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Law, market building and public health in the European Union

Chris Holden and Ben Hawkins

Abstract

European Union (EU) law is based upon a liberalising imperative, the goal of which is to construct a single market between member states. Yet the EU is no ordinary trade pact, incorporating as it does a range of supranational political institutions and common policies in a range of areas beyond simple market building. Scholars have nevertheless noted a distinction between ‘positive’ integration (the formulation of common policies applying to all member states) and ‘negative’ integration (the removal of national-level regulations acting as barriers to market integration). In the context of debates about the implications of trade law and corporate activity for health, this article poses three related questions. First, to what extent does EU law afford corporations opportunities to challenge national-level health regulations? Second, to what extent do EU legal and political processes provide opportunities for positive pro-health supranational regulation, including that which might offset the effects of negative liberalising integration? Third, how do EU market-building processes differ from those of more narrowly-drawn trade agreements and organisations in their implications for health? We analyse and compare two recent sets of health-related legal proceedings under EU law, the first of which challenges legislation passed by the Scottish Government to introduce minimum unit pricing for alcohol, and the second of which addresses the legality of specific aspects of the EU’s 2014 Tobacco Products Directive. We find, first, that EU law offers ample opportunities for corporations to challenge national health regulations; second, that there is significant scope for pro-health supranational regulations, but that these must be couched in the language of facilitating the single market, and are dependent on the political commitment of key policy actors; and, third, that this (limited) scope for pro-health supranational regulation distinguishes EU legal and political processes from those of other trade agreements and organisations.

Keywords

Trade; health; European Court of Justice; Court of Justice of the European Union; constitutionalisation; judicialisation; liberalisation; negative/positive integration.

Introduction

The literature on trade and health has analysed the policy implications of a wide array of trade agreements and entities, including those of the World Trade Organisation (WTO) and a number of plurilateral, regional and bilateral agreements (Friel et al., 2015). It has further analysed the opportunities that trade law affords transnational corporations (TNCs) to challenge national-level health regulations (Jarman, 2015). Many of the concerns raised about trade agreements, for example their implications for food hygiene standards, mirror debates which accompanied the construction of the European Union (EU) single-market. Yet the EU is different to more narrowly-drawn trade entities in the extent of its political and legal development, which allows for some degree of supranational (re)regulation as part of the EU's market-building project. The EU's implications for health, while sharing some similarities, are therefore different to those purely trade-focussed agreements and organisations, such as the WTO, for which social concerns are peripheral. As elaborated below, the EU allows for both 'negative' and 'positive' integration. While the EU thus offers opportunities for corporations to use single-market law to attempt to remove national-level health regulations which can be portrayed as barriers to internal trade, it also potentially permits, under certain conditions, the creation of pro-health EU-level regulation. Central to such considerations is the role of the European Court of Justice (ECJ)¹ in ruling on whether regulations at both the national and EU levels are compatible with EU law and the founding treaties on which the EU's legal order is based.

In the context of debates about the implications of trade law for health, this article poses three related questions. First, to what extent does EU law afford corporations opportunities to challenge national-level health regulations? Second, to what extent do EU legal and political processes provide opportunities for pro-health supranational regulation, including that which might offset the effects of negative liberalising integration? Third, how do EU market-building processes differ from those of more narrowly drawn trade agreements and organisations in their implications for health? We attempt to answer these questions by analysing and comparing two recent sets of health-related legal proceedings brought under EU law. The first of these challenges legislation passed by the

¹ The European Court of Justice (ECJ) was renamed the Court of Justice of the European Union (CJEU) with the entry into force of the Lisbon Treaty in 2009. We refer here to 'the ECJ' when specifically discussing its actions prior to the Lisbon Treaty and to 'the CJEU' when discussing its actions subsequent to that treaty. Otherwise we refer to 'the European Court' or simply to 'the Court' when discussing the entity in general.

Scottish Government to introduce minimum unit pricing for alcohol; the second addresses the legality of specific aspects of the EU's 2014 Tobacco Products Directive. First, in order to elaborate some of the key similarities and differences between EU processes and those of narrower trade agreements, we discuss the development of EU law in relation to the single market and the protection of health, and the relationship of this to its political processes, particularly with reference to the concepts of negative and positive integration.

