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Gloss to the Judgment of the Court of Justice of 17 November 2022, C-224/20

Glosa do wyroku Trybunału Sprawiedliwości z dnia 17 listopada 2022 r., C-224/20

Научный комментарий к решению Европейского суда от 17 ноября 2022 г., C-224/20

Глосарій до рішення Суду Європейського Союзу від 17 листопада 2022 року, C-224/20

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Summary: The commented judgment concerns the admissibility of repackaging medicinal products in parallel trade. It was issued in connection with new EU regulations aimed at counteracting the counterfeiting of such products. The Court examined how the regulations in question affect the scope of rights enjoyed by the owners of trademarks affixed to products, as well as the rights of entrepreneurs engaged in parallel trade.

Key words: free movement of goods, intellectual property, exhaustion of the rights conferred by a trademark, parallel import of medicinal products

Streszczenie: Glosowane orzeczenie dotyczy problematyki dopuszczalności przepakowywania produktów leczniczych w ramach handlu równoległego. Zostało ono wydane w związku z nowymi regulacjami prawa unijnego, które mają przeciwdziałać fałszowaniu tego rodzaju produktów. Trybunał ocenił, jak przedmiotowe regulacje wpływają na zakres uprawnień właścicieli znaków towarowych, którymi są opatrzone produkty, oraz na uprawnienia przedsiębiorców zajmujących się handlem równoległym.

Słowa kluczowe: swobodny przepływ towarów, własność intelektualna, wyczerpanie prawa do znaku towarowego, handel równoległy produktami leczniczymi

Резюме: Комментируемое решение касается вопроса о допустимости переупаковки лекарственных препаратов в рамках параллельной торговли. Оно было вынесено в связи с новыми нормами законодательства ЕС, направленными на противодействие фальсификации таких препаратов. Суд проанализировал, как рассматриваемые нормы влияют на объем прав владельцев товарных знаков, которыми маркируется продукция, и на права участников параллельной торговли.

Ключевые слова: свободное перемещение товаров, интеллектуальная собственность, истечение срока действия права на товарный знак, параллельная торговля лекарственными препаратами

Резюме: Рішення, що розглядається, стосується питання допустимості перепакування лікарських засобів у паралельній торгівлі. Воно було винесене у зв'язку з новими правовими нормами ЄС, спрямованими на протидію фальсифікації такої продукції. Суд оцінив, як ці норми впливають на обсяг прав власників товарних знаків, якими маркується продукція, і на права права підприємців, які займаються паралельною торгівлею.

Ключові слова: вільний рух товарів, інтелектуальна власність, вичерпання права до товарного знаку, паралельна торгівля лікарськими засобами

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Theses of the Judgment

1. Article 9 (2) and Article 15 of Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark, and Article 10 (2) and Article 15 of 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 trade marks, read in conjunction with Articles 34 and 36 TFEU,

must be interpreted as meaning that the proprietor of a trade mark is entitled to oppose the marketing, by a parallel importer, of a medicinal product repackaged in new outer packaging to which that trade mark is affixed where the replacement of the anti-tampering device of the original outer packaging, carried out in accordance with Article 47a (1) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012, would leave visible or tangible traces of that original outer packaging having been opened, provided that:

there is no doubt that those traces of opening are attributable to the repackaging of that medicinal product by that parallel importer and

those traces do not cause, on the market of the Member State of importation or on a substantial part of it, such strong resistance from a significant proportion of consumers to the medicinal products repackaged in that way that it would constitute a barrier to effective access to that market.

2. Directive 2001/83, as amended by Directive 2012/26, and Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83,

must be interpreted as precluding a Member State from requiring that medicinal products imported in parallel must, in principle, be repackaged in new packaging and that recourse may be had to relabelling and to the affixing of new safety features to the original outer packaging of those medicinal products only on application and in exceptional circumstances, such as, inter alia, a risk of disruption to the supply of the medicinal product concerned.

3. Article 9 (2) and Article 15 of Regulation 2017/1001 and Article 10 (2) and Article 15 of Directive 2015/2436, read in conjunction with Articles 34 and 36 TFEU,

must be interpreted as meaning that a Member State rule which requires that medicinal products imported in parallel must, in principle, be repackaged in new packaging and that recourse may be had to relabelling and to the affixing of new safety features to the original outer packaging of those medicinal products only on application and in exceptional circumstances does not impede the exercise by

a trade mark proprietor of his or her right to oppose the marketing by a parallel importer of a medicinal product repackaged in new outer packaging to which that mark is affixed.

