OPINION

Intra-brand competition in the pharmaceutical sector: comments to the CJEU Advocate General's Opinion in cases C-147/20, C-204/20 and C-224/20

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On 13 January 2022, Advocate General Szpunar delivered his opinion in cases *Novartis Pharma GmbH v Abacus Medicine A/S* (C-147/20), *Bayer Intellectual Property GmbH v kohlpharma GmbH* (C-204/20) and *Merck Sharp & Dohme BV, Merck Sharp & Dohme Corp., MSD DANMARK ApS, MSD Sharp & Dohme GmbH, Novartis AG, FERRING LÆGEMIDLER A/S, H. Lundbeck A/S v Abacus Medicine A/S, Paranova Danmark A/S, 2CARE4 ApS* (C-224/20). The Opinion diverts significantly from other case law from the European Court of Justice (CJEU) and would set the precedent for a new doctrine on intra-brand competition in the EU's Internal Market. Hence, the Opinion contains several points which could give rise to considerable concerns from a competition point of view.

Assessing the economic aspects

While the cases at hand concern the necessity to re-box versus the option to re-label pharmaceuticals following the implementation of the Falsified Medicines Directive (FMD) and its Delegated Regulation in relation to the safety features placed on medicinal packaging, AG Szpunar's introductory considerations set the scene for a significant new doctrine by the European Court of Justice (CJEU) in relation to its view on intra-brand competition—should the court decide to follow it. In essence, AG Szpunar seems to suggest that, besides the privileges and protection given in the form of patent rights and significant public funding etc., the pharmaceutical sector should enjoy special protection in relation to (intra-brand) competition.

In his introductory remarks, AG Szpunar outlines how—not least in light of the COVID-19 pandemic and the necessity of research & development (R&D)—pharmaceuticals must be considered "special" goods. While obviously pharmaceuticals serve an important function in society, the European Commission and the CJEU have upheld, that in terms of the Treaty on the Functioning of the European Union (TFEU), pharmaceuticals should not enjoy a special status in relation to the free movement of goods.[1]

The extent to which the EU competition law analysis should take into account the supposedly "unique" characteristics of the pharmaceutical industry has been the subject of debate and discussion for decades, not least within the CJEU itself. These discussions have related to factors such as pricing and reimbursement regulation, as well as the impact of the costs of conducting research and development. Following two contrasting Opinions in the *Glaxo Greece* cases by AG Jacobs (in *Syfait* (C-53/03)) and AG Ruiz-Jarabo Colomer (Joined Cases *Lelos* (C-468–478/06)), the Grand Chamber of the CJEU finally resolved many of these issues in its landmark 2008 judgment in *Lelos*, upholding the approach advocated by AG Ruiz-Jarabo Colomer.

In its introduction, AG Szpunar's Opinion is remarkable in that it runs directly counter to many of the key legal and factual findings of the CJEU in *Lelos*.

First, AG Szpunar states that the benefits of parallel trade accrue "mainly to the parallel traders themselves and only to a much lesser extent to patients or health insurance systems".[2] This statement is factually wrong and is in direct contrast to the findings of the CJEU. Indeed, the Grand Chamber in *Lelos* (at [52]–[56]) has already trumpeted the clear benefits of parallel trade to patients and health systems:

> "55. Nevertheless, the attraction of the other source of supply which arises from parallel trade in the importing Member State lies precisely in the fact that that trade is capable of offering the same products on the market of that Member State *at lower prices* than those applied on the same market by the pharmaceuticals companies.
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> 56. As a result, *even in the Member States where the prices of medicines are subject to State regulation, parallel trade is liable*

[1] Cf. European Commission, Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted COM(2003) 839 final, p.6; European Commission, Commission Notice Guide on Articles 34–36 of the Treaty on the Functioning of the European Union (TFEU) [2021] OJ C100/38, p.21; *Merck v Primecrown and Beecham/Europharm* (C-267/95 & C-268/95) EU:C:1996:468; [1997] 1 C.M.L.R. 83 at [46] and [47]; *Bristol-Myers Squibb v Paranova* (C-427/93, C-429/93 & C-436/93) EU:C:1996:282; [2003] Ch. 75 at [46]; *Officier van Justitie v De Peijper* (104/75) EU:C:1976:67; [1976] 2 C.M.L.R. 271 at [16].