The European Court and the EU integration process

The EU incorporates a range of political, legal and economic institutions, which both bind its member states and facilitate their interaction. Less than a federation, but more than an intergovernmental organisation, it has been characterised as a complex system of multi-level governance (Marks et al., 1996; Hooghe and Marks, 2001). The European Court has been central to the EU integration process. Indeed, during its formative stages, the EU integration process was marked by a 'fundamental asymmetry' stemming from the intergovernmental process of EU policy making on the one hand, and the supranational nature of EU law on the other (Scharpf, 1996: 15; see also Weiler, 1981; Scharpf, 2002). Although intergovernmentalism in EU law making has since been superseded to a significant degree by the process of co-decision between the European Parliament (EP) and the Council of the European Union (the 'Council')² (acting on proposals put forward by the European Commission), the opportunities for veto (Tsebelis, 2002; Holden and Hawkins, 2016) within the EU political system continue to make the creation of new supranational regulation more difficult than the removal of existing national-level regulations. EU legal processes, by contrast, have resulted in a powerful body of supranational law (based on the treaties) which is interpreted by the European Court and which binds its member states. Nevertheless, as will be elaborated below, such legal systems proceed not merely on the basis of obvious or neutral technical principles, but must be analysed in the context of broader political processes (Burley and Mattli, 1993: 44).

An important distinction can be made between 'positive' and 'negative' integration in the EU system (Scharpf, 1996). The distinction relates to the treatment of regulation in the attempt to remove regulatory differences between countries, which can act as barriers to the free movement of goods,

² The Council of the European Union is composed of ministers from relevant departments of member states' governments (depending upon the policy area being discussed) meeting in a legislative capacity. Until the entry into force of the Lisbon Treaty in 2009, the Council of the European Union was referred to as the Council of Ministers.

services, people and capital on which the single market is founded. Positive integration refers to efforts to formulate common policies and standards that apply to all member states, whereas negative integration aims to remove barriers to integration and common action that arise from national regulations (Anderson, 2015: 4). The difference between positive and negative integration within the single market is linked to processes of 'harmonisation' on the one hand, and 'mutual recognition' of member states' goods on the other. The former usually takes place via the adoption of a common EU standard on a particular product or good. The latter, in contrast, allows goods legally produced in one member state to be sold in all others, thereby removing impediments to trade that arise from different regulatory regimes. The European Court is a key site of negative integration, deepening economic integration via a series of rulings based on a broad interpretation of EU primary (i.e. treaty) and secondary (e.g. directives and regulations) law. A key feature of this process is the way in which it allows private actors wide scope to litigate via national courts.

Constitutionalisation, negative integration and corporate activity

To be effective, processes of trade liberalisation require a system that enables the monitoring and enforcement of agreements between parties. Without this, the incentive for parties to gain advantage by ignoring their obligations to open markets while others obey them will threaten to undermine the system (Stone Sweet, 2004: 8). Crucially, this must involve some form of third-party dispute resolution, i.e. an arbitration mechanism or a court. For these reasons, the formation of the WTO led to a significant strengthening of the dispute resolution system compared to its forerunner in the General Agreement on Tariffs and Trade (GATT). In the EU, the European Court plays this role. The Court, however, is more than simply an arbitration mechanism. Scholars have noted how, through successive rulings over time, it has come to operate as the constitutional court for the EU (Stone-Sweet, 2004). However, in contrast to most national-level constitutions, the treaties that form the EU's 'constitution', and the interpretation of these by the Court, have prioritised market building over market 'correction' (Scharpf, 1996: 18). Indeed, Stone Sweet (2004: 15) argues that a key motivation for litigating under EU law is for transnational economic actors to seek the removal of national regulations that hinder their activities and 'to fix market rules in their favour'.

Certain ECJ decisions in the 1960s on the doctrines of direct effect and supremacy represent key moments in the EU's process of constitutionalisation. The doctrine of direct effect allows natural (citizens) and legal (corporations) persons to plead rights enshrined in EU law in national courts. The direct effect doctrine thus gradually constructed a set of individual rights from a body of law initially

intended to apply only to states (Burley and Mattli, 1993: 60). The doctrine of supremacy specifies that, where national law comes into conflict with EU law, the latter has primacy (Stone Sweet, 2004: 68). This compels national courts to resolve contradictions between national and EC law by deferring to the latter (Stone Sweet, 2004: 53). As Scharpf (1996: 18) notes, '[o]nce the direct effect and supremacy of European law was accepted, the Commission and the Court of Justice had the opportunity to continuously expand the scope of negative integration without involving the Council of Ministers.'

Stone Sweet (2004: 74) argues that '[t]he constitutionalisation process has been driven primarily by the relationship between private litigants, national judges and the ECJ', as various groups bring cases in an attempt to secure their rights and advance their interests via EU law. As Conant (2007: 58–60) notes, the literature on the Court demonstrates that greater organisational capacity, the ability to track official developments, and access to funds mean that powerful interests are most able to exploit litigation opportunities. According to Stone Sweet (2004: 74), as TNCs target national regulations that impede their interests, 'the regulatory state can – potentially at least – be peeled away, like layers from an onion', so that 'by the later 1970s governments had discovered that adjudication in the area of free movement of goods had exposed to challenge virtually any national rule that might affect intra-EC trade'.