4. Article 9 (2) and Article 15 (2) of Regulation 2017/1001 and Article 10 (2) and Article 15 (2) of Directive 2015/2436, read in conjunction with Articles 34 and 36 TFEU,

must be interpreted as meaning that the first of the five conditions set out in paragraph 79 of the judgment of 11 July 1996, Bristol-Myers Squibb and Others (C-427/93, C-429/93 and C-436/93, ECLI:EU:C:1996:282) – according to which the proprietor of a trade mark may legitimately oppose the further marketing in a Member State of a medicinal product bearing that mark and imported from another Member State, where the importer of that medicinal product has repackaged that product and reaffixed that trade mark to the packaging and where such repackaging of that medicinal product in new outer packaging is not objectively necessary for the purposes of its being marketed in the Member State of importation – must be satisfied where the trade mark which appeared on the original outer packaging of the medicinal product concerned has been replaced by a different product name on the new outer packaging of that medicinal product, provided that the immediate packaging of that product bears that trade mark and/or that new outer packaging refers to that mark.

5. Article 9 (2) and Article 15 (2) of Regulation 2017/1001 and Article 10 (2) and Article 15 (2) of Directive 2015/2436

must be interpreted as meaning that the proprietor of a trade mark may oppose the marketing in a Member State by a parallel importer of a medicinal product imported from another Member State which that importer has repackaged in new outer packaging to which he or she has reaffixed the trade mark of the proprietor specific to that product, but not the other trademarks and/or other distinctive signs which appeared on the original outer packaging of that medicinal product, where the presentation of that new outer packaging is in fact liable to damage the reputation of the trade mark or where that presentation does not enable normally informed and reasonably attentive consumers, or enables them only with difficulty, to ascertain whether that medicinal product originates from the proprietor of the trade mark or an undertaking economically linked to him or her or, on the contrary, originates from a third party, thus adversely affecting the function of indicating the origin of the mark.

Introduction

Medicinal products are a special type of commodity. The costs of their development and marketing borne by their manufacturers are enormous. What is more, their production entails the risk that they will not bring the desired returns for manufacturers**.** Furthermore, public authorities in different countries control their prices in different ways. Finally, their specificity stems also from the fact that the use of medicinal products directly affects human health and life. As was correctly observed by M. Szpunar, Advocate General, "the need for a return on investment, on the one hand, and the regulatory constraints on prices, on the other hand, lead manufacturers of medicinal products to set widely differing prices for the same product, even in highly interconnected markets, as is the case in the Member States of the European Union. The indicated situation, in turn, results in the profitability of the practice of purchasing medicinal products on markets with low prices and reselling them on markets with higher prices."[1] It is referred to as parallel import (parallel trade). Defining the said form of trading as parallel import results from the fact that it takes place parallel to the manufacturers' distribution channels, while involving the same medicinal products registered in the country of destination.[2] This is why entities that are independent of manufacturers take advantage of the practice described above, which is opposed by manufacturers. Trademark rights constitute the weapon that the latter can use to fight back. The entity that holds the right of registration (right of protection) of a trademark may, in fact, oppose the use of that trademark, including for the marketing of the product in question, by a third party. At the same time, manufacturers of medicinal products take various measures to prevent parallel imports.[3]

One of the risks associated with parallel trade, even if not linked thereto in an inextricable way, is the risk of introducing falsified medicinal products on the market. In particular, there may be a danger of their repackaging, which is often necessary to place such products on the market in Member States other than the one in

1 The opinion of Advocate General M. Szpunar presented on 13 January 2022, C-147/20, C-204/20 and C-224/20, ECLI:EU:C:2022:28.

2 M. Królikowska-Olczak, *Import równoległy produktów leczniczych a zasada swobodnego przepływu towarów*, Studia Prawno-Ekonomiczne 2016, vol. 100, pp. 35–36.

