

day become the standard in the negotiation of patents and technologies. It is especially effective in the university-industry setting, where companies usually take advantage of their stronger position and there is not yet a simple way of finding an “objective” range to use as a starting point for negotiations. We can conclude that the PVAE method and tool are the best fit to evaluate technologies or patents that pertain to particularly “dangerous” fields, where environmental and human safety issues might hinder a prosperous future for the technology or patent in question.

In fact, a proper use of the PVAE tool allows the parties to a license agreement or assignment to change the variables and adjust the value to the current situations. For instance, a novel molecule engineered through nanotechnology could face hard times in governmental approval because of potentially adverse side effects to humans and/or the environment. In this case, the parties could simply adjust the “Technology” and “Regulation” variables to make the value of the innovation more adherent to its current market potential.

Lifestyle Risks

This section discusses the regulation of “lifestyle risks”, a term that can apply to both substances and behaviours. Lifestyle risks take place along the line of “abstinence – consumption – abuse – addiction”. This can concern substances such as food, alcohol or drugs, as well as behaviours such as gambling or sports. The section also addresses the question of the appropriate point of equilibrium between free choice and state intervention (regulation), as well as the question of when risks can be considered to be acceptable or tolerable.

In line with the interdisciplinary scope of the journal, the section aims at updating readers on both the regulatory and the scientific developments in the field. It analyses legislative initiatives and judicial decisions and at the same time it provides insight into recent empirical studies on lifestyle risks.

Internet-Based Trade and the Court of Justice: Different Sector, Different Attitude

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I. Introduction

E-commerce and information society services became part of the quotidian language of the European institutions in the mid-1990s, as the European institutions gazed into a crystal ball wherein electronic commerce would further the competitiveness of the internal market.¹ Gradually increasing volumes of customers began to purchase goods and services via the internet, reflecting the development by undertakings of the internet as a sales channel and also due to the regulation of such transactions.² Concurrently the internet can be characterised by its tendency to bring market actors closer together, and the case of *DocMorris*,³ concerning the sale of medicinal products via the internet, has been described as constituting an instance whereby the technological revolution which the internet embodies has “well and truly reached the doors” of the Court of Justice.⁴

With a proliferation of cross-border economic activity, it was only a matter of time before the Court faced preliminary references from national courts confronted with measures restricting internet-based trade. Many of the sectors concerned have not been subject to any degree of harmonisation through sec-

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1 European Commission, *Europe’s Way to the Information Society. An Action Plan*, 19 July 1994, COM(94) 347 final.

2 For example, Council Directive 2000/31/EC of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (‘the Directive on electronic commerce’), which states in the Preamble in Recital 3 “Community law and the characteristics of the Community legal order are a vital asset to enable European citizens and operators to take full advantage, without consideration of borders, of the opportunities afforded by electronic commerce” whilst Recital 5 realises that “[t]he development of information society services within the Community is hampered by a number of legal obstacles to the proper functioning of the internal market which make less attractive the exercise of the freedom of establishment and the freedom to provide services; these obstacles arise from divergences in legislation...”.

3 Case C-322/01, *Deutscher Apothekerverband eV v. 0800 DocMorris NV and Jacques Waterval* [2003] ECR I-14887.

4 Richard Lang, “Case C-322/01, *Deutscher Apothekerverband eV v. 0800 DocMorris NV and Jacques Waterval*, judgment of the Full Court of 11 December 2003, nyr”, 42 *Common Market Law Review* (2005), pp. 189 *et seq.*, at p. 190.

ondary legislation, thus leaving the Court with the role of filling regulatory gaps by interpreting primary law, i.e. the Treaty on the Functioning of the European Union. This proliferation reflects a change in the lifestyles of individuals, but to what extent does this transition create new, or magnify existing, risks? As the nature of the risks to consumers evolves as a consequence of migration to the internet, what are the consequences in terms of consumer protection and what role has the Court played in shaping national responses to this evolution?⁵ When responding to preliminary references in the gambling field, the Court has shown considerable deference to the Member States in permitting them a wide margin of discretion within which they are able to maintain measures which are restrictive of the cross-border movement of gambling services and service suppliers. An integral part of this deference relies upon the approach of the Court to the risks associated with gambling on the internet; the Court appears to be overly accommodating of the concerns of the Member States.