[2] All English language quotations of AG Szpunar's Opinion in *Novartis* are the author's own translations from the French original.

> *to exert pressure on prices and, consequently, to create financial benefits not only for the social health insurance funds, but equally for the patients concerned,* for whom the proportion of the price of medicines for which they are responsible will be lower. At the same time, as the Commission notes, parallel trade in medicines from one Member State to another is likely to *increase the choice available* to entities in the latter Member State which obtain supplies of medicines by means of a public procurement procedure, in which the parallel importers can offer medicines at *lower prices*."

This is confirmed by ample research into the benefits of parallel imports, which finds significant savings for national healthcare systems and patients.[3] One clear example of such benefits is Poland, where savings from parallel imports amounted to more than €720 million between 2010 and 2018 and added up to €124 million just in 2018.[4]

Furthermore, for some countries, depending on the individual parallel import framework established, the fact that healthcare payers (typically) and patients enjoy savings are beyond discussion. For example, in Italy, Ireland, and the United Kingdom (UK) a specific percentage on the turnover of imports is reclaimed by the national healthcare payer.[5] In other countries such as Denmark, and particularly in the hospital segment, tendering is used as the sole price determinant for a range of products and only the offer of lower prices will give market access to parallel importers.[6]

Second, AG Szpunar states that "drug prices are rarely governed by market mechanisms alone". While this statement is factually true in itself, in isolation, the clear contextual implication is that pharmaceutical manufacturers have little say in the level of medicinal prices and are simply the victim of government regulation. The CJEU dispelled this notion in *Lelos*. The CJEU concluded (at [61]) in this case that the role of certain Member States in price setting and reimbursement does not "remove the prices of those products from the law of supply and demand". It further states:

> "62. Thus, in some Member States, the public authorities do not intervene in the process of setting prices or limit themselves to setting the scale of reimbursement of the cost of prescription medicines by the national health insurance systems, thereby leaving to the pharmaceuticals companies the task of deciding their selling prices. Furthermore, even though the public authorities in other Member States set the selling prices of medicines as well, *that does not in itself mean that the manufacturers of the medicines concerned have no influence upon the level at which the selling prices are set or the proportion of those prices which is reimbursed.*
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> 63. *As the Commission has pointed out, even in the Member States where the selling prices or the amounts of reimbursement of medicines are set by the public authorities, the producers of the medicines concerned take part in the negotiations which are initiated by those producers and take their price proposals as a starting point and end with the setting of the prices and the amounts of reimbursement* to be applied […]".

This position had also been clearly stated by AG Ruiz-Jarabo in *Lelos* (at [93]):

> "In summary, although the pharmaceuticals market does not operate under normal competitive conditions, the *price regulation system is not completely free from the influence of the manufacturers*, which negotiate prices with the Member State health authorities, *enjoy a degree of*

[3] Cf. S.J. Mendez, "Parallel Trade of Pharmaceuticals: The Danish Market for Statins" Melbourne Institute of Applied Economic and Social Research (2016); U. Enemark and K.M. Pedersen, "Parallel imports of pharmaceuticals in Denmark, Germany, Sweden and the UK. An analysis of savings", University of Southern Denmark (2011); U. Enemark, K.M. Pedersen, J. Sørensen, "The economic impact of parallel import of pharmaceuticals" (2006); Copenhagen Economics, "Savings from Parallel Import of Pharmaceuticals in Finland 2016–2020" (2021) *https://www.copenhageneconomics.com/publications/publication/savings-from-parallel-import-of-pharmaceuticals-in-finland-2016-2020*; Copenhagen Economics, "The Economic Impact of Parallel Imports of Pharmaceuticals—An Assessment of Savings in Denmark" (2019); Nera Consulting, "Indirect Savings from Parallel Trade in the Pharmaceutical Sector: the German and the Swedish cases" (2019) *https://affordablemedicines.eu/wp-content/uploads/2020/01/DESE-2019.07.24-Indirect-Savings-from-Parallel-Trade.pdf*; Peter Heydebreck, "Secondary analysis of indirect savings effects and potentials of parallel imports of pharmaceuticals", INNO (2019) *https://affordablemedicines.eu/portfolio-item/secondary-analysis-of-indirect-savings-effects-and-potentials-of-parallel-imports-of-pharmaceuticals/*; Association of Parallel Importers of Medicinal Products (audited Deloitte), "The impact of import on the competitive situation on the market for medicinal products in Poland in the years 2010–2018" (2019) *https://affordablemedicines.eu/portfolio-item/secondary-analysis-of-indirect-savings-effects-and-potentials-of-parallel-imports-of-pharmaceuticals-2/*; P. Hortlund, G. Rönnholm, P. Skiöld, N. Stridsberg, "2020 års uppföljning av apoteksmarknadens utveckling", TLV (2020) *https://www.tlv.se/download/18.659f4b7617597464fbb8257d/1605533427173/rapport_uppfoljning_apoteksmarknaden_2020.pdf*; P. Hortlund, G. Rönnholm, P. Skiöld, N. Stridsberg "2018 års uppföljning av apoteksmarknadens utveckling" TLV (2018); EAEPC, "The Parallel Distribution Industry—A closer look at savings" (2013); Affordable Medicines Europe, "Savings from Parallel Import in Europe" (2020) *https://affordablemedicines.eu/portfolio-item/savings-from-parallel-imports-in-europe/*.