3 R. Skubisz, *Wyczerpanie prawa ochronnego na znak towarowy*, in: *System Prawa Prywatnego*, vol. 14B. *Prawo własności przemysłowej*, ed. R. Skubisz, 2nd ed., Warszawa 2017 [Legalis database], no. 85. As for parallel import see also T. Sieniow, *Rozkład ciężaru dowodu w sprawach importu równoległego*, Europejski Przegląd Sądowy 2006, no. 7, p. 19.

which they were sold originally.[4] Another example of interference with the original packaging on which the trademark has been affixed is placing an additional label that covers the original packaging, applied by the authorized trademark holder, in whole or in part.[5] The EU legislator has introduced mechanisms to verify the authenticity of medicinal products to counteract the said risks.[6] Directive 2011/62 (Falsified Medicines Directive, FMD)[7] thus inserted into Article 54 of Directive 2001/83 the point (o) pursuant to which the outer packaging or, where there is no outer packaging, the immediate packaging of medicinal products other than radiopharmaceuticals referred to in Article 54a (1) of that directive must be equipped with safety features enabling wholesale distributors and persons authorised or entitled to supply medicinal products to the public to verify the authenticity of the medicinal product concerned, to identify individual packs and to verify whether the outer packaging of that medicinal product has been tampered with. Pursuant to Article 54a (2) of Directive 2001/83, Delegated Regulation 2016/161[8] establishes the detailed rules for those safety features. Recital 1 of that delegated regulation identifies two types of safety features, namely (i) a unique identifier and (ii) an anti-tampering device. An anti-tampering device is defined in Article 3 (2) of that delegated regulation as the safety feature allowing the verification of whether the packaging of a medicinal product has been tampered with.

On the said background, the Court of Justice of the European Union rendered a series of judgments on the interpretation of the rules on falsified medicinal products. The main judgment, that takes into account the complexity and multiplicity of

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4 The opinion of Advocate General M. Szpunar presented on 13 January 2022, cases C-147/20, C-204/20 and C-224/20, ECLI:EU:C:2022:28, Section 10. Simultaneously, on the same day, the Court rendered in particular judgments in the cases C-147/20 and C-204/20. Due to the vastness of the subject matter, these are only hinted at.

5 K. Szczepanowska-Kozłowska, *Import równoległy produktów leczniczych oznaczonych znakiem towarowym*, Przegląd Prawa Handlowego 2007, no. 12, p. 12.

6 See *inter alia* Articles 54, 54 (a), 57, 59, 60 of Directive 2001/83; Articles 3 (2), 10, 16 (1), 24, 25, 30 of Delegated Regulation 2016/161.

7 The Falsified Medicines Directive was published on 1 July 2011, and applies since 2 January 2013.

8 This regulation details the characteristics of the safety features, as well as how medicine authenticity should be verified and by whom. It has been in force since 9 February 2019. The EU system aims to facilitate the verification of the authenticity of medicinal products directly with the manufacturers at any stage of the distribution chain and at any point within the internal market of the European Union, until the medicinal product is delivered to patients. The provisions stipulate that once the medicine is delivered, usually to the patient, the unique identifier will be withdrawn from the database system, so that no other package with the same unique identifier can be 'positively verified,' cf. I. Kalinowska-Maksim, *Fałszowanie produktów leczniczych. Zagadnienia prawne i kryminologiczn*e, Warszawa 2020, p. 49.

issues involved, is the said case C-224/20.[9] On the basis of the relevant statement of the Advocate General, the fundamental legal issue addressed in these cases involves the consideration of whether the requirements in question, intended to counteract the falsification of medicinal products, change the status quo with respect to the rights of parallel traders of medicinal products as well as the rights of their manufacturers as proprietors of the trademarks under which the said products are marketed.[10]

The commented judgment is also relevant to the Polish pharmaceutical market, where the share of parallel traders is significant. The aim of the present gloss is to examine the extent to which the aforementioned FMD regulation [Falsified Medicines Directive] affects the issue of parallel trade and entrepreneurs' entitlements.

1. De facto and de jure situation

The commented judgment has been rendered on the request made in the context of seven sets of proceedings between (i) manufacturers of medicinal products – proprietors of trademarks under which the medicinal products they produce are sold, and (ii) parallel importers of pharmaceutical products, concerning the importation into Denmark of medicinal products placed on the market in other Member States by those manufacturers. Once they are placed on the market in Denmark, those medicinal products are repackaged in new outer packaging. Parallel importers purchase medicinal products in EU countries offering lower prices and sell them in EU countries where the prices are higher. To do this, the parallel traders must change the directions for use and the drug packages in each case to be in the language of the country of destination. In some of the disputes in the main proceedings, the trademarks of those manufacturers are affixed to the new outer packaging, whereas, in other disputes, these trademarks are replaced by new product names. In the latter case, the new outer packaging indicates that the medicinal product it contains corresponds to the medicinal product marketed by the proprietor under his or her trademark and that the blister packs inside that new outer packaging bear that mark. The new package leaflet accompanying the medicinal product in question also indicates that the product corresponds to that sold by the proprietor under his or her trademark. The companies which manufacture the original medicinal prod-