While this is interesting as an independent phenomenon, it is of heightened intrigue when the gambling case-law is compared with that which has emerged from other sectors where commerce, such as that of medical devices and medicinal products, has migrated to the online environment. It is the objective of this short article to compare the approach of the Court in responding to concerns of national authorities arising from the risks associated with the provision of gambling services via the internet with the sale of medical devices and medicinal products

via the internet.⁶ Consequently, the case of *Ker-Optika* will be reviewed with reference to the earlier *Doc-Morris* judgment before moving onto the gambling related case-law to offer a comparison.

II. Sale of medical devices and medicinal products

*Ker-Optika*⁷ concerns the sale of contact lenses via the internet and the relationship between the requirements of Hungarian law specifying that such medical devices can only be sold in shops which specialise in the sale of medical devices or by delivery to the home of the final customer. *Ker-Optika* was engaged in the business of selling such lenses via its internet site, when the competent regional directorate of the national public health and medical services (referred to hereafter by its Hungarian acrostic, *ÁNTSZ*⁸) sought to prohibit this activity. The plaintiff countered that decision on the basis that it contradicted its alleged right as an information society service provider to freely sell such products via the internet. In response, and relying upon the E-Commerce Directive, *ÁNTSZ* claimed that such an activity was not an information society service because it required the physical examination of the patient.⁹ A preliminary ruling was sought by the national court seized of the matter¹⁰ to ascertain whether the sale of lenses constituted medical advice requiring the physical examination of the patient, thus taking it outside the scope of the E-Commerce Directive. Furthermore, the national court sought clarification on whether the domestic requirements surrounding the sale of contact lenses were compatible with the free movement of goods.

Before assessing the Hungarian measure in question, the Court first of all had to establish whether the measure was contrary to secondary law, i.e. the E-Commerce Directive, or primary law in terms of Article 34 TFEU upholding the free movement of goods. In view of the focus of this report it will suffice to note that the Court found with regards to the E-Commerce Directive, through its prohibition of the sale of contact lenses via the internet, that Hungarian law came within the scope of the Directive because of the separability of the medical advice from the actual sale of the contact lenses.¹¹ The Court readily found that the measure was a restriction in terms of Article 34 TFEU because it impeded access to the market for products from other Member States more than it did for domestic products.¹²

5 Synergies thus prevail with the issues arising within the emerging field of 'lifestyle risks'. See Simon Planzer and Alberto Alemanno, "Lifestyle Risks: Conceptualisation of an Emerging Category of Research", 4 *European Journal of Risk Regulation* (2010), pp. 337 *et seq.*

6 As such it will not be the objective of this report to assess whether the considerable deference to the Member States when regulating gambling is liable to unduly hinder the development of the internal market for this particular economic activity.

7 Case C-108/09, *Ker-Optika v. ÁNTSZ Dél-dunántúli Regionális Intézet*, judgment of the Third Chamber of 2 December 2010, nyr.

8 *ÁNTSZ Dél-dunántúli Regionális Intézet*.

9 Council Directive 2000/31 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce'), OJ 2000 L 178/1.

10 The Baranya megyei bíróság (county court of Baranya).

11 *Ker-Optika*, paras. 39–40.

12 See *Ker-Optika*, at para. 54 for how the Court views the internet as a means of providing non-domestic suppliers an opportunity to enter a market.

