Totally Wicked case: Advocate General's flawed reasoning would protect the cigarette trade

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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. My full account of the case and its history is here. End of update.

On 23rd December, the *Totally Wicked case* against the EU tobacco products directive treatment of e-cigarettes suffered a setback at the European Court. The Advocate General, Dr Julianne Kokott issued her opinion on the case – this was hostile to the case and deeply disappointing. It confirmed my fear that good legal judgements could only be made with a sound grasp of the science, ethical issues and commerce of the products facing disproportionate regulation. I think that was lacking in Dr Kokott's opinion. I don't think a line-by-line critique is worthwhile, but I do want to draw out what I consider are major flaws in her

reasoning. This post covers:

- The AG did not base her reasoning on what is known and exaggerated what is uncertain
- Is the directive proportional and non-discriminatory?
- Treatment of e-cigarettes is disproportionate and much worse than cigarettes
- The AG misapplies the precautionary principle
- The AG waves aside the absence of consultation and impact assessment

The AG did not base her reasoning on what is known and exaggerated what is uncertain

First, it is necessary to be clear what science does and does not tell us. The AG tends to assume little is known, and that every theory that would create a basis for health concern is equally plausible. She pays little attention to the large body of science that suggests that there are significant harm reduction health benefits, arising from smokers switching or quitting smoking.

There are three key scientific arguments that should underpin the law – though great scope for deeper insight and more nuanced positioning.

1. The risk of vaping is a lot lower than smoking – likely to be at least 95% lower
2. Early studies have shown that vaping is a workable alternative to smoking for many users
3. There is a not a single scrap of evidence anywhere to suggest that the emergence of these products is causing adverse population effects – such as gateway effects, renormalising smoking or reducing the likelihood of people quitting

I am not going to repeat the evidence base for this (again) – the Court should have the resources to establish this. I'll simply to refer to the Public Health England Evidence Review:

- E-cigarettes around 95% less harmful than tobacco estimates landmark review
- E-cigarettes: an evidence update

This is a government body and has no reason to mislead the court about the science. It was published in August 2015, in plenty of time for the AG to incorporate into her 23 December 2015 opinion.

Is the directive proportional and non-discriminatory?

A major principle of EU law and a significant component of the case are the principles of proportionality and non-discrimination. Are the measures proportional to the risk and designed to meet the objectives in the least expensive and least disruptive manner possible? Are the measures non-discriminatory: do they place excessive burdens on one product class to the advantage of a competitor? (Note: I've written more about these principles here)

The AG's opinion gets in a terrible mess about discrimination – in several places arguing that the measures are no more restrictive than on tobacco. That's a fail: the guiding principle on discrimination is set out in 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.*

The point is that the e-cigarettes and cigarettes are very '*different situations*' in the most important respect for European law – the harm to human health. This is critical given that any restriction placed on the unfettered free movement of these goods must be justified with respect to achieving a high level of health protection. So simply applying the same provisions to e-cigarettes and cigarettes can easily be discriminatory given that the former are likely to be at least 95% lower risk and likely to have net health *benefits*.

Treatment of e-cigarettes is disproportionate and much worse than cigarettes

There are several areas where the directive is more onerous for e-cigarettes than for conventional cigarettes, especially when differences in the real-world business

models and health risks are taken into account. Without being exhaustive, I suggest the court considers the following 11 issues:

1. Notification regime. The detailed notification requirements *per unique product* are actually more demanding for e-cigarettes than for conventional cigarettes – you can see this in a comparison of the detailed implementing acts, not just directive text:

- E-cigarettes / liquids
- Tobacco products

But the *per product burden* is a small part of the full story. The vapour/e-cigarette business model involves massive diversity (multiple strength, flavour, diluent variations)… whereas cigarettes come in a few mass market brands and variants. So a company some companies will have to make over 1,000 notifications for their product range and one estimate has 25,000 notifications for the UK alone – then multiple repeat notifications for member states if there is international trading (the purpose of the directive being to encourage this). The cost of notification for cigarettes is easily carried by a few mass market brands sold by large companies, but it will be excessive for the long tail of niche and low turnover e-cigarette products. For these products and the companies that make them, it is massively more burdensome.

2. Delay in accessing the market. There is a six-month delay between notification and placing an e-cigarette product on the market. No delay for a new cigarette product. Again, this hurts the new vapour product disproportionately because there is a much greater pace of innovation in e-cigarette than cigarettes – perhaps a 12-month product cycle. It will also hurt law-abiding EU suppliers as people will shop outside the EU for new products.

