characterisations require some *obligation* either voluntarily assumed (for contract) or imposed by law (for tort) in order for the rules of the Regulation to operate. The obligation is a creature of law. Although the legal rules are not tested at the jurisdictional stage, they are not irrelevant. The manner in which a claimant frames a claim before a national court has to take into account that legal context. Therefore, the final decision on characterisation for the purpose of jurisdiction is likely to continue to be difficult to predict.

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THE ALCOHOL (MINIMUM PRICING) (SCOTLAND) ACT 2012 AND THE COLLISION BETWEEN SINGLE-MARKET OBJECTIVES AND PUBLIC-INTEREST REQUIREMENTS

THE recent and high-profile decisions of the Court of Justice (Case C-333/14, ECLI: EU:C:2015:845) and of the First Division of the Inner House of the Court of Session ([2016] CSIH 77) in *The Scotch Whisky Association and Others v The Lord Advocate and The Advocate General for Scotland* have shed further light both on the role of national courts in cases where Member States invoke the protection of public health to justify derogations from the TFEU provisions on the free movement of goods and on the application of the proportionality test. The model of free movement provided in the Treaty is not one that guarantees an entirely untrammelled freedom of trade across the EU or the automatic precedence of common-market objectives. While Article 34 TFEU provides for the removal of national obstacles of a non-fiscal nature, Article 36 TFEU allows Member States, in the absence of harmonisation, to argue a number of public-interest grounds to justify national measures that, in principle, contravene Article 34 TFEU. The protection of public health ranks very prominently in this list of interests. However, although it is for the Member States to decide the appropriate level of health protection that they wish to ensure (C-174/82, *Sandoz* [1983] E.C.R. 2445), the national action must be proportionate and national authorities must select the action that is the least restrictive of intra-Union trade (Case 40/82, *Commission* v *UK* [1984] E.C.R. 283). The outcome in *The Scotch Whisky Association* case has highlighted the difficulties involved in choosing among alternatives the least restrictive measure that would achieve the public-health objectives of the national legislation. Moreover, it has demonstrated clearly, in these difficult times for the EU, that EU law can be interpreted and applied to safeguard sensitive national policies.

In response to alarming statistics on the excessive consumption of alcohol in Scotland, and as part of a general strategy espoused by the Scottish Government to tackle this problem, the Scottish Parliament passed the Alcohol (Minimum Pricing) (Scotland) Act in 2012. This Act provided for the imposition of a minimum price per unit of alcohol (MPU) and empowered the Government to determine the MPU by secondary legislation. Accordingly, the Government published a draft Order, setting the MPU at 50 pence. The primary aim of the legislation was to reduce the consumption of alcohol by harmful or hazardous drinkers – who, according to the available evidence, purchased large quantities of cheap strong alcohol – but the measures also sought to reduce the consumption of alcohol in general.

The Scotch Whisky Association and two EU associations of producers and traders in the alcoholic drinks sector brought a petition for judicial review against both acts. The essence of the petitioners' argument was the incompatibility of the Scottish rules with EU law on two counts: first, because they created a disproportionate barrier to trade that was contrary to Article 34 TFEU and could not be justified under Article 36 TFEU; second, because minimum pricing contravened the EU rules on the common organisation of the market in agricultural products, one of whose objectives is to maintain effective competition in an open market. At first instance, the Lord Ordinary dismissed the petition for judicial review (Opinion of Lord Doherty in the petition of *The Scotch Whisky Association and Others* [2013] CSOH 70). On appeal, the Inner House of the Court of Session made a detailed preliminary reference to the Court of Justice, which allowed the Court to deal with a range of important issues on the interplay between Articles 34 and 36 TFEU and between EU secondary legislation on the common organisation of agricultural markets and public-interest objectives.

It had been undisputed before the national court that the Scottish legislation constituted an obstacle to intra-Union trade within the meaning of Article 34 TFEU and the Court of Justice classified it as a measure having an equivalent effect to a quantitative restriction (at [32]). Yet, as Advocate General Bot explained in his Opinion (at [47]–[69]), it would have been plausible to argue that rules on minimum pricing could be classified as a "selling arrangement" within the meaning of the *Keck and Mithouard* (Joined Cases C-267/91 and C-268/9 [1993] E.C.R. I-6097) line of case law, since they applied to the retail stage (see also the Opinion of Advocate General Wahl in Case C-221/15, *Etablissements Fr. Colruyt* (ECLI:EU:C:2016:704), at [52]). Either way, the Scottish legislation would have constituted an obstacle to trade but the categorisation of the measure as a selling arrangement would have placed a stronger onus on the petitioners to show the impact on market access.

Most of the Court's ruling concentrated on the application of the principle of proportionality under Article 36 TFEU. The classic formulation of this principle by the Court comprises a two-pronged test that ascertains, first, that the national measure is appropriate to secure the public interest pursued and, second, that the measure does not go beyond what is necessary to achieve it (Case C-110/05, *Commission v Italy* [2009] E.C.R. I-519, at [59]). The Court examined the two limbs of the test in relation to the Scottish legislation. First, it found the legislation suitable to achieve the protection of public health: by essentially increasing the price of alcohol that was cheap in relation to its high strength, it was capable of reducing specifically the harmful or hazardous consumption of alcohol and, more generally, the overall consumption of alcohol. Interestingly, the Court not only looked at the objectives underpinning the imposition of a MPU, but also placed the legislation within the wider context of the general alcohol strategy pursued by the Scottish Government. The fact that the MPU legislation genuinely reflected an aim consistently pursued by a broader framework of national measures reinforced the finding that it was an appropriate measure. Second, at the necessity stage, the Court explained that the test was whether public health could be "as effectively protected" by alternative measures less restrictive of trade (at [41]). The Court gave a very strong signal indicating that there were questions about the proportionality of the Scottish legislation. In particular, a general increase in the taxation of alcoholic drinks could also be expected to combat alcohol misuse and would be less restrictive of trade than the imposition of a minimum price. This was because, unlike MPU, it would not restrict significantly the freedom of businesses to determine their retail selling prices. In reaching this conclusion, the Court largely ignored the fact that the Scottish Parliament did not have the legal competence to increase the taxation of alcohol. Crucially, however, the Court left the final determination of whether the MPU legislation was proportionate to the national court.