[4] Association of Parallel Importers of Medicinal Products (audited Deloitte), "The impact of import on the competitive situation on the market for medicinal products in Poland in the years 2010–2018" (2019).

[5] For Italy, cf. Decreto-Legge 31 maggio 2010, n.78, art.11 comma 6 and AIFA Determina DG 357/2021. In Ireland, pricing of medicines is regulated by agreements between the State and IPHA. For more information please check: "Framework Agreements on Pricing and Supply of Medicines 2021–2025" and EAEPC, "The Parallel Distribution Industry—A closer look at savings" (2013), p.18. For the UK, cf. Department of Health & Social Care, "The 2019 voluntary scheme for branded medicines pricing and access: payment percentage for 2021": *https://www.gov.uk/government/publications/voluntary-scheme-for-branded-medicines-payment-percentage-for-2021/the-2019-voluntary-scheme-for-branded-medicines-pricing-and-access-payment-percentage-for-2021#:~:text=percentage%2Dfor%2D2021-,Summary,the%202019%20voluntary%20scheme%20documents*.

[6] For a description of the Danish system in the hospital sector, please check Danish Medicine Agency, Priser på medicin, 2019, 2019. Website accessed 7 February 2022: *https://laegemiddelstyrelsen.dk/da/tilskud/priser/*.

> *strength in the market* and are able to adapt easily to the vicissitudes of health policy, at least as far as medicines are concerned."

Third, AG Szpunar relays the oft-repeated argument from the pharmaceutical sector that, in essence, parallel trade impedes the ability of research-intensive pharmaceutical manufacturers to reap an adequate return on their investments, which creates a negative incentive to invest further in R&D, ultimately damaging efficiency and consumer welfare.

With specific reference to data published by EFPIA (the European Federation of Pharmaceutical industries and Associations), the interest organisation representing the innovative pharmaceutical industry, AG Szpunar asserts that the R&D of pharmaceuticals should be particularly high risk.[7] This is surprising since much independent research suggest that the pharmaceutical sector is not overall a specifically high-risk sector in relation to returns on investment. Rather research suggest that 84% of R&D funds for new breakthrough medicines are public funds.[8] The search for treatment and vaccination against COVID-19 is no exemption. According to the Global Health Centre at the Graduate Institute in Geneva, more than 90% of R&D funds invested in COVID-19 treatment/vaccines, are public funds.[9]

It is therefore not surprising, that the CJEU has not accepted this argument. In *Lelos*, AG Ruiz-Jarabo dismissed this exact argument—in that case argued by GSK—by stating: "I find the argument that the loss of income resulting from parallel imports of patented medicines acts as a disincentive *misleading*, since it is aimed only at *seducing public opinion*" (at [113]). The CJEU in that case rightly reclassified GSK's claim concerning the impact of parallel trade on R&D investments as rather the impact "on the pharmaceuticals companies' revenues" (at [29]).