9 Judgments on similar legal issues were passed in the cases of C-253/20 and C-254/20.

10 The opinion of Advocate General M. Szpunar presented on 13 January 2022 item 11.

ucts claim that, in circumstances such as those covered by the disputes in the main proceedings, trademark law confers on them the right to oppose the repackaging of the medicinal products in question in the new outer packaging. The companies that import medicinal products into Denmark contend that repackaging is necessary and therefore lawful.

Given the above-mentioned circumstances, the Landgericht Hamburg (Hamburg Regional Court) addressed the Court with questions that could be summarised as follows: (1) Do the new rules counteracting the falsification of medicinal products introduced by the FMD and Delegated Regulation 2016/161 oblige parallel traders to give preference to the repackaging of parallel imported medicinal products into new packaging over the use of original packaging with new labels affixed to it? (2) Do, and if so, to what extent, the new rules in question alter the scope of the right of proprietors of trademarks related to medicinal products to counteract the repackaging of parallel traded medicinal products into new packaging vis-à-vis the legal situation resulting from the present case-law of the Court of Justice? (3) Are the Member States' authorities entitled to lay down stricter rules concerning the manner in which parallel traded medicinal products are repackaged and, if so, what are the consequences thereof for the rights of the manufacturers of these medicinal products? 4) To what extent does the proprietor of a trademark relating to a parallel traded medicinal product have the right to counteract the repackaging of the medicinal product in question where the parallel trader does not reproduce, or only partially reproduces the trademarks used by the owner in respect of the said medicinal product.[11]

Parallel traders argue that, due to the new regulations of Directive 2011/62 and Delegated Regulation 2016/161, repackaging into new packaging is now the rule, and resealing of the original packaging is only allowed as an exception. In contrast, trademark owners of medicinal products maintained that the new legislation did not fundamentally change the existing rules. According to these entrepreneurs, both the re-use of the original packaging and repackaging into new packaging are in principle permissible, and the regulations for medicinal products do not provide for the priority of one or the other method.[12]

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11 The opinion of Advocate General M. Szpunar presented on 13 January 2022, Section 52. For the formulation of the questions at issue, see Section 42 of the judgment under review C-224/20, ECLI:EU:C:2022:893.

12 The opinion of Advocate General M. Szpunar presented on 13 January 2022, Section 57. According to Article 47a (1) of Directive 2001/83: The safety features referred to in point (o) of Article 54 shall not be removed or covered, either fully or partially, unless the following conditions are fulfilled:

2. Comments

The view that dominates in the literature is that the judgment in Bristol Myers Squibb, BMS, is of fundamental importance for the repackaging of medicinal products.[13] This judgment included five conditions to be fulfilled by an entity repackaging a medicinal product to be able to invoke exhaustion of the trademark right against the proprietor.[14] They are called BMS conditions.[15] Other judgments of the Court of Justice of the European Union [CJEU] also addressed the problem of legal issues related to the exhaustion of the right to register a mark. The literature points out that even the judgment in Boehringer Ingelheim and Others C-348/04 case[16] seemed to rule out further discussion on the premises of admissibility of repackaging.[17] Furthermore, it was pointed out in the doctrine that the CJEU rulings showed that "only a change in the condition of the goods that adversely affects the consumer's perception of the product can threaten trademark infringement. If the change is not perceptible by the consumer or is neutral to his/her perception, it should not

(a) The manufacturing authorisation holder verifies, prior to partly or fully removing or covering those safety features, that the medicinal product concerned is authentic and that it has not been tampered with;

(b) The manufacturing authorisation holder complies with point (o) of Article 54 by replacing those safety features with safety features which are equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering of the medicinal product. Such replacement shall be conducted without opening the immediate packaging as defined in point 23 of Article 1. Safety features shall be considered equivalent if they: (i) comply with the requirements set out in the delegated acts adopted pursuant to Article 54a (2); and (ii) are equally effective in enabling the verification of authenticity and identification of medicinal products and in providing evidence of tampering with medicinal products;

(c) the replacement of the safety features is conducted in accordance with applicable good manufacturing practice for medicinal products; and

(d) the replacement of the safety features is subject to supervision by the competent authority.