Proportionality testing

Provisions on the free movement of goods have influenced the relationship between EU law and the regulatory autonomy of member states more than any other area of EU activity. Important in the Treaty of Rome and in this body of jurisprudence is the prohibition of regulatory measures having an effect equivalent to quantitative restrictions on trade. In the *Dassonville* case (ECJ 8/74 [1974] ECR 837) the Court declared that '[a]ll trading rules enacted by the Member States, which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade are to be considered as measures having an effect equivalent to quantitative restrictions' (cited in Stone Sweet, 2004: 123).

As in other forms of trade arbitration, European Court judges refer to the principle of 'proportionality' when deciding what exceptions to single-market principles are permissible. In the context of the single market, and similar to WTO and other trade agreements, this entails a consideration of whether the same policy aim could have been attained by a measure less restrictive of trade. The grounds on which exceptions to the principle of free movement could be justified were

explicitly set out in Article 30 of the Treaty of Rome (now Article 36 TFEU), but must meet specific criteria in order to be allowed. Thus, while regulation in the public interest was permissible, it would be subject to tests of proportionality and must not constitute a disguised restriction on trade. The ECJ asserted this proportionately test in the *De Peijper* case (ECJ 104/75 [1976] ECR 613), stating that '[n]ational rules or practices do not fall within the exception specified in Art. 30 if the health and life of humans can be as effectively protected by measures which do not restrict intra-community trade so much' (cited in Stone Sweet, 2004: 126). In the *Cassis de Dijon* ruling (ECJ 120/78 [1979] ECR 649), the ECJ established that even national measures that did not formally discriminate between domestic and foreign products, but that had a protectionist effect, were contrary to EC law unless they met tests of proportionality.³

Stone Sweet (2004) notes how, in the process of negative integration, traders began by targeting the most obvious barriers to free movement, but that to the degree that these were removed by the Court, they then went on to target an ever-broader range of regulations. By the end of the 1980s, therefore, national rules on marketing rather than trading or production – including those with particular importance for health, such as on minimum pricing, labelling and packaging requirements – were being contested under EU law (Stone Sweet, 2004: 132). Collectively, these cases helped to create a framework, based on legal precedent, for dealing with public health exceptions (Stone Sweet, 2004: 133).

Health in the EU Treaties

When in the 1980s EU member states acted to deepen European integration via new treaties, they did so primarily on the basis of provisions aimed at deepening market integration (Anderson, 2015: 29). A shift towards a more pro-market consensus in member states led them towards the further development of the internal market project via, initially, the Single European Act (SEA), which entered into force in 1987. However, Alter (2009: 155) argues that they did this not on the basis only of mutual recognition and liberalisation, but also on a foundation of 'negotiated harmonization', whereby mutual recognition was applied 'on top of a base of harmonization, so as to minimise its deregulatory effects'.

³ Limitations were later placed upon the scope of EC law in this area by the *Keck* case (ECJ C-267 and C-268/91 [1993] ECR I-4879). A summary of this jurisprudence, which is too elaborate to outline here, can be found in Stone Sweet, 2004: 139–144. See also Alter (2009) for an analysis of the role of the *Cassis de Dijon* ruling in providing the basis for the European Commission to press ahead with an agenda of mutual recognition of national regulations.

This had some important, though limited, implications for public health. The SEA for the first time recognised health as an important dimension of economic integration (Duina and Kurzer, 2004: 58), although it was not until the Treaty on European Union (TEU; commonly known as the Maastricht Treaty) entered into force in 1993 that the EU acquired explicit competence in the field of public health (McKee et al., 2010: 235–36). Following the entry into force of the Treaty of Amsterdam in 1999, the EU was required to ‘ensure a high level of human health protection’ in all its policies and activities (Article 152(1) TEC [now Article 168 TFEU], as cited in McKee et al., 2010: 236). Despite the move to ‘mainstream’ health in all EU policies, Article 152(2) TEC makes clear that the main responsibility for public health remains with the member states, with EU-level action aimed at complementing this. The Treaty of Lisbon, which entered into force in 2009, ‘reiterates the obligation on the EU to take into account “protection of human health” in defining and implementing its other policies’ (McKee et al., 2010: 239).

The EU treaties thus provide a limited foundation for health-protective legislation at the EU level and a recognition of member states’ rights to protect the health of their citizens at the national level, while simultaneously providing extensive scope for corporations to challenge regulations in court. Below we investigate these issues further by examining two recent sets of legal proceedings before the European Court. The first involves a challenge to the Scottish Government’s enactment of measures to set a minimum unit price (MUP) for alcohol, while the second involves a challenge to specific aspects of the EU’s 2014 Tobacco Products Directive (TPD). In order to explore the questions set out above, we take a comparative case study approach drawing upon relevant legal documents and other literature, examining first a case of the attempted overturn of (sub)national legislation and, second, a challenge to EU-level regulations.

