and Council created a brand new legislative proposal through amendment and trilogue in October-December 2013. The Commission proposal had 272 words, compared to 1900 in the final text of Article 20 (plus greatly expanded recitals and text of other articles that Article 20 applies to e-cigarettes) – and final text is completely different to the Commission proposal. It is a brand new legislative proposal constructed and passed through Trilogue, side-stepping the full process and disciplines of Ordinary Legislative Procedure. Trilogue is really there to close narrow differences, not to completely change the underlying principles or be a vehicle for smuggling new legislative proposals through the legislature.

These process arguments show why such poor legislation came to be made – they lend weight to TW's contention that the measures are disproportionate, and exactly what you might expect when policy is made on the hoof in a negotiation.

Challenges to the directive

- Totally Wicked case – C-477/14
- Government of Poland – Case C-358/14 – is challenging the menthol ban. Poland has a high use of menthol.
- Phillip Morris International – is challenging several aspects of the directive, and is supported by Japan Tobacco and Imperial Tobacco. The PMI statement of facts and grounds alleges that the directive is invalid because the EU Legislature has acted without a valid legal basis, that parts of the Directive are disproportionate, that it delegates too much power to the European Commission and that it infringes the principle of

subsidiarity (encroaches on powers of member state parliaments. BAT is challenging several aspects of the directive, using similar legal arguments to PMI… see article here. The BAT/PMI cases have been joined: case 547/14. See commentary here.

Video discussion of the Totally Wicked case

In which I interview the Totally Wicked boss, Fraser Cropper, and TW's lawyer.