It is particularly evident that AG Szpunar does not support the above assertions on the basis of concrete recitals from the leading case covering these issues, *Lelos*. It would have been appropriate for AG Szpunar to disclose in the Opinion, that the basis of his arguments, specifically the references on the economic perspective of parallel trade in pharmaceuticals (see footnotes 2, 3, 4 and 8 of the Opinion), stem from articles and books written by lawyers and economists who have a track record of working for or directly build on data exclusively provided by the pharmaceutical manufacturers.

Trademark as a defence against parallel trade?

In recital 6, AG Szpunar asserts that "Trademark rights are manufacturers' defence against parallel trade". While he subsequently clarifies how the exhaustion principle has been developed by the CJEU (at [7] and [8]) to ensure that trademarks are not used to fragment the internal market, what it is stated in this recital 6 represents the very starting point of the AG's considerations and deserves, therefore, further analysis.

The essential function of a trademark is to enable consumers to distinguish between the origin of alternative products.[10] Trademarks, by their nature of identifying origin, thus offer the protection against imitators and counterfeits, etc.[11] Hence, from its origin, trademarks were not put in place to protect the trademark proprietor against products which he himself placed on the market. Neither internally in a country nor in cross-border contexts. However, since the global trademark framework originates from different jurisdictions (e.g., potentially awarding same or similar trademarks to different products) trademarks were from their "birth" territorial—but that was neither their purpose nor essence.

The above considerations forced the CJEU jurisprudence to clarify the relationship between trademarks and free movement of goods in the context of the EU's Internal Market. AG Szpunar rightly refers to the *De Peijper* case when outlining the exhaustion principle within the EU/ European Economic Area (EEA). However, it is important to note two crucial points that the CJEU concluded in that case in relation to the purpose and the essence of trademarks:

> "8. In relation to trade marks, the specific subject-matter of the industrial property is the guarantee that the owner of the trade mark has the exclusive right to use that trade mark, *for the purpose of putting products protected by the trade mark into circulation for the first time, and is therefore intended to protect him against competitors wishing to take advantage of the status and reputation of the trade mark by selling products illegally bearing that trade mark"*.

In the same case the court further conclude that:

[7] AG Szpunar makes reference to the following quote "It is estimated that out of 10,000 new active substances synthesized in laboratories, only one or two reach the marketing stage and that the process takes approximately 12 to 13 years". See E. Navarro Varona and C. Caballero Candelario, "The pharmaceutical sector and parallel trade", in P. Figueroa and A. Guerrero (eds), *EU Law of Competition and Trade in the Pharmaceutical Sector* p.428. However, the authors refer directly to an EFPIA publication: "The Pharmaceutical industry in Figures, Key Data 2015" where these numbers are put forward by the industry.

[8] Donald Light, "Basic research funds to discover important new drugs: Who contributes how much?", in M.A. Burke and A. de Francisco (eds), *Monitoring Financial Flows for Health Research 2005: Behind the Global Numbers* (Geneva: Global Forum for Health Research, 2006).

[9] The Knowledge Network on Innovation and Access to Medicines is a project of the Global Health Centre at the Graduate Institute, Geneva (2021). Website accessed 24 January 2022: "COVID-19 Vaccine R&D Funding", Knowledge Portal (knowledgeportalia.org). Note that some private R&D expenditure may be underreported (to a lesser extent the same is the case for public R&D expenditure).

[10] Cf. N. Eonomides, "The Economics of Trademarks" (1988) 78 TMR 523. Cf. Directive (EU) 2015/2436 of the European Parliament and of the Council of 16 December 2015 to approximate the laws of the Member States relating to trademarks [2015] OJ L336/1 recital 31. Cf. World Intellectual Property Organization (WIPO), "Introduction to trademark law and practice. The basic concepts" (1993) *https://www.wipo.int/edocs/pubdocs/en/wipo_pub_653.pdf*.

[11] WIPO, "Introduction to trademark law and practice. The basic concepts" (1993).

> "11. In fact, if a trade mark owner could prevent the import of protected products marketed by him or with his consent in another member state, he would be able to partition off national markets and thereby restrict trade between member states, *in a situation where no such restriction was necessary to guarantee the essence of the exclusive right flowing from the trade mark*."