Consequently the Court proceeded to consider whether the restriction can be justified as a public health measure as provided for in Article 36 TFEU, having accepted that the measure is intended to ensure the health of contact lens users.¹³ Attention was then directed to ascertaining whether the restriction is both appropriate for attaining the given objective and necessary in terms of there being no other measure which would achieve the objective while being less restrictive on the free movement of goods. The Court was relatively brief in considering the appropriateness of the measure. Due to the risk of eye ailments – or even lasting visual impairment – arising from the incorrect use of contact lenses, the Court recognised that, with a view to protecting public health, Member States are competent to require that lenses be supplied by qualified staff who advise individual consumers on whether lenses should be worn. If lenses are deemed appropriate for an individual then Member States can also require that such staff ensure that the correct lenses are supplied, correctly positioned on the eyes and that they provide consumers with information on the correct use and care of such lenses. Although the risks to public health are not wholly eliminated by restricting the sale of contact lenses to opticians' shops, by establishing a link to the services of a qualified optician such dangers are likely to be reduced. The likelihood of reducing risk in this manner is deemed sufficient to consider the measure as appropriate for its objective, although the Court did not attempt to provide a more precise indication as whether there is a threshold at which point the restrictive measure has the capacity to eliminate a sufficient degree of risk to be appropriate.

The compatibility of Hungary's law faltered however on the necessity test. In other words having examined the assumption that every sale of contact lenses requires direct contact between an optician and the consumer, the Court ultimately found that the objective of protecting public health could be achieved in a less trade-restrictive manner. Initially the Court noted that precautionary examinations before contact lenses are purchased do not necessarily have to occur on the premises of an optician, if indeed a need for them exists in the first place. Secondly, the Court discovered no evidence in the case file to suggest that every single instance of lenses being supplied is dependent upon a precautionary examination or medical advice. Indeed, the Court noted that where a user is purchasing his or her regular supply of lenses it is not a requirement of Hungarian

law that the user is examined upon each and every purchase, but it is a responsibility of that consumer to be examined and obtain medical advice.¹⁴

Having established as a matter of fact that an examination, and any advice to which the examination may give rise, is not conditional for each sale, the Court considered that advice can be provided to consumers when sales are concluded via the internet by way of "the interactive features on the Internet site concerned, the use of which by the customer must be mandatory before he can proceed to purchase the lenses."¹⁵ The Court drew heavily upon its approach to the selling of non-prescription medicines via the internet in *DocMorris*, concerning the incorrect use of medicines and the possibility that an online pharmacy may be abused. As to the incorrect use of medicine the Court countered that the risk of this arising could be reduced through increasing the "number of online interactive features" which must be completed before a purchase can be made. It then stated that it saw no difference in terms of difficulty in acquiring non-prescription medicines unlawfully between traditional pharmacies and those online, thus dismissing the abuse-related concern.¹⁶

Furthermore, an examination to determine whether lenses are required, the appropriate type and advice on the correct use and care thereof, only arises as a 'general rule' when lenses are first supplied and for subsequent supplies there is "as a general rule, no need to provide the customer with such services".¹⁷ The Court considered a sufficient degree of protection to be afforded by customers advising the seller of the type of lenses required including any changes arising from the issue of a new prescription by an optician. Importantly, for the purposes of internet-based trade the Court also held that interactive features on a supplier's website will suffice for providing supplementary information and advice on the continued use of contact lenses. Yet the Court did not stop there but drew upon its earlier decision in *DocMorris* as it detailed how Member States could require suppliers to ensure that qualified opticians

13 *Ker-Optika*, para. 59.

14 It should be borne in mind that in *DocMorris* the Court felt that the need to ensure that prescriptions are genuine was reason enough to restrict the sale of prescription-only medicines via the internet. See *DocMorris*, at para. 106.

15 *Ker-Optika*, para. 69.

16 *DocMorris*, para. 114.

17 *Ker-Optika*, para. 71.

are available to provide individualised information and advice via their websites. The Court displayed considerable faith in the internet to deliver, noting how this may “offer advantages, since the lens user is enabled to submit questions which are well thought out and pertinent, and without the need to go out”.¹⁸ This reflects *DocMorris*, where “time to think about the questions to ask the pharmacists” in relation to the sale of non-prescription medicines online was viewed as an advantage of the internet.¹⁹ For the elderly or those with reduced mobility the provision of such advice (be it on medical devices or medicinal products) in the comfort of their own homes may be advantageous, and it appears that the Court is suggesting that there is a danger that some customers will fail to ask the right questions while standing in a busy shop and yet communication at a distance will alleviate such problems.²⁰

18 *Ker-Optika*, para. 73.