13 Judgment of the Court of 11 July 1996, Bristol-Myers Squibb and Others, C-427/93, C-429/93 and C-436/93, ECLI:EU:C:1996:282.

14 E. Traple, *Import równoległy a wyczerpanie prawa z patentu i prawa ochronnego na znak towarowy*, in: *Prawo farmaceutyczne*, eds. E. Traple, M. Krekora, M. Świerczyński, Warszawa 2020, p. 661.

15 R. Skubisz, in: *System Prawa Prywatnego*, vol. 14B, p. 1085.

16 Judgment of Court of 26 April 2007, Boehringer Ingelheim and Others, C-348/04, ECLI:EU:C:2007:249.

17 Read more widely on the topic: K. Szczepanowska-Kozłowska, *Ewolucja koncepcji wyczerpania prawa ochronnego na znak towarowy w orzecznictwie Trybunału Sprawiedliwości*, Glosa 2014, no. 1, pp. 65–68. To learn more about the evolution of the CJEU's views on repackaging, see also: W. Olszewski, *Ewolucja zasad przepakowania produktu leczniczego w ramach importu równoległego. Glosa do wyroku Trybunału Sprawiedliwości z 28.07.2011 r. w sprawach połączonych: C-400/09 i C-207/10 „Orifarm i inni"*, Europejski Przegląd Sądowy 2015, no. 1, pp. 46–48.

create a premise for the trademark holder to use his/her rights."[18] Tampering with the packaging of a medicinal product may take various forms.[19] In parallel imports of medicinal products, the rule is to tamper with the packaging in which the product was originally placed on the market by the right holder, and this is due to the need to comply with standards arising from legislation in force in the importing country, not yet standardised in the Member States.[20]

As far as more recent rulings are concerned, it is also important to recall the judgment of the Court in the C-642/16, Junek Europ-Vertrieb case.[21] It concerned parallel imports of medical products and tampering with the outer packaging, consisting of affixing a small information sticker that did not cover or contain the trademark. The Court ruled that this form of tampering with packaging is not repackaging within the meaning of the earlier case law developed in relation to medicines and does not require compliance with the requirements set out in the earlier judgments, including, in particular, the notification of the trademark proprietor.[22]

Then, usually parallel traders typically had to add labels to the existing packaging (relabelling) and could only introduce replacement packaging (reboxing) where that was necessary, for instance due to different pack sizes or "such strong resistance from a significant proportion of consumers to relabelled pharmaceutical products that there must be held to be a hindrance to effective market access."[23]

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18 M. Kondrat, *Przepakowanie leków w imporcie równoległym*, in: *100 lat ochrony własności przemysłowej w Polsce. Księga jubileuszowa Urzędu Patentowego Rzeczypospolitej Polskiej*, ed. A. Adamczak, Warszawa 2018, p. 471.

19 In the practice of marketing medicinal products, it is becoming increasingly common for importers to place their own trademarks on the packaging alongside the manufacturer's trademark, which is seen as an attempt to promote the parallel importer or to highlight the name of the medicinal product from the country of destination, if this name is different from the name of the product used in the country from which the product is exported. This is known as co-branding. There is also the practice of removing the trademark that is used in the country of origin of the medicinal product from the packaging and replacing it with the trademark from the country of destination. This in turn is called re-branding. A third method is to remove the trademark from the packaging and replace it with a trademark from the country of origin (de-branding). R. Stankiewicz, *Reguły importu równoległego ustalone w orzecznictwie unijnym*, in: *Instytucje rynku farmaceutycznego*, ed. R. Stankiewicz, Warszawa 2016, p. 335. Also in this matter see J. Chlebny, *Dopuszczalność usuwania cudzego znaku towarowego na gruncie prawa znaków towarowych (część 1)*, Przegląd Prawa Handlowego 2020, no. 1, p. 39.

20 R. Skubisz, *Import równoległy produktów leczniczych. Glosa do wyroku ETS z 26.04.2007 r. (C-348/04)*, Europejski Przegląd Sądowy 2007, no. 7, p. 48.

21 Judgment of the Court of 17 May 2018, Junek Europ-Vertrieb, C-642/16, ECLI:EU:C:2018:322.

22 Read more widely on the topic: M. Kondrat, in: *Prawo własności przemysłowej. Komentarz*, ed. M. Kondrat, Warszawa 2021 [LEX database], Commentary on Article 155.