These conclusions clearly outline that exclusive rights are not bestowed to protect trademark owners against their own products. This is also very specifically outlined by WIPO.[12]

Hence, AG Szpunar's starting point seems to be fundamentally flawed when he suggests that trademarks are manufacturers' defence against parallel trade and omits to note that such protections are instead a consequence of the territoriality emanating from fragmented jurisdictions. In this regard, speaking of territoriality, the EU/EEA must be considered a single jurisdiction since the Treaty of the Functioning of the European Union precedes national laws restricting the free movement of goods.[13]

Following this, AG Szpunar's statement that "Any proprietor of a trademark for a product may oppose the use of that trade mark and thus the marketing of that product by a third party" (second part of [6]) is furthermore faulty. In fact, AG Szpunar, while correctly referring to arts 9(1)–(3) and 15(1) of Regulation (EU) 2017/1001 (paras 13 and 14), arts 10(1)–(3) and 15(1) of Directive (EU) 2015/2436 (paras 15 and 16), overlook the fact that in national jurisdictions (pre-dating the EU acquis) this is simply a wrong claim. When referring to the marketing of products by third parties, trademark doctrine clearly refers only to products in that jurisdiction *not* launched onto market by the trademark proprietor himself (or his licences etc.). Therefore, it is clear how trademark law is not by nature a defence mechanism against intra-brand competition, and it is also crucial to acknowledge that, in the Internal Market, parallel trade constitutes just that—intra-brand competition.

It is true, however, that parallel trade in pharmaceuticals must always be re-packaged (either re-boxed or re-labelled), and therefore in relation to exhaustion, based on art.15(2) of both Regulation (EU) 2017/1001 and Directive (EU) 2015/2436 which establish that "paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialisation of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market", the manufacturer enjoys some protection. However, this is only the case when parallel importers re-package, which is primarily necessitated by regulatory requirements in the field of pharmaceuticals. Therefore, the CJEU has long established that changes necessitated by regulatory requirements (or access to market) may not be used to protect the trademark proprietor from parallel trade.[14] For goods that do not need such changes, and where the parallel trader therefore refrains from undertaking any changes, the trademark proprietor would enjoy no protection against parallel trade.

In conclusion, it is therefore obvious why this wrong assertion by AG Szpunar is crucial in relation to the general view on the interplay between trademark law and competition from parallel trade. In fact, the case law from the CJEU is rather narrow in its interpretation of the rights given to trademark proprietors vis-à-vis changes made by parallel importers.[15] Moreover, the CJEU has been explicitly clear that intra-brand competition in the form of parallel trade enjoy special protection under the TFEU.[16] His conclusion at [192(2)] therefore sets the bar for repackaging unreasonably high under the circumstances of the Falsified Medicines Directive (Directive (EU) 2011/83), indirectly giving priority to trademark law at the expense of parallel trade. Finally, he states in his Opinion that on the substantive parts the Commission and the Polish Government agree with him that FMD does not alter the existing rules in the area (at [57]). Reading their statements in full, however, suggests the opposite.

(Mis)understanding necessities dictated by FMD

The main question in the case, whether the Falsified Medicines Directive (Directive (EU) 2011/83) necessitates re-boxing rather than re-labelling, should be considered in light of the purpose of that regulation (safety) as well as its implementation and administration by national authorities. In the assessment of this, no special credence should be given to trademark law.

AG Szpunar states in recital 10 that the introduction of falsified medicines constitutes "another risk linked to parallel trade". It is telling that, in order to justify this assertion, the AG simply states in a footnote that "[t]his risk is documented" and refers the reader to an