19 *DocMorris*, para. 113.

20 In *Ker-Optika* the Court does not repeat the view aired in *DocMorris* that the internet offers improved access to the products in question given that it allows consumers to place their order from their home or office. However, the discourse at this part of the ruling in *Ker-Optika* was concerned with the provision of individualised information and advice rather than the ease of consumers being able to purchase contact lenses per se.

21 Case C-42/07, *Liga Portuguesa de Futebol Profissional, Bwin International Ltd v. Departamento de Jogos da Santa Casa da Misericórdia de Lisboa* [2009] ECR I-7633, para. 57.

22 Case C-338/04, *Criminal proceedings against Massimiliano Placanica* [2007] ECR I-1891, para. 48.

23 *Liga Portuguesa*, para. 57.

24 In *Liga Portuguesa* the Portuguese court had not raised the issue of the chance of fraud against consumers, but rather, as several authors have criticised, this was assumed to be an objective by the Court. In this regard see Simon Planzer, “*Liga Portuguesa – the ECJ and its Mysterious Ways of Reasoning*”, 11 *European Law Reporter* (November 2009), pp. 368 *et seq.*, at p. 370 and Justin Franssen and Frank Tolboom, “*Practical Implications of the Santa Casa Judgment*”, in Alan Littler, Nele Hoekx, Cyrille Fijnaut and Alain-Laurent Verbeke (eds), *In the Shadow of Luxembourg: EU and National Developments in the Regulation of Gambling* (Leiden: Martinus Nijhoff Publishers, 2010), p. 91. The prevention of excessive gambling was of particular relevance in Cases C-243/01, *Gambelli and others* [2003] ECR I-13031 and C-338/04, *Placanica* [2007] ECR I-1891.

25 Alan Littler, “*Has the ECJ’s Jurisprudence in the Field of Gambling Become More Restrictive when Applying the Proportionality Principle?*”, in Alan Littler and Cyrille Fijnaut (eds), *The Regulation of Gambling. European and National Perspectives* (Leiden: Martinus Nijhoff Publishers, 2007), p. 15 *et seq.*

26 Dimitrios Doukas and Jack Anderson, “*Commercial Gambling without Frontiers: When the ECJ Throws the Dice is Loaded*”, 27 *Yearbook of European Law* (Oxford: Oxford University Press, 2008), pp. 237 *et seq.*, at p. 253. See also Edward Morse, “*Free Trade and Consumer Protection: Competing Interests in the Regulation of Internet Gambling*”, *European Journal of Consumer Law* (2010), Vol. 2, pp. 289 *et seq.*, at p. 289.

Given the separation of the need for an examination and medical advice upon each and every instance in which contact lenses are sold, the Court found that the requirement that such medical devices should only be sold in optician’s shops to be overly restrictive of trade since less trade restrictive alternatives prevail. As this amounts to Hungary exceeding its margin of discretion, the measure was found to be unnecessary, and thus in so far as the rules relate to the selling of contact lenses they are incompatible with the E-Commerce Directive and the free movement of goods. In essence, the Court deconstructed and challenged measures which Hungary found necessary for mitigating the risks associated with the sale of contact lenses, and thereby the Court paved the way for such products to be sold via the internet. This contrasts starkly with how the Court responds to national perceptions to, and management of, risks associated with online gambling.

III. Gambling case-law

1. Background to the Court’s approach

The gambling case-law of the Court is well known for the considerable deference which it sustains towards Member States through providing a substantial margin of discretion which national authorities enjoy when regulating gambling. At pains of repeating earlier literature on this point, this discretion is based upon the “significant moral, religious and cultural differences between the Member States”.²¹ Given the lack of harmonisation in this field, Member States are “free to set the objectives of their policy on betting and gaming and, where appropriate, to define the level of protection sought”²² “in accordance with [their] own scale of values”.²³ One such objective is consumer protection in terms of protecting consumers against fraud committed by operators or, less controversially, in terms of preventing the stimulation of excessive gambling.²⁴ The upshot of such a generous margin of discretion arises in the application of the proportionality principle,²⁵ namely that the Court is only prepared to declare as incompatible “manifestly discriminatory or disproportionate national measures”.²⁶