23 Judgment of 23 April 2002, Merck, Sharp & Dohme v. Paranova, C-443/99, ECLI:EU:C:2002:245, § 31.

The first thesis of the commented judgment of the Court concerns the interpretation of Article 9 (2) and Article 15 of Regulation (EU) 2017/1001 and Article 10 (2) and Article 15 of Directive (EU) 2015/2436,[24] read in conjunction with Articles 34 and 36 TFEU. The Court indicated that these provisions must be interpreted as meaning that the proprietor of a trademark is entitled to oppose the marketing, by a parallel importer, of a medicinal product repackaged in new outer packaging to which that trademark is affixed where the replacement of the anti-tampering device of the original outer packaging, carried out in accordance with Article 47a (1) of Directive 2001/83/EC, would leave visible or tangible traces of that original outer packaging having been opened, provided that: (I) there is no doubt that those traces of opening are attributable to the repackaging of that medicinal product by that parallel importer and (ii) those traces do not cause, on the market of the Member State of importation or on a substantial part of it, such strong resistance from a significant proportion of consumers to the medicinal products repackaged in that way that it would constitute a barrier to effective access to that market. In reaching its decision in this regard, the Court referred to its previous judgments that formulated the conditions under which a trademark holder is entitled to counteract the repackaging of a product, including the BMS judgment.[25] First, the Court indicated that repackaging into new packaging must be regarded as objectively necessary where the anti-tampering device with which the outer packaging of the medicinal product concerned is equipped cannot objectively be replaced by an equivalent device, within the meaning of Article 47a (1) (b) of Directive 2001/83, however, the presence of traces of opening is, in itself, insufficient to support the inference that the condition of equivalence has not been satisfied. On the other hand, according to the Court, a parallel importer cannot rely on a general presumption of consumer resistance to relabelled medicinal products whose anti-tampering devices have been replaced. Then, the possible existence of such resistance and its extent must be assessed *in concreto*, taking into account, in particular, the circumstances prevailing in the Member State of importation at the time at which the medicinal product

[24] The transposition of the rule expressed in the provision of Article 15 of Directive 2015/2436 is the provision of Article 155 of the Act of 30 June 2000 – Industrial Property Law. The provision of the Directive constitutes, in turn, a normative sanctioning of the concept of exhaustion developed earlier in the jurisprudence of the CJ against the background of Articles 34 and 36 of the Treaty on the Functioning of the European Union (ex Articles 28 and 30 of the Treaty Establishing the European Community) relating to the free movement of goods within the internal market. Cf. more widely: M. Bohaczewski, in: K. Osajda, *Komentarze Prawa Przemysłowego*, vol. 8B. *Prawo własności przemysłowej. Komentarz*, ed. Ł. Żelechowski, 2nd ed., Warszawa 2022 [Legalis database], Commentary on Article 155.

[25] C-224/20, § 52–57.

concerned was marketed, and of the fact that traces of opening are visible or, on the contrary, can be detected only after a thorough verification by wholesalers or persons authorised or entitled to supply medicinal products to the public pursuant to their verification obligations under Articles 10, 24 and 30 of Delegated Regulation 2016/161. The Court in this case resisted the automatic presumption that recipients of medicinal products would refrain from purchasing relabelled medicinal products whose anti-tampering devices have been replaced. The circumstances of a particular case must be examined on a case-by-case basis by the national court.

Also, the Court clearly indicated that provisions of the Directive 2001/83 and Delegated Regulation 2016/161 preclude a Member State from requiring that medicinal products imported in parallel trade must, in principle, be repackaged in new packaging and that recourse may be had to relabelling and to the affixing of new safety features to the original outer packaging of those medicinal products only on application and in exceptional circumstances, such as, inter alia, a risk of disruption to the supply of the medicinal product concerned. Such finding of the Court has been issued as a reaction to the actions of the Danish Medicines Agency. This Agency considered that it is a general rule that parallel importers must repackage the products in new packaging according to the new rules of the regulation. According to this Agency, that also follows from the purpose of the new rules of the regulation, including the requirement for an anti-tampering device to be designed in such a way that any opening of, or tampering with, the package can be identified. Parallel importers who opened the packaging of medicinal products and broke the anti-tampering device for the purpose of placing a Danish package leaflet etc. in the packaging must therefore, in accordance with the new rules of the regulation, repackage the products in new packaging and attach a new unique identifier and anti-tampering device on the packaging, as well as upload information etc. Such interpretation provided by this Agency has been questioned by the Court. The Court has pointed out, inter alia, that a systemic interpretation of Article 47a of Directive 2001/83, read in the light of the objectives of that directive and of Directive 2011/62, that this article brings about exhaustive harmonisation as regards the conditions under which safety features may be replaced. Then, the Member States cannot create further conditions, as it can impede the marketing of medicinal products. As has been highlighted by the Advocate General, pursuant to the provision of Article 47a (1) (d) of Directive 2001/83, the substitution of the safeguards referred to in Article 54 (o) of that Directive is subject to supervision by a competent authority. It is obvious that the competent authority of the Member State may issue guidelines informing on the conditions and modalities thereof under the said supervision. However, the indicated guidelines may not amend the existing provisions of EU