[12] WIPO, "Introduction to trademark law and practice. The basic concepts" (1993), p.51.
[13] The primacy of EU Law has been affirmed by the CJEU in several cases, including *Costa v Ente Nazionale per l'Energia Elettrica (ENEL)* (6/64) EU:C:1964:66; [1964] C.M.L.R. 425; *Internationale Handelsgesellschaft mbH v Einfuhr- und Vorratsstelle fur Getreide und Futtermittel* (11/70) EU:C:1970:114; [1972] C.M.L.R. 255, *Amministrazione delle Finanze dello Stato v Simmenthal SpA* (106/77) EU:C:1978:49; [1978] 3 C.M.L.R. 263. Moreover, the judgment known as "*Cassis de Dijon*" *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein* (120/78) EU:C:1979:42; [1979] 3 C.M.L.R. 494, is a keystone of the development of case-law relative to the prohibition of quantitative restrictions on imports and of measures having equivalent effect on the free movement of goods (art.30 of the EEC Treaty, now art.28 of the EC Treaty).
[14] Cf. *Bristol-Myers Squibb v Paranova* EU:C:1996:282, at [3], [52]–[56]; *Boehringer Ingelheim KG v Swingward Ltd* (C-348/04) EU:C:2007:249; [2007] Bus. L.R. 1100 at [16]; *Ferring* (C-297/15) EU:C:2016:857 at [15]; *Junek Europ-Vertrieb* (C-642/16) EU:C:2018:322 at [25]; *Hoffman-La Roche v Centrafarm* (102/77) EU:C:1978:108 at [11]–[16].
[15] Ibid, Footnote 16.
[16] Cf. Joined cases *Sot Lelos kai Sia EE v GlaxoSmithKline AEVE Farmakeftikon Proionton (formerly Glaxowellcome AEVE)* (C-468–478/06) EU:C:2008:504; [2008] 5 C.M.L.R. 20; *Procureur de la Republique v X* (C-373/90) EU:C:1992:17; *Pippig Augenoptik GmbH & Co KG v Hartlauer Handelsgesellschaft mbH* (C-44/01) EU:C:2003:205; [2004] 1 C.M.L.R. 39.

Organisation for Economic Co-operation and Development (OECD) paper, which in fact does not refer to such a risk. Rather the one reference to parallel imports in the whole report is on the increased costs of security measures; "Incorporating anti-counterfeiting technologies into their products and packages raises the costs for legitimate pharmaceutical manufacturers (OECD, 2016). The costs of introducing a unique identifier for manufacturers and parallel importers have been estimated by European Commission at EUR 50 to 320 million annually". It is worth observing, that in relation to FMD parallel importers are considered as marketing authorisations holders (MAHs) and in general are subject to the same Good Manufacturing Practices (GMP) requirements as manufacturers.

For the same abovementioned reasons, it is incorrect when AG Szpunar suggests in recital 11 that "In order to counter this risk, the Union legislature amended the legislation, introducing devices to verify the authenticity of medicinal products". The FMD contains no language to suggest parallel trade was a specific cause for falsified medicines entering the legal supply chain or for it to be adopted.[17] In fact, most falsified medicines reach the patients via illicit trade to and/or between entities authorised to supply the public with medicines. Extremely few cases historically pertain to illegal or negligent behaviour of parallel importers.

To understand the logic of how the FMD ensures the integrity of pharmaceuticals placed in the EEA, one has to understand that an unbroken bond must exist between the anti-tampering device (ATD) and the unique identifier (UI). Only the MAH uploading the UI into the European Medicines Verification Organisation (EMVO) Hub (EU Hub), should be able to place the UI and ATD. If the two may be affixed to a pack outside the control of the legitimate MAH, then the integrity of the system is compromised. One is not more or less important than the other.

Nonetheless, AG Szpunar suggests that it is easy to imagine that some types of ATD's may be easier to remove and replace than others (at [78]). As referred to at [76], ISO standard 21976:2018 indeed sets out the functional requirements for ATD's. But whereas AG Szpunar only refers to the publicly available (for free) table of contents and informative parts of said standard, a closer review of the actual content reveals that ATDs in general should result in the "visible, irreversible damage of the packaging".[18] If ATD's did not leave such visible signs of tampering, they would simply not meet their purpose. One may speculate, that this is why AG Szpunar reaches the very surprising conclusion at [82] (as well as at [140] and his final conclusions at [190(1)]), stating that:

> "As the trade mark proprietors rightly point out in their observations, the new anti-tampering device is intended to guarantee that the package has not been opened between the premises where the repackaging took place and the sale to the end user. The fact that there is trace of a lawful opening for repackaging does not affect the purpose of the anti-tampering device if it is clear that such a lawful act was involved."