We do this by analysing relevant legal documents and other texts. Literature searches were undertaken using Google Scholar and Web of Science databases in relation to the TPD and MUP cases to identify sources on the origins and development of the relevant legislation and legal cases. A snowballing approach was then applied to studies returned in searches, as well as those known to the authors from their previous work in these areas, to identify additional sources. Relevant commentaries on contemporary events in the media and academic blogs were also consulted. Primary legislation, including relevant directives and the EU’s foundational treaties, and judgements of the CJEU, were examined to identify the relevant legal basis of the legislation discussed and the points of contention in the subsequent litigation. Although the two legal cases are the focus of the analysis, we took a political science approach throughout, rather than conducting a narrowly legal

analysis, attempting to understand the intersection of legal and political processes in producing policy outcomes.

Minimum unit pricing and alcohol industry litigation

The EU has regarded alcohol regulation primarily as a national responsibility, with EU-level initiatives taking the form not of harmonisation but of coordination, via the EU Alcohol Strategy for the period 2006–2012 (EC, 2006; Holden and Hawkins, 2016). The expiry of the alcohol strategy, and the failure to renew it after 2012, reflect the relatively weak political priority given to alcohol policy. Attempts to mandate health-oriented labelling of alcohol products via harmonisation measures were dropped as a result of industry lobbying (other than for ‘alcopops’) (Kurzer, 2013: 163; Cisneros Ornberg, 2013: 175). Simultaneously, measures implemented by member states have been challenged by alcohol corporations for breaching single-market rules. Baumberg and Anderson (2008: 394) conclude that significant ‘juridification’ of alcohol policy has taken place, with these policies being ‘re-framed’ from health/social policy to competition policy.

Minimum pricing policies have been ruled by the European Court to be trade distorting and to constitute measures having equivalent effects to quantitative restrictions (Baumberg and Anderson, 2008: 393). Minimum pricing policies for tobacco offer a precedent for the alcohol minimum pricing case considered here. Such measures have been ruled by the Court as unacceptable on the basis that increased taxation could achieve the same goals (Baumberg and Anderson, 2008: 395–96; McKee et al., 2010: 275). The CJEU (2010) found that minimum pricing of tobacco contravened Directive 95/99 (pertaining to excise levels of tobacco) in that it removed the potential for imported products to compete on price with established products. The Court also held that the imposition of a minimum price went against the specific stipulation, in Article 9(1) of the directive, that manufacturers and importers retain the ability to set the maximum retail price of their products. Increases in taxation, it stated, would not contravene single-market laws.

The Scottish government’s decision to introduce MUP for alcohol in 2008 was an attempt to use the specific and circumscribed powers devolved to it under the Scotland Act (1998) to respond to the very high rates of alcohol consumption and alcohol-related harm in Scotland, which are far in excess of the UK average (Scottish Government, 2008). It is impossible to understand the dynamics of the MUP debate without placing it in the constitutional and political context of post-devolution Scotland (Holden and Hawkins, 2013). Constitutionally, while taxation remained a ‘reserved competence’, decided exclusively by the UK Government in Westminster, health matters were devolved to the

Scottish Government. This removed the possibility for Scottish ministers to use increases in Duty and VAT levied on alcoholic beverages to address the issue of harms driven by the wide availability of cheap alcohol (Katikireddi et al, 2014). It was also argued by public health campaigners that MUP would be more effective in addressing alcohol-related harms than taxed-based measures, especially among the most harmful drinkers (SHAAP 2010). In terms of politics, the Scottish National Party (SNP) became the largest party in the Scottish Parliament for the first time in 2007, forming a minority government having committed to address health inequalities through a radical reorientation of Scottish alcohol policy. Having failed to pass legislation on MUP as a minority government in 2010, the SNP again committed to the policy in its 2011 manifesto and won a clear majority of seats at the subsequent Scottish elections. In May 2012, the Scottish Parliament passed the Alcohol (Minimum Pricing) (Scotland) Act to bring MUP into law (Holden and Hawkins 2013). A subsequent order set the level of MUP at 50p.

The SNP's commitment to introduce MUP represented a definitive shift in UK alcohol policy away from ineffective, industry-favoured approaches (Hawkins and Holden, 2013) towards effective whole-population measures, such as price increases (Babor et al., 2010). Having failed to stop the legislation being enacted, the alcohol industry sought to stymie implementation and overturn the law through legal challenges. The Scotch Whisky Association (SWA) announced on 19 July 2012 that it had begun proceedings under both UK and EU law. It was joined in its action by EU-level alcohol industry associations *Confédération Européenne des Producteurs de Spiritueux* (Spirits Europe) and the *Comité Européen des Entreprises Vins* (The European Committee of Wine Businesses, CEEV).