The devolution of the application of the proportionality test to the national courts in free movement cases is fairly common in the context of preliminary rulings (see C-34/95, *Konsumentombudsmannen v De Agostini* ([1997] E.C.R. I-3843), at [45]) but the judgment of the Court broke new ground in clarifying the burden of proof that needs to be satisfied by the national authorities and the extent and temporal scope of the review that should be performed by the national courts. First, the Court emphasised that national authorities have a margin of appreciation in the protection of public health and that, although they must submit specific evidence to justify their arguments, they are not obliged to prove that "no other conceivable measure" could achieve the same objective (Case C-333/14, at [55]). Second, the Court identified some factors that should inform the review by the national court. These were the existence of scientific uncertainty as to the actual effects of the MPU legislation, the fact that the legislation

would be subject to review after six years to ascertain its actual repercussions on the consumption of alcohol and the impact of the measure on the functioning of other EU policies such as the common organisation of agricultural markets (at [57]–[58]). Finally, the Court held that the review of proportionality should be undertaken on the basis of all the evidence at the time when the national court gives its ruling (at [63]).

The Court also considered the clash between the principles pervading the common organisation of the markets in agricultural products laid down in secondary EU legislation (Regulation 1308/2013, O.J. [2013] L 347/671) and the protection of human health. The Court observed that the setting of minimum prices was indeed at variance with the objectives of that Regulation, notably the "free formation of selling prices on the basis of fair competition" (at [21]). However, it explained that the Regulation did not prevent Member States from attaining public-interest objectives – such as public health – not addressed by the Regulation so long as the national measures satisfied the demands of the proportionality test as construed in the application of Article 36 TFEU.

Following the preliminary ruling of the Court of Justice, the Inner House of the Court of Session dismissed the appeal brought by the Scotch Whisky Association and found that the Scottish legislation was compatible with EU law. Applying the necessity limb of the proportionality test, and relying on the parameters provided by the Court of Justice, the Inner House of the Court of Session concluded that a general increase in the taxation of alcohol might be less restrictive of trade but would not be "as effective" as the introduction of a MPU in securing the primary objective of the legislation. In particular, it would not be able to target alcohol that was cheap in relation to its high strength.

Historically, the review by the Court of Justice of the proportionality of national measures that derogate from fundamental Treaty freedoms has been both intrusive and intense because of the exceptions that these measures create to single-market principles (Case 124/81, *Commission v United Kingdom* ([1983] E.C.R. 203). The emphasis has generally been on securing the least possible disruption to intra-Union trade. As a result, the margin of appreciation afforded to national authorities in carrying out the initial balance between free trade and public-interest benefits has been significantly curtailed (Case C-387/99, *Commission v Germany* [2004] E.C.R. I-3751). However, the decisions of the Court of Justice and of the Court of Session in *The Scotch Whisky Association and Others v The Lord Advocate and The Advocate General for Scotland* reflect a more nuanced approach towards public-health considerations that collide with common-market principles embodied in both primary and secondary EU law. The conclusion that it is possible for national authorities to select the most effective measure to achieve the principal and specific public-health goals pursued by the national legislation (even

if measures less restrictive of trade would be likely to achieve its broader and more general health objectives) subtly moderates free movement and other common-market principles in favour of national autonomy. This was neatly exemplified in the decision of the Inner House of Court of Session. Furthermore, the principles provided by the Court of Justice to guide the review undertaken by the national court in the application of the principle of proportionality have begun to create a clearer framework for the appraisal of the weighing of competing EU and national interests.

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REVERSE PATENT SETTLEMENTS AND EU COMPETITION LAW

THE judgment of the General Court in Case T-472/13, *Lundbeck v Commission* EU:T:2016:449 is the first decision of the CJEU on the application of EU competition law to reverse patent settlements. It confirms that Article 101 TFEU applies to agreements that restrict potential competition, and discusses the circumstances in which reverse patent settlements will amount to a restriction by object. However, the judgment provides little by way of practical guidance for those involved in negotiating patent settlements and leaves many questions unanswered.

"Reverse patent settlements" between originator drug companies and their generic counterparts are so called because they involve the originator making a payment to the generic. They are not necessarily problematic under EU competition law, where they seek to settle a genuine patent dispute and do not prevent generic entry. But they may infringe Article 101 TFEU where the originator pays the generic to stay out of the market (referred to as "pay-for-delay"). The concern is that the originator is able to continue earning monopoly profits even after its patent has expired, frustrating the normal effect of generic entry (which causes prices to fall). The European Commission has had reverse settlements between originators and generics firmly within its sights since their widespread usage became apparent during the course of its pharmaceutical sector inquiry in 2008–09, and it continues to monitor them, publishing annual update reports.

However, the Commission's interest in the reverse settlement agreements entered into by the Danish originator, Lundbeck, with four generic firms, pre-dates the sector inquiry and goes back to 2003, following a tip-off from the Danish competition authority. The Commission investigated, carrying out dawn raids between 2003 and 2006, though only opening formal proceedings in 2010. In 2013, the Commission issued an infringement decision, imposing fines totalling nearly €150 million on Lundbeck and the