law. In its judgment concerning the matter, the Court adopted the interpretation developed by the Advocate General. The interpretation in question seems to be correct and based on both the wording and the purpose of the relevant provisions. It will furthermore provide a clear guideline for action with regard to the EU's national regulatory authorities in terms of establishing regulation modelled on the one submitted by the Danish regulatory authority in the case in question.

In the commented judgment, the Court also addressed the scope of the trademark proprietor's right relating to a medicinal product engaged in parallel trade. The Court has analysed the case, where the trademark which appears on the original outer packaging of a medicinal product is replaced by a different product name on the new outer packaging of that medicinal product, the parallel importer uses in the course of trade a sign identical with that mark, within the meaning of Article 9 (2) (a) of Regulation 2017/1001 and Article 10 (2) (a) of Directive 2015/2436, in relation to the imported medicinal products which he or she wishes to place on the market of a Member State. The Court emphasised that the repackaging of those medicinal products in new outer packaging is liable to affect the functions of the trademark and, therefore, the proprietor may have a legitimate interest in opposing it. The Court stressed that that new outer packaging or label must not be defective, of poor quality, or untidy.[26] Moreover, a repackaged pharmaceutical product could be presented inappropriately and, therefore, damage the trademark's reputation in particular where the packaging or label, while not being defective, of poor quality or untidy, is such as to affect the trademark's value by detracting from the image of reliability and quality attaching to such a product and the confidence it is capable of inspiring in the public concerned.[27] The Court remarked that, according to the that rule, a presentation of a product which does not enable normally informed and reasonably attentive consumers, or enables them only with difficulty, to ascertain whether the product originates from the proprietor of the trademark or an undertaking economically linked to him or her or, on the contrary, originates from a third party, adversely affects the function of indicating the origin of the mark.[28] The labelling on the packaging may include the name of the parallel trader's company. In such a situation, consumers, who may not be aware of the existence of parallel trade, may even think that this manufacturer is a parallel trader. This is why reaffixing the proprietor's trademark specific to a medicinal product to the new outer packaging of that product, without reproducing on that packaging the other

26 See Judgment of the Court of 26 April 2007, Boehringer Ingelheim and Others, § 40 and 43.

27 Ibidem.

28 Judgment of the Court of 8 July 2010, Portakabin, C-558/08, ECLI:EU:C:2010:416, § 34.

trademarks and/or the other distinctive signs which appeared on the original packaging of that medicinal product, adversely affects the function of indicating the origin of the mark. The Court's jurisprudence to date has indicated that a trademark holder may counteract the repackaging of products if this is likely to damage the reputation of the trademark placed on that product. What is new is the highlighting that – as far as the repackaging of medicinal products is concerned – the key functions of a trademark include, particularly, the essential function of indicating the product's origin. However, these functions are not limited to the essential function of the mark, which is to guarantee to consumers the origin of the product or service, but they also cover the other functions of the mark, such as, in particular, that of guaranteeing the quality of the product or service, or those of communication, investment or advertising.[29]

Conclusions

The reasons that countries or regions allow or prevent parallel importing are not exclusively a matter of legal rules. Rather, there are economic considerations that determine and shape the legal rules.[30] The issues that are the subject of the judgment are related to the functions of trademarks. In the course of the evolution of trademark law, there has been a shift away from the close connection of a trademark with an enterprise towards the distinctive function of the mark.[31] K. Szczepanowska-Kozłowska indicates that a trademark is a symbol of a product.[32] The importance of this function is also recalled in the commented judgment. This means that the repackaging of medicinal products in new outer packaging is liable to affect the functions of the trademark and, therefore, the proprietor may have a legitimate interest in opposing it. Indeed, it appears that the Court has accepted the approach taken by the manufacturers of original medicinal products. It should be remembered that they invest heavily in the development and implementation

29 See Judgment of the Court of 25 July 2018, Mitsubishi Shoji Kaisha and Mitsubishi Caterpillar Forklift Europe, C-129/17, ECLI:EU:C:2018:594, § 34 and the case-law cited.