Its case centred on the claim that the Scottish Government, in enacting MUP, had overstretched its legal competence under both the terms of the Acts of Union (1707) and the Scotland Act (1998). Furthermore, it claimed the policy infringed Article 34 (TFEU) prohibiting quantitative restrictions on the movement of goods between member states and measures having equivalent effect, and that no exemption could be justified under Article 36 TFEU (previously Article 30 of the Treaty of Rome). As discussed above, the latter allows governments to put in place trade-restrictive measures where they are essential for 'the protection of health and life of humans', so long as these do not constitute indirect attempts at protectionism. Health exemptions are permissible where similar effects cannot be brought about by less trade-distorting measures. On 3 May 2013, Judge Lord Doherty, rejected the plaintiff's case, ruling that the Act was not outside the legislative competence of the Scottish Parliament, and that the proposed Order to set a minimum price was within devolved competence and the powers of the Scottish Ministers. Furthermore, he concluded that the proposed measures were compatible with EU law, and that a further referral to the CJEU on the matter was unnecessary.

The SWA appealed the decision to the Inner House of the Court of Session (i.e. the court of appeal in Scotland) and, in April 2014, the Lord Justice Eassie referred the case to the CJEU to provide its opinion on the compatibility of MUP with EU law. On 3 September 2015 CJEU Advocate General, Yves Bot, published his opinion on the case. This reaffirmed that MUP *did* constitute a measure having equivalent effect to quantitative restrictions, since it removed the ability of exporters to benefit from the comparative advantage they may have through lower cost bases and thus to compete with domestic producers on price. However, he accepted that measures such as MUP may be effective in reducing alcohol-related health harms and thus could be justified under Article 36 *if* it could be demonstrated that equivalent outcomes could *not* be brought about through less trade-restrictive measures such as taxation (Advocate General, 2015).

The tenor of the opinion seemed to favour tax-based measures over MUP, mirroring arguments brought forward by the alcohol industry. Taxation, the Advocate General argued, maintained the ‘free formation of price by the market’ and could, potentially, be more effective in achieving the policy’s stated goals by combatting alcohol misuse across the spectrum, not simply targeting those drinking at the cheapest end of the market. This seemed to undermine the Scottish Government’s claims that MUP represented a uniquely effective approach.

The Advocate General’s Opinion, was widely reflected in the final judgement of the CJEU delivered on 23 December 2015. However, the CJEU reiterated the responsibility of courts in the member state to determine the necessity of MUP in light of other available measures, such as increased taxation, which might be less restrictive of trade (CJEU, 2015). In October 2016, the Court of Session ruled, in light of the CJEU opinion, that MUP was indeed legal on the grounds that no other measure would produce the same effect as MUP. In delivering their judgment, Lord Carloway, Lord Brodie and Lord Menzies held that “the fundamental problem with an increase in tax is simply that it does not produce a minimum price” and that retailers such as supermarkets could absorb any tax increases “by off-setting them against the price of other products unrelated to alcohol” (Court of Session, 2016).

The judgement of the CJEU thus struck a careful balance. While clearly preferring taxation to MUP as a means of pursuing the policy’s goals, the European judges gave the Court of Session sufficient latitude to find in favour of MUP. In its judgement, the CJEU recognised that member states remain sovereign in questions of public health in line with the principle of subsidiarity and that Scottish ministers, under the terms of devolution, are competent to enact measures such as MUP for the purpose of health protections (Andreangeli, 2016). The CJEU, however, was silent on the specific policy options available to the Scottish Government within the UK’s devolution settlement. This is

unsurprising, given that such internal constitutional matters are regarded as being for member states to determine. In line with CJEU practice, it was ultimately for the Court of Session to determine whether MUP was more effective than taxation. For its part, the Court of Session found in favour of MUP not because it was the only measure open to the Scottish Government, but because it was the most effective. It nevertheless noted that the decision not to consider the precise measures available to the Scottish government was “a curious anomaly in the context of a legal argument that increasing tax is a viable alternative, when the political reality is that it is clearly not” (Court of Session, 2016), i.e., under the UK’s prevailing devolution settlement, in which duty and VAT are set at Westminster, the Scottish government was unable to use the option of increasing tax. The complex multi-level machinery of EU governance thus produced an anomaly, which the European Court did not explicitly take into account, but which it was able to work around by referring the case back to the relevant member-state court. This outcome is perhaps consistent with the arguments of those, like Stone Sweet (2004), who have argued that the European Court is aware of the political implications of its decisions and takes these into account within the ‘zone of discretion’ that the law affords it. The decision was appealed to the UK Supreme Court by the SWA and, at the time of writing, we await the very final ruling in the case.