Indeed a considerable margin of discretion manifests itself in the Court refraining from critiquing national restrictions in a manner comparable to that which has been described regarding *Ker-Optika*. Ear-

lier cases relating to the use of the internet to provide gambling services, such as *Zenatti* and *Gambelli*,²⁷ saw bookmakers established and licensed in the United Kingdom rely upon ‘data transmission centres’ on the ground in Italy to act as intermediaries with local customers. However, it was not until the case of *Liga Portuguesa* that true cross-border internet gambling services came to be discussed, in the sense that the operators in question sought to supply their services solely via the internet without having any commercial presence or any relationship with an agent in the Member States in which the services were being offered. In this case the Court did not cast a critical eye over the reasoning advanced by Portugal for its restrictions on cross-border internet gambling.²⁸ *Liga Portuguesa* will now be reviewed in terms of illustrating the Court’s approach to regulating online gambling before briefly turning to later gambling case-law.

2. *Liga Portuguesa*

To briefly recall the facts, Portugal had entrusted the provision of lotteries, lotto games and sports betting services solely to Santa Casa,²⁹ which had been in existence since 1783. In 2003 the monopoly enjoyed by Santa Casa was extended to the internet. On the basis of a licence issued by Gibraltar, Bwin, an operator providing a wide range of gambling services via the internet, supplied these services to Portuguese residents. Bwin was subsequently fined for providing gambling services in Portugal in contravention of Santa Casa’s monopoly, and in the course of an action seeking the annulment of this decision, the national court handling the matter referred a preliminary reference to the Court.

Without entering into a detailed analysis of the questions asked and the entirety of Court’s response, its views on the necessity of a monopoly operator providing online gambling services mark a stark contrast with its stance in *DocMorris* and *Ker-Optika*. Portugal claimed that authorities of Member States do not have the same means of control over operators established in other Member States and providing their gambling services via the internet as they have over operators established in the Member State where the service is provided. (i.e. Portugal would have less control over an operator established in another Member State which supplies services in Portugal than it enjoys over Santa Casa).³⁰

Given the lack of harmonisation in the field of gambling services,³¹ the Court found that the Portuguese authorities were entitled to disregard the fact that Bwin was already subject to statutory conditions and controls by the competent authorities of another State. Due to the difficulties which the Court perceived as prevailing in the regulation of private operators in this sector, authorities in the operator’s Member State of establishment are unable to assess the “professional qualities and integrity of operators”. Therefore Portugal as the Member State receiving the service is entitled to conclude that there is insufficient assurance that national consumers are protected against the risks of crime and fraud in such a cross-border situation.³² Note that Portugal had not asserted any doubts as to the regulatory capacity of authorities in other Member States, but rather queried its own ability to effectively supervise and control operators established and licensed in other Member States who were supplying services in Portugal.³³ Nevertheless, by taking this “radical” view,³⁴ the Court cast doubt upon the ability of all national authorities seeking to regulate private operators due to what it perceived as their inability to assess the qualities and the integrity of the operators which they regulate. This may be attributable to the Court’s reformulation of the question posed by the national court which in essence altered the focus of Court’s inquiry so as to polarise the monopolist – private operator relationship.³⁵

The Court then proceeded to profess reasons as to why internet gambling may be more dangerous than offline gambling, but failed to explain their relevance to the particular case and facts at hand. Firstly the

27 Case C-67/98, *Zenatti* [1999] ECR I-7289 and *Gambelli*.

28 See, for example, Planzer, “Mysterious Ways of Reasoning”, *supra* note 24; Littler, “Gambling Regulation in the European Union: Recent Developments”, and Franssen and Tolboom, “Practical Implications”, both in Littler, Hoekx, Fijnaut and Verbeke (eds), *In the Shadow of Luxembourg*, *supra* note 24.

29 The Departamento de Jogos da Santa Casa da Misericórdia de Lisboa.

30 *Liga Portuguesa*, para. 68.