3. Flavours. Whilst it is correct that flavours are to be banned in tobacco products, they are not and never have been especially important for cigarettes (only 4% in the EU, and mostly in Poland which is challenging the menthol ban as arbitrary and disproportionate). But for e-cigarettes flavours are *central* to the product value proposition. The power to ban flavours in e-cigarettes is allowed in the directive and given that almost all products sold are flavoured amounts to a power to wipe the product out. It will also create a patchwork of bespoke regulation and different standards.

4. Internet sales. The same article of the directive (Article 18 – cross-border and distance sales) allows the option to ban both cigarette and e-cigarette distance sales (i.e. over the internet). Several member states are adopting (not the UK) this option for e-cigarettes. The issue is not that the wording is harder on e-cigarettes, it is the same. It is that internet sales are integral to the vaping business model but incidental in the cigarette trade. Two factors drive the importance of the internet to e-cigarettes: (1) very high product diversity, which makes it costly for any bricks and mortar shop to hold the necessary inventory, and (2) the relatively low density of consumers – meaning an internet seller can reach a much larger total population of users. Removing internet sales is thus highly damaging for e-cigarettes relative to cigarettes. It will also favour firms with established bricks and mortar distribution presence. Yes! Another win for the tobacco industry.

5. Advertising ban. The EU-imposed advertising bans are more or less the same for tobacco and e-cigarettes (see 2003/33/EC and Article 20.5). However, the difference is that tobacco companies have decades of brand incumbency, familiar products, and minimal innovation to communicate. The e-cig ad-ban works in favour of the tobacco companies in at least three ways: it reduces the visibility of alternatives to smoking; it favours businesses with existing channels (i.e. the cigarette trade); it favours established incumbents. So while the measure may be the same on paper, the impact is far greater on the entrant novel technology. In relation to risk, these advertising bans are not equally proportionate. The tobacco ad ban was justified by reference to "*an addictive product responsible for over half a million deaths in the Community annually*" [2003/33/EC recital 3]. No such equivalence exists, or ever will, for e-cigarettes. In fact, it may well be that e-cigarette advertising has a *negative death toll* if, as seems likely, it decreases smoking by promoting switching to a safer product. The justification at recital 43 for the advertising ban is wholly inadequate and unsupported

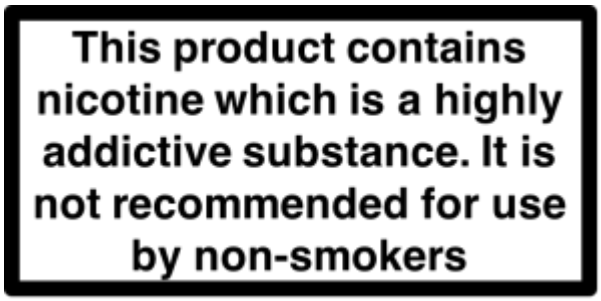
6. Consistent dose. There is a requirement for 'consistent dose' of nicotine for e-cigarette – with very poorly specified and ambiguous meaning – is it consistent through the life of the battery? Consistent for all users regardless of their nicotine demand? Consistent between batches and devices within a batch? The nicotine yield measurement required of cigarettes is based on a long-established (and pointless) protocol that does not require a consistent dose.

7. Leaflet. There is a requirement for what amounts to a 'patient information leaflet' for e-cigarettes and liquids, detailing the following:

(i) instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers;
(ii) contra-indications;
(iii) warnings for specific risk groups;
(iv) possible adverse effects;
(v) addictiveness and toxicity; and
(vi) contact details of the manufacturer or importer and a legal or natural contact person within the Union;

No equivalent exists for cigarettes. This is just grabbed from medicine regulation and thrown into the directive for good measure. To argue that this is unnecessary for cigarettes is wrong – why not provide consumers with detailed information covering, *at least*, points iii, iv and v above?

8. Warnings. While the warnings and graphics on cigarette packs are basically a fair-ish representation of risks, the warnings on e-cigarette are wrong and disproportionate to risk – in both prominence and wording. Nicotine is 'not highly addictive' – it depends on how it is administered. The warning has to be placed on devices that contain no nicotine or liquid. The size (30% of the packaging) and same visual semantics as the warnings on cigarette packs convey far greater risk than there actually is. So this style of warning discriminates against e-cigarette by degrading the consumer awareness of the most important difference, and selling



point, between e-cigarettes and cigarettes.
And the warning is large and bold like the current generation of cigarette warnings. At the same time as reducing the size of e-liquid container that can be sold to tiny 10ml containers, the EU imposes multiple warnings and other textual requirements related to CLP, ingredient disclosure etc – that will overwhelm the packaging real estate. An example (h/t Dick Puddlecote) is given below:

9. Comparing health impacts e-cigarettes and cigarettes. Cigarette producers are prevented from making relative health claims (shall not include any elements that "*suggests that a particular tobacco product is less harmful than others or aims to reduce the effect of some harmful components of smoke*") and other statements (Article 13) but that is justifiable because these claims are highly unreliable and likely to be misunderstood in the case of cigarettes. Article 13 is also applied to e-cigarettes, and it means the companies are prevented from saying things that Public Health England says about their products. For cigarettes, it is a reasonable ban on claims that are or likely to be misleading. For e-cigarettes, it is a ban on conveying the most important factual health-relevant consumer information about the product. The wording might be the same, the effect is radically worse for e-cigarettes.

10. Technical limitations. The directive places arbitrary design limitations on e-liquids, tanks and refill containers (Article 20.3) for which no credible health rationale exists and that were explicitly criticised by scientists who wrote to the Commission: Scientific Errors in the Tobacco Products Directive – A letter sent by scientists to the European Union. Placing limits on nicotine strength in e-liquids is not equivalent to controlling the nicotine yield of cigarettes, but to controlling the nicotine concentration in the tobacco – something that is not required in the directive. The limits on container size simply place impediments on the convenience of e-cigarette consumers for no commensurate reduction in risk. These measures have the effect of degrading the commercial value proposition of e-cigarettes relative to smoking, but for no reason at all.

11. Single market harmonisation. The directive provides a single regulatory framework for cigarettes than is easy to comply with and broadly similar in each country, with national variations in packaging that exist inevitably because of language differences. For e-cigarettes, the range of different measure in each country is likely to be far greater – including differences in ingredient requirements, testing procedures, flavours, internet sales etc. As a harmonising

directive, the TPD is far worse for e-cigarettes because of what it doesn't harmonise. Further, the Commission has advised that a completely separate regulatory regime – medicines – can be imposed (not just offered as an option).

The key to understanding regulation is its impact on the businesses and consumers affected by it – not just the wording – and its proportionality in meeting whatever objectives are set. The problem is that no impact assessment, consultation or options appraisal was ever done on the e-cigarette measures written into the directive in a secret process conducted by amateurs. Whilst I understand the instinct to be optimistic about the TPD (and I hope it turns out less burdensome in reality than it actually looks), there is the taking excessively sanguine view of very badly designed and disproportionate regulation that will be applied to many SMEs. The fact that the tobacco industry can cope with both the cigarette regs and the e-cigarette regs is of little comfort commercially or legally.

The AG misapplies the precautionary principle

Perhaps the most egregious weakness of the AG's opinion was its naive treatment of the precautionary principle. Much of the AG's justification for the directive's measures does not rest on evidence that they are effective, proportionate and non-discriminatory, but that because the risks are unknown the precautionary principle can be invoked to justify restrictive measures. As the AG puts it (see opinion 60-67)…

> *The Union legislature was required to take account of the precautionary principle when it adopted the Directive. (47) Precisely where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists if the risk materialises, the precautionary principle justifies the adoption of restrictive measures, provided those measures are non-discriminatory and objective. (48)*

The AG has missed the most important nuance in the precautionary principle: precaution is applied *symmetrically – considering risks arising from intervention as well as non-intervention*. The 'restrictive measures' the AG refers to here may well be the cause of harm to human health through the creation of foreseeable

but unintended consequences. These consequences arise from a regulatory over-reaction to risks, meaning that fewer people migrate to the safer products and, therefore, harms arise mainly in the form of more smoking, disease and premature death than would otherwise arise. This has been seen most obviously with the 'precautionary' EU ban on snus outside Sweden, a product which is responsible for record low smoking prevalence (11% in Sweden compared to the 26% EU average) and resulting good health outcomes (see Ramström & Wikmans, 2014) where it is permitted in Europe.

This thinking is codified into the formal EU approach to the PP. To the extent that the EU embraces the precautionary principle [COM(2000)001 – The Precautionary Principle], then it defines six principles that should be applied:

> - *proportional to the chosen level of protection,*
> - *non-discriminatory in their application,*
> - *consistent with similar measures already taken,*
> - ***based on an examination of the potential benefits and costs of action or lack of action** (including, where appropriate and feasible, an economic cost/benefit analysis),*
> - *subject to review, in the light of new scientific data, and*
> - *capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.*

As well as requiring proportionate and non-discriminatory measures as discussed above, this rightly requires a *symmetric* approach to costs and benefits of intervention or non-intervention (highlighted). So restrictive measures that may have the effect of deterring switching from smoking to vaping (beyond doubt a positive thing to do for health) cannot be justified using the precautionary principle without weighing the *risks arising from intervention* – something the AG simply has not done. The Commission policy page on the precautionary principle adds further requirements for application of this principle:

- the fullest possible scientific evaluation, the determination, as far as possible, of the degree of scientific uncertainty;
- a risk evaluation and an evaluation of the potential consequences of inaction;
- the participation of all interested parties in the study of precautionary measures, once the results of the scientific evaluation and/or the risk evaluation are available

None of these conditions has been met.