The 2014 Tobacco Products Directive and tobacco industry litigation

Since the 1990s the European Commission has been active in the area of tobacco control, and in contrast to alcohol policy it has steered through a series of directives related to labelling, product regulation, advertising and sponsorship, and taxation (see McKee et al., 2010: 259–60). Given the limited competence of the EU in the area of health, all these directives, other than those on taxation, were based on treaty provisions relating to the internal market (McKee et al., 2010: 262). These directives have been subject to legal challenge by the tobacco industry and sympathetic member states. However, with some notable exceptions, the European Court has found in favour of the Commission, upholding health promotion measures (see McKee et al., 2010, for a comprehensive summary).

Particularly significant is the Tobacco Advertising Directive (TAD) (98/43/EC), which was adopted almost 10 years after its initial proposal by the Commission, following significant opposition by the tobacco industry (Neuman et al., 2002). It sought a complete ban on the marketing of tobacco products across all media (e.g. in print, on television, in cinemas) and at the point of sale and consumption (e.g. branded ashtrays, parasols and other items). The legal basis of the TAD was

Article 100a TEC (subsequently Article 95 TEC; now Article 114 TFEU),⁴ pertaining to measures necessary to ensure the functioning of the single market. Paragraph 3 of the Article also requires the Commission, in considering new proposals, to ‘take as a base a high level of protection’ relating to consumer health. The Directive was challenged by the German government and four tobacco companies on the grounds that it was public health legislation and thus *ultra vires* (i.e. exceeded the stated legal basis in the treaties) (Boessen and Maarse, 2008). The ECJ annulled the Directive in October 2000, ruling that measures within the Directive (e.g. the ban on cinema advertising) did not have the effect of facilitating cross-border trade or competition (Mandal et al., 2009; Hervey, 2001). An amended Directive, focusing explicitly on cross-border advertising (i.e. television and magazines) was enacted in 2003, despite similar legal challenges (Boessen and Maarse, 2008).

These cases highlight the importance of the legal basis of EU legislation and the principles of proportionality (that legislation should not go beyond what is necessary for the achievement of treaty objectives) and subsidiarity (that the EU shall act ‘only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States’) (Mandal et al., 2009). They also demonstrate the inclination of the judges to privilege these principles over the objective of securing public health. However, they established that legislation correctly adopted under the single market rules, for the intended market-oriented purpose of those articles, *can* have the (secondary) effect of harmonizing health policies (Boessen and Maarse, 2008). Thus, they created a clear precedent for the adoption of additional single market legislation which furthered public health objectives.

The first Tobacco Products Directive (2001/37/EC) was enacted in 2001 following extensive opposition from industry and certain member-states (McKee et al., 2010). The TPD’s main provisions related to the maximum tar yields, labelling, ingredients disclosure and the banning of misleading descriptors (i.e. ‘light’ and ‘mild’) and a ban on the sale of snus outside of Sweden (Mandal et al., 2009). The TPD was subject to legal challenges by the tobacco industry citing the annulment of the TAD (Mandal et al., 2009). They questioned the legal basis of the TPD under Article 95 TEC (formerly Article 100a TEC; now Article 114 TFEU), arguing that the proposed legislation did not serve the objectives of the single market but instead pursued overtly public health objectives, and citing the principles of proportionality and subsidiarity. The descriptors ban and increased labelling requirements were also claimed to infringe producers’ trademark and intellectual property rights. In

⁴ Some treaty articles were renumbered following the entry into force of the Amsterdam Treaty on 1 May 1999 and again following the entry into force of the Lisbon Treaty on 1 December 2009. The Lisbon Treaty also changed the name of the Treaty Establishing a European Community (TEC) to the Treaty on the Functioning of the European Union (TFEU).

its 2002 ruling the ECJ found the Directive to be valid, reinforcing the precedent that measures with significant public health impacts could be enacted under single- market legislation if they are strictly necessary for the functioning of the internal market.

The second, revised, TPD (2014/40/EU) entered into force on 19 May 2014, following a long and highly controversial legislative process and an unprecedented lobbying campaign by the tobacco industry (Peeters et al., 2015; Hoerz, 2014). The TPD contained a range of measures on the content, labelling and packaging of tobacco products and sought to put in place a regulatory framework for electronic cigarettes (e-cigarettes). Most notably it included mandatory increases in the size of health warning labels and an explicit recognition that member states could unilaterally introduce standardised ('plain') packaging at the national level. The specific legal basis was again Article 114 TFEU (formally Article 95 TEC; formerly Article 100a TEC). The rationale for adopting the TPD centred on the potential barriers to the functioning of the single market which arose from the diverging regulatory regimes which had emerged since the adoption of the last TPD in 2001. In particular, differences in labelling requirements, for example with some member states requiring graphic warning labels while others do not, was seen as a disruption to the market.