30 S. Frankel, *The Dynamic and Unsettled Evolution of Parallel Importing*, Zeszyty Naukowe Uniwersytetu Jagiellońskiego. Prace z Prawa Własności Intelektualnej 2017, no. 3, p. 29.

31 See further: Ł. Żelechowski, *Funkcje znaku towarowego a naruszenie prawa ochronnego na znak towarowy (cz. I)*, Przegląd Prawa Handlowego 2015, no. 5, pp. 5–6; R. Skubisz, *Znaki towarowe – ewolucja przedmiotu ochrony prawnej*, Przegląd Prawa Handlowego 2008, no. 12, p. 17.

32 K. Szczepanowska-Kozłowska, *Wyczerpanie praw własności przemysłowej. Patent i prawo ochronne na znak towarowy*, Warszawa 2003, p. 69.

of new medicinal products. It is also the matter of public interest to protect the interests of these manufacturers because it can encourage them to invest in creating new products.

Also, the Court agreed with the Advocate General that a parallel importer cannot rely on a general presumption of consumer resistance to relabelled medicinal products whose anti-tampering devices have been replaced. I also agree with this statement. Although the requirements of the Medicines Directive and the FMD mean that the parallel importers of pharmaceutical products will have to open the original outer packaging of the products, which may leave visible traces of the packaging being opened, this does not automatically mean that an equivalent anti-tampering device cannot be applied by the parallel importer. Also, if it was objectively possible to relabel the product, rather than repackage it, and still be compliant with the Medicines Directive and the FMD, then the proprietor would be entitled to enforce their rights against the repackaging. Then, the importers of pharmaceutical products wouldn't be able to treat the provisions of the FMD as an automatic right to repackage. They will need to provide specific reasons why it is necessary to repackage the product, and why they could not simply replace the security features of the packaging with new security features of equivalent effect.

The crucial thing is to balance, on the one hand, the basic function of the trademark and, on the other hand, maintain effective access to the market of the importing Member State. However, the arguments regarding the effectiveness of the fight against the counterfeiting of medicinal products, which provided the basis for adopting new regulations of the FMD, cannot be regarded as a sufficient argument to limit the rights of holders. Taking the above-mentioned into account, even if complying with the directives will leave visible traces that the packaging had been opened, this does not necessarily mean that the importers' access to the market will be hindered.

The judgment under review is largely based on previous case law of the Court. It is not out of the ordinary. With that in mind, the view has so far been advanced in the doctrine that the Court has focused excessively on the problem of ensuring maximum facilitation of the free movement of goods. This has weakened the trademark protection.[33] This time, the Court tended to favour the arguments of the original medicine manufacturers.

It should be stressed that, despite the efforts made at EU level to harmonise the safety features for medicinal products as much as possible, the question whether

[33] M. Roszak, *Handel równoległy produktami leczniczymi w prawie unijnym. Granice swobody przepływu towarów na rynku farmaceutycznym*, Warszawa 2014, p. 210.

traces left by the original safety seal can provoke a strong reaction from consumers. It also should be emphasised that, according to the Court, any national legislation imposing full repackaging cannot curtail a trademark owner's rights. It is also an important indication for Polish lawmakers. Besides, the commented judgment will be also important in respect to the application of Article 155 of Act of 30 June 2000 – Industrial Property Law.[34]

The commented judgment still leaves the assessment in this matter for the national courts. It means a certain degree of uncertainty for parallel traders. As a result, regardless of whether there are anti-tampering device traces, parallel importers still need to prove in a concrete manner that it is objectively necessary to rebox before being allowed to do so. The fact that the opening of the original packaging and the replacing of the original anti-tampered device leaves visible or tangible traces does not amount to objective necessity to re-box the product. Although we can probably expect further judgments of the Court making the rules set out by this judgment more specific, the commented judgment is a sensible interpretation of the provisions of the directives, which protects the rights of manufacturers of original products, without unduly restricting the principle of free movement of goods.

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