31 Incidentally, there is a lack of harmonisation in the supply of medical devices.

32 *Liga Portuguesa*, para. 69.

33 Planzer, “Mysterious Ways of Reasoning”, *supra* note 24, at p. 372; Littler, “Recent Developments”, *supra* note 28, p. 15 *et seq.*

34 Nele Hoekx, “Noot: Kansspelen op het internet: heeft *Bwin vs. Santa Casa* de kaarten geschud?”, 6 *Tijdschrift voor Consumentenrecht & Handelspraktijken* (2009), pp. 249 *et seq.*, at p. 253.

35 Hoekx, “Kansspelen op het internet”, *ibid.*, at p. 250.

Court claimed that, due to the “lack of direct contact between consumer and operator”, gambling services offered via the internet harbour “different and more substantial risks of fraud by operators against consumers compared with the traditional markets for such games” (the objective of the Portuguese legislation was to prevent consumers from being defrauded by operators).³⁶ Furthermore, the Court conjectured that an operator which sponsors some competitions upon which it accepts bets may be in a position to influence the outcome of the competitions in order to increase its profits.³⁷ Once again, this was not a concern put forward by the Portuguese authorities and the Court did not elaborate on why these two concerns were inapplicable to the public monopolist.

3. Going too far?

With such reasoning the Court inexplicably favours those Member States wishing to ignore regulatory attempts made by other Member States. It is clear from long-standing case-law that Member States are free to select how they organise their gambling markets, and, without doubt, had Portugal been required to recognise Bwin’s Gibraltar licence this would have signalled the death of the monopoly holder, and the competence of Member States to design the regulation of their national markets. Nevertheless, the attitude of the Court directly contradicts its approach in *DocMorris* and *Ker-Optika* where it sought to balance the interests of the Member State in terms of achieving its desired level of consumer protection and exposure to risk with the interests of the internal market.³⁸ Moreover, instead of examining why in

some instances national restrictions may be unnecessary, the Court conjectured risks which may exist in the cross-border supply of gambling but which were not only absent in the party’s pleadings, but failed to mitigate the restrictiveness of the prevailing restrictions.³⁹ Arguably, the Court is in danger of hindering development of the internal market; it could have found that the monopoly system was appropriate and necessary without making overly inclusive and broad statements which threaten the development of the internal market in relation to Member States which uphold different regulatory regimes to that of Portugal.

4. Subsequent cases dealing with online gambling

Questions relating to the supply of gambling services via the internet have arisen following *Liga Portuguesa in Carmen Media* and *Markus Stoß* where the German regulatory regime for sports-betting was scrutinised.⁴⁰ These cases are of interest, given that they show how the Court appreciates that forms of gambling differ in relation to the characteristics of each type of game, including the “reactions which they arouse in players”.⁴¹ In *Carmen Media* the Court proceeded to consider that the internet amounts to a “channel through which games of chance may be offered”, before returning to its earlier observation that the lack of direct contact between consumer and supplier entails that “different and more substantial risks of fraud by operators against consumers compared with traditional markets for such games” arise.⁴² Without elaborating on how this could prevail, the Court considered why gambling supplied via the internet may “prove to be a source of risks of a different kind and of a greater order in the area of consumer protection”, with contributory factors being the “potentially high volume and frequency of such an international offer” combined with the isolation of the player, anonymity and a lack of social control.⁴³

5. A little more depth in the Court’s reasoning

Although such issues are real, the degree to which they are a cause of gambling addiction depends upon regulation. A variety of controls can be introduced to ensure that players do not spend excessive amounts of time and money on gambling services, and some jurisdictions require online operators to abide by

36 *Liga Portuguesa*, para. 70.

37 *Liga Portuguesa*, para. 71.

38 In both *DocMorris* (paras. 103 and 124) and *Ker-Optika* (paras. 58–9) the Court justifies the measures in question on the grounds of protecting the health and life of humans as enshrined in Article 36 TFEU. In contrast overriding reasons in the public interest are relied upon in the gambling case-law, such as consumer protection as in *Liga Portuguesa*, para. 56.