Two transnational tobacco companies, Philip Morris International (PMI) and British American Tobacco (BAT) with support from other industry actors, launched a legal challenge to the Directive via the High Court in London, arguing that, in enacting the Directive and delegating such wide-reaching regulatory powers to the Commission, the EU had acted beyond its legal competence, contravened the principle of subsidiarity and infringed consumer's fundamental rights to product information. More specifically, they questioned whether Article 114 (TFEU) provides a sufficient legal basis for several of the measures contained within the Directive, including the prohibition of flavourings, labelling requirements and the provision enabling member states to enact standardised packaging, and whether these measures contravened the principle of proportionality contained within the treaties (PMI, 2014). On 3 November 2014, the High Court referred the case to the CJEU for a preliminary ruling. Following submission to the Court from interested parties on 23 December, Advocate General Kokott delivered her preliminary ruling on the case in which she summarily dismissed the plaintiffs' claims. The position of the Advocate General was upheld in the final ruling of the CJEU delivered on 4 May 2016. The Court held that all aspects of the TPD were both within the competence of the EU and proportionate for achieving the stated aims of the Directive. After this potential legal impediment had been cleared the TPD came into effect on 20 May 2016 as stipulated in the Directive, although transitional arrangements were set out for some measures.

Discussion

The centrality of the EU single market within the European integration project is clearly evident in the area of public health. In the case of alcohol, and of minimum pricing more broadly, the potential for corporations to use EU law to challenge national-level regulation is clear, despite the CJEU's nuanced judgement on the MUP case. Even in the case of tobacco control, where the Commission has played an agenda-setting role, the market-building foundations of the EU treaties take precedence over health objectives. Given the ambiguity and limited scope of the treaty provisions on public health, a series of EU tobacco directives have been based on single-market provisions in the treaties, since they deal with harmonisation of rules concerning product packaging and marketing (Anderson, 2015: 175). This has opened them up to legal challenge on the grounds that they violate those same market principles, or that their objectives lie outside the legal remit of the treaty articles on which they are based. As McKee et al. (2010: 279) note, the European Court's previous rulings on tobacco advertising 'make it clear that the EU may not lawfully use internal market law simply to achieve public health goals', although they do acknowledge that single-market legislation can have the secondary effect of harmonising health policies. The market-building focus of EU law thus affords corporations ample opportunities to challenge both national-level health regulations and EU-level regulations, given that the latter must be based on single-market law.

Not only does the EU's complex legislative machinery provide multiple opportunities for policy influence by corporations, and 'veto points' at which laws may be stymied (Holden and Hawkins, 2016), corporations are able to challenge EU-level, national and sub-national legislation directly on the grounds that they infringe specific aspects of EU law. The EU's highly developed legal order thus offers a powerful mechanism through which corporations may seek to challenge public health measures that run counter to their interests. Furthermore, the robust legal basis in the treaties and the existential importance of the single market to the European integration project mean that there is a strong bias towards trade facilitation in the jurisprudence of the Court, which may be seen as being undermined by health and social policies that seek to curtail health-harming industries. Despite commitments to guaranteeing 'health in all policies,' therefore, the limited explicit competence of the EU in health policy has important consequences. First, it means that health-relevant harmonisation across the EU must be justified in terms of single-market rules. Second, it means that national-level health regulations must be constructed in the least trade-restrictive way possible and may be struck down by the Court if deemed inconsistent with this principle.

There is a clear difference, however, in the way the two product areas considered here have been approached at the EU level. In the case of tobacco, despite the bias towards market building, EU legal and political processes have provided significant opportunities for pro-health supranational regulation. While minimum pricing of tobacco products has been prohibited, directives enforcing minimum standards of tobacco control across the EU have been enacted in a way that has not been accomplished for the field of alcohol policy. In the case of alcohol, the Commission has relied heavily on ‘soft law’ approaches, such as information sharing and voluntary agreements among civil society and business. Since the expiry of the EU alcohol strategy in 2012, there is no significant framework for tackling alcohol harms at the EU level. Alcohol policy has therefore been left more to the member state (and sub-state) level. Consequently, while in the area of tobacco control the European Court has played a role in the interpretation of EU-level law, in the realm of alcohol policy it has focussed on the compatibility of domestic laws with EU law. Thus, while in both policy areas the Court continues to play a crucial role in determining what measures are compatible with single-market requirements and the free movement of goods, the potential for negative integration is much clearer in the case of alcohol than tobacco. While in the MUP alcohol case discussed here the Court seems to have taken a nuanced approach to the complex national and sub-national political context (involving an implicit, if not explicit, acknowledgement of the Scottish government’s limited powers), there is currently no prospect of any meaningful health-related regulation of alcohol at the EU level. The different outcomes between the two policy areas thus reflect the different approaches to these products by the European Commission and member-state governments, whereby alcohol is seen to be less harmful than tobacco (and alcohol corporations are treated as partners capable of helping to reduce harm) (Hawkins et al., 2016). It demonstrates that EU law *can* be used to construct supranational public health regulations, but that whether or not this occurs depends on the political will of the Commission and of member states.