Where is the scientific evaluation, assessment of uncertainty and risk evaluation of inaction? Note that 'inaction' does not mean 'unregulated' in this context. It means that the numerous consumer protection directives that already apply continue to apply – the situation as it stands at present would continue. There is no sign of anything going wrong in the situation at present despite millions of users: smoking rates are falling among adults and children; there are many accounts of happy vapers; and very few complaints. Where is the dossier of credible evidence to show *any material problem* in the market as it exists at present? We don't have complete uncertainty – we have widespread of these products in Europe, regulated as consumer products and not showing any problems that require restrictive action.

The AG waves aside the absence of consultation and impact assessment

Article 20 of the directive was made in a vacuum (the secretive trilogue process) and the measures proposed have never been subject to any impact assessment or consultation. The AG waves this aside (68-72):

> *69. It is true that in its proposal for a directive the Commission had used a different, stricter regulatory model for e-cigarettes. It had supported the idea of treating e-cigarettes essentially as medicinal products. (50)*
>
> *70. However, this does not mean that the less strict rules on e-cigarettes which were ultimately adopted at the end of the legislative procedure and which can now be found in Article 20 of the Directive were created in a 'vacuum', as it were, and were enacted without any impact assessment.*
>
> *71. On the contrary, the evidence on which the Commission relied in its impact assessment (51)– even though it was not binding on the Union legislature (52) — was a useful basis for the less strict provisions laid down in Article 20 of the Directive. (53) Aside from this, it is recognised that the Parliament and the Council may have recourse to additional sources of information in the legislative procedure. (54) It is not disputed in the present case that during the course of the legislative procedure the competent institutions obtained further information on the issue of e-cigarettes and, in particular, that the Commission*

> *conducted further consultations on the subject with interest groups and the Parliament held its own hearings. (55)*

Please note how bizarre this reasoning is. It argues that because there was consultation and an impact assessment on a set of different measures, then the responsibility has been met. The measures adopted are not envisaged or considered *at all* in the 2012 impact assessment. These were the policy proposals for 'nicotine-containing products' (see page 52 of the IA for more detail):

- *Option 0: No change*
- *Option 1: Subject NCP to labelling and ingredients requirement under TPD*
- *Option 2: Establish a new authorisation scheme for NCP*
- *Option 3: Subject NCP over a certain nicotine threshold to the medicinal products' legislation and the remaining NCP to labelling requirements*
- *Option 4: Subject all NCP to the medicinal products' legislation*
- *Discarded option: Development of minimum safety standards for NCP under the General Product Safety Directive*

You can find almost none of the most damaging measure in Article 20 (advertising ban, internet sales ban, strength limit etc) in this options appraisal and absolutely none of the specifics.

Perhaps noticing this inconvenient truth, the AG waves it aside:

> *72. If the law-making EU institutions were limited to adopting only provisions which were specifically the subject of an impact assessment by the Commission, the freedom enjoyed by the Parliament and the Council would be restricted appreciably and the legislative procedure would be rendered largely meaningless.*

That statement is reasonable when the differences between measures assessed in the impact assessment were similar but not identical to those agreed in the final text. It is not reasonable when they are *completely different*. So this can only be argued as a matter of degree – an argument the AG has not made.

In fact, most of the ordinary legislative procedure, Council Working Group and committee work of the European Parliament proceeded with the assumption that Option 3 (the Commission proposal) would proceed. That was rejected by the Parliament as an excessive and ill-fitting regulatory framework on 8 October 2013 and completely new measures designed in the trilogue process from (Oct-Dec 2013) with no consultation or impact assessment. The fact that there was a (wholly inadequate) impact assessment for medicine regulation is of no comfort or value if this was rejected as excessive by the European Parliament.

If the AG's reasoning was accepted, then any proposal could be justified without impact assessment simply by choosing an extremely restrictive policy and doing an impact assessment on that.

The Advocate General's opinion is not binding on the court and the justices can take a different view. I hope they do a better job at bringing the science, risk politics and commerce of harm reduction into the legal reasoning.