39 See Planzer, “Mysterious Ways of Reasoning”, *supra* note 24 and Littler, “Recent Developments”, *supra* note 28.

40 Case C-46/08, *Carmen Media Ltd v. Land Schleswig-Holstein and Innenminister des Landes Schleswig-Holstein*, judgment delivered on 8 September 2010, nyr and Case C-316/07, *Markus Stoß v. Weteraerkreis*, judgment delivered on 8 September 2010, nyr.

41 *Carmen Media*, para. 62.

42 *Liga Portuguesa*, para. 102.

43 *Carmen Media*, para. 103.

these as well as bricks and mortar operators.⁴⁴ While there will always be some unregulated and under-regulated offers of gambling services; from criminal organisations within the Member States, or operators who are under-regulated in jurisdictions outside the EU, it is questionable whether the entirety of the regulated industry within the EU should be tarnished with the same brush. Through such an approach the Court ignores the fact that that Member States may choose to counter the negative externalities of online gambling through seeking to effectively regulate suppliers. Ultimately the choice remains with each Member State, but it is remarkable that the Court only referred to those measures which lack the capacity to provide scope for cross-border trade.

The Court entered into further debate on limiting the risks associated with online gambling services which flow from the Member States' competence to grant exclusive rights to a private operator for the provision of such services in *Markus Stoß*. The Court considered that national authorities are "entitled to take the view" that direct supervision over a single operator will enable "tight control" to be exercised over the monopolist so as to "tackle the risks connected with the gambling sector" and pursue legitimate objectives more effectively than would otherwise be the case if there were multiple operators in a non-exclusive legislative framework.⁴⁵ Furthermore, reliance on "a measure as restrictive as a monopoly" can only be justified "in order to ensure a particularly high level of consumer protection". This strongly suggests that the risks associated with online gambling can be managed through reducing the regulatory burden on the state; while it is easy to understand this logic, it is still dangerous as long as the outer boundaries of its application remain undefined. Should we, for example, conclude that there should be only one online pharmacist? Significantly, the Court specified that a monopoly regime must be supported by a legislative framework suitable for achieving, in a consistent and systematic manner, the given regulatory objectives.⁴⁶ However, determining whether a regulatory body is actually exercising tight control over the monopolist in question will be less than apparent where regulatory transparency does not prevail.

IV. Concluding remarks

In *Markus Stoß* the Court was directly faced with the impact of technology on undermining national

regulatory choices, thus including those related to the exposure of consumers to risk. The Court noted that illicit transactions are more difficult to control, given the transnational character of the internet, but that such transience should not undermine national rules which seek to uphold national preferences in legislating in the public interest.⁴⁷

As this report attests, national rules are open to challenge by regulated undertakings established within the internal market when their activities conflict with the public policy choices made by Member States in whose markets such undertakings seek to do business. No longer do divergent national policy preferences clash in the context of the internal market mechanisms via the postal system, as was the case for the lottery tickets in *Schindler*, but through the internet⁴⁸ and the capacity for cross-border communications which the latter provides.

How to give effect to national policy choices in light of the internet is likely to be a factor which unites online gambling services with the sale of medical devices and medicinal products over the internet as it constitutes a reflection of the challenges posed by the internet to national regulatory regimes in all their forms. Yet a considerable chasm exists within the case-law when these two forms of internet-based trade are compared in terms of the willingness of the Court to challenge the necessity of measures through which Member States seek to uphold policy preferences regarding the exposure of their consumers to risk.

44 See, for example, Jakob Jonsson and Sten Rönberg, "Sweden", in Gerhard Meyer, Tobias Hayer and Mark Griffiths (eds), *Problem Gambling in Europe: Challenges, Prevention and Interventions* (New York: Springer, 2009), pp. 299 *et seq.*, at pp. 311–2.

45 *Markus Stoß*, para. 81.

46 *Markus Stoß*, para. 82.

47 *Markus Stoß*, para. 86.

48 Case C0275/92, *H.M. Customs and Excise v. Schindler* [1994] ECR I-1039.