The EU is consistent with more narrowly-drawn trade agreements and organisations in that the fundamental principles underlying EU law are premised upon market building. The single market is the cornerstone of the EU and the source of much of the jurisprudence of the Court. Many of the core principles of EU law, as well as the rights enjoyed by both corporate actors and EU citizens, are derived from Court rulings on different aspects of single-market law. While some of these decisions have been socially progressive, extending for example the right of movement for workers’ dependents across member states and equal pay for women (Stone Sweet, 2004), the centrality of the single market to the European integration project means that trade is the primary lens through which policy and law are viewed, and trade facilitation becomes the key objective to be pursued. Yet EU processes differ from those of purely trade-focussed agreements and organisations in their

implications for health. Other goals *can* be accommodated where they are able to demonstrate their compatibility with the overarching objective of EU trade liberalisation. Thus supranational regulation to protect health, including that which might offset the effects of negative market-building integration, is possible where sufficient political will exists among key policy actors.

The comparison of EU legal proceedings with dispute-resolution processes in other international trade and investment forums is instructive. In the WTO, for example, only states have legal standing to initiate disputes, although corporations can and do lobby sympathetic governments to undertake such action on their behalf (Eckhardt et al., 2015). In many bilateral and regional trade and investment agreements, however, corporations can initiate disputes with governments directly through investor-state dispute settlement (ISDS) procedures (Hawkins and Holden, 2016), just as they can under EU law. In contrast to ISDS mechanisms, however, the European Court's doctrine of direct effect does not only provide opportunities for corporations to utilise EU law, but also provides citizens with fundamental rights that can be pleaded before national courts under EU law.

Further, the political roles of the Commission, the Council and the Parliament are crucial in producing EU-level law that, at its best, can construct a health-protective floor across all member states. This contrasts starkly with the WTO, which, despite the existence of health exceptions in its agreements, has failed to attach even the most basic common health or social standards, such as core labour standards, to those agreements (Peels and Fino, 2015)⁵. 'Mega-regional' trade and investment agreements that have been the subject of recent negotiation, such as the Trans-Atlantic Trade and Investment Partnership (TTIP) and the Trans-Pacific Partnership (TPP), do include provisions for 'regulatory coherence' and 'regulatory cooperation', which are similar in some respects to the formulation of common standards in the EU. However, these do not envisage the creation of political institutions akin to those of the EU, and have prompted concern that they may lead to a lowering, rather than simply a harmonisation, of standards (Holden and Hawkins, in press).

Conclusion

In answer to the three research questions posed at the beginning of this article, our analysis suggests, first, that EU law offers ample opportunities for corporations to challenge national health regulations; second, that there is significant scope for pro-health supranational regulation in the EU, but that such regulation must be couched in the language of facilitating the single market, and is

⁵ Some bilateral and regional trade agreements do include provisions on minimum labour standards and on regulatory cooperation relevant to health. For a discussion of the latter in relation to 'next generation' trade agreements, see Holden and Hawkins (in press).

dependent on the political commitment of key policy actors; and, third, that this (limited) scope for pro-health supranational regulation distinguishes EU legal and political processes from those of most other trade agreements and organisations, which include exceptions for action at the national level to protect health, but which currently provide no opportunity to attach common minimum health standards to their trade provisions.

In different ways, the legal cases reviewed here demonstrate the predominance of market principles within the European integration project, and its relevance for health policy at both the member state and EU levels. They demonstrate also the interconnection between legal judgements and the wider political agenda. Despite its market-building bias, the EU's much more developed political institutions allow for greater health-protective legislation at the supranational level than more narrowly-drawn trade agreements and organisations. The importance of the political commitment of key policy actors is clear in this regard, where there is evidence of substantially greater political will to pursue regulation of tobacco products at the EU level when compared to the alcohol field, with EU regulation of tobacco exceeding national measures in some cases. However, even then this has had to be couched in the language of market facilitation. The alcohol case demonstrates both a lack of political ambition at the EU level to enact effective common measures to reduce harm, but also that national-level regulation is permissible if the proportionality test is met. However, the history of both tobacco and alcohol litigation suggests that certain types of regulation will be subject to particular scrutiny, with an underlying bias against minimum pricing of health-harming products evident.

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