How exactly wholesalers and persons authorised to supply medicines to the public should know when an ATD has been legally broken (and replaced) and when it has been illegally broken (and possibly replaced) is not clarified by AG Szpunar. Also, this argument completely overlooks the fact that a product placed on the market by parallel importers may also be subject to attempts of falsification, where their ATD's were broken *after* the packs left the parallel importer. This is just as real a scenario as scenarios where falsifications happen from the premises of manufacturers, via wholesalers and pharmacies/hospitals, to end-users. Therefore, this argument is simply non-sensical.

Of even further concern is AG Szpunar's remark at [89]:

> "However, I do not think that it can be stated in principle that one type of repackaging is better than the other. Although one of these approaches in a specific case may have benefits, in my view this will not apply in general. *More directly, it is not rocket science to produce a medicines package or replace an anti-tampering device. It is ultimately about closing a simple cardboard box, neither more nor less. If criminals are able to falsify the drug, they will also be able to falsify the packaging*."

It is hard to find a statement on the logic of the FMD that is more misunderstood than this. Yes, criminals will be able to falsify the packaging, *but* they will not be able to upload the UI to the EU Hub(!) That is the essence of the system, and the reason why there must be the unbroken bond between the UI and the ATD. The ATD ensures that a pack with a legitimate UI may not be tampered with. For example, criminals would otherwise be able to remove and replace the original high value medicines (inner packaging) with falsifications only to re-affix a new ATD on top of the original outer packaging, whereby the FMD system via the legitimate UI will consider the pack legitimate. Or conversely where the UI is copied (scanned and reprinted) from an original pack (subsequently sold somewhere outside Europe) to a label containing the UI and then affixed to a falsified pack with an ATD placed by the falsifier.

Therefore, it is surprising that AG Szpunar agrees in his conclusion (at [190(2)]) that "the unique identifier referred to in Article 3 (2) of the said Delegated

[17] Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products [2011] OJ L174/74.
[18] International Organization for Standardization (ISO), 21976:2018, Packaging—Tamper verification features for medicinal product packaging.

Regulation. 2 (a) may be affixed by means of a label affixed to the packaging, provided that the label, in addition to complying with the requirements of Articles 5, 6 and 17 of the delegated regulation, is affixed to the packaging on a in such a way that it is impossible to remove it *without damaging it and without damaging the packaging* or leaving traces after the removal of the label", while he does not consider equally that an ATD must be impossible to break/remove without damaging it and without damaging the packaging. Understanding the disconnect in this (wrong) logic applied by AG Szpunar does not align well with the practical reality of the FMD system. It is, furthermore, difficult to appreciate why anyone would suggest affixing the UI with a label is safe. It inherently means that the ATD may be affixed by a different entity than the UI. As explained above, one is not more important than the other—the two must remain in an unbroken bond.

Taking the above into consideration, AG Szpunar actually delivers the simple answer to the questions at hand in the cases at [80] (and subsequently at [134]):

> "A parallel distributor who repackages medicinal products may comply with the requirements of Article 47a (1). 1 (b) of Directive 2001/83 by using the original package if the parallel distributor is able to replace the original anti-tampering device with an anti-tampering device which meets the criteria described above. *If, on the other hand, this proves to be impossible, in particular because the anti-tampering device is designed in such a way that the packaging is damaged at the opening, the parallel distributor will objectively have to use new packaging*."

As the very nature of an ATD is in fact to *irreversibly damag*e, as generally outlined in ISO standard 21976:2018, the pack it has been implemented on, in this context, AG Szpunar's own definition of the functioning of an ATD at [94] is irrelevant. Rather, it should be clear from the practical functioning of the FMD system, that re-boxing is a practical necessity to ensure the integrity of the system, why it becomes a practical necessity in itself to re-box in order to have effective access to the market.

Concluding remarks

While the cases at hand concern the question of the practical necessity to re-box versus re-label parallel imported goods, AG Szpunar in his Opinion takes substantial inroads into the established principles on the balance between trademark rights and competition stemming from the free movement of goods and in general and intra-brand competition specifically. It is therefore to be expected that this Opinion will be subject of some debate before the CJEU will deliver its judgment later this year. Therefore, it should also be expected that the CJEU be explicit in its ruling if it decides to diverge from established case law and follow the direction of AG Szpunar.

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