ISSN 2308-0361

TRADEMARK LAW ISSUES RELATED TO REPACKAGING OF PHARMACEUTICAL PRODUCTS IN THE EUROPEAN UNION

Ольга Ямпольська (Olha Yampolska),
юрист відділу товарних знаків патентно-юридичної фірми KATZAROV (м. Женева), магістр Мюнхенського центру права інтелектуальної власності при Інституті ім. Макса Планка, магістр міжнародного та європейського права Женевського університету,
аспірантка (PhD) Женевського університету

Питання права товарних знаків, пов'язані з перепакуванням лікарських засобів у Європейському Союзі. Стаття присвячена проблемі перепакування лікарських засобів при їх паралельному імпорті в межах ЄС, причиною якого є різний рівень цін на лікарські засоби в країнах-членах ЄС. Для паралельного імпорту лікарських засобів потрібне отримання відповідного дозволу в країні-імпортері. Оскільки в законодавстві країн-членів ЄС у сфері паралельного імпорту фармацевтичних препаратів можуть міститися відмінні одна від одної вимоги, в багатьох випадках необхідне перепакування лікарських засобів паралельним імпортером. У цій статті автор з'ясовує, в яких випадках таке перепакування є порушенням прав власників товарних знаків у ЄС.

Ст. 7 Директиви № 2008/95/ЕС «Про зближення законодавств держав-членів щодо товарних знаків і знаків обслуговування» від 22.10.2008 року встановлює принцип регіонального вичерпання прав у ЄС: власник товарного знака не може забороняти його використання для товарів, які під цим знаком були введені в торговий обіг у Співтоваристві власником або за його згодою (п. 1), крім випадків, коли для власника існують правомірні підстави заперечувати подальший збут товарів, зокрема, якщо після введення товарів у торговий обіг їх стан змінився або погіршився (п. 2).

Виняток, що міститься в п. 2 вищевказаної статті Директиви, часто використовувався власниками товарних знаків у ЄС для можливої заборони перепакування лікарських засобів. Це призвело в 1974–2011 роках до появи цілої низки складних для тлумачення рішень з цього приводу, винесених судовими інстанціями ЄС.

Зокрема, в рішенні Суду ЄС у справі *Bristol-Myers Squibb v Paranova* встановлено п'ять основних умов, за яких власник товарного знака не може забороняти перепакування лікарських засобів: необхідність перепакування для виведення на ринок у країні-імпортері; відсутність упливу перепакування на первинний стан лікарського засобу в упаковці; чітка вказівка на новій упаковці перепаківника та виробника; відсутність ризику завдання шкоди репутації товарного знака чи його власника презентацією перепакованого засоба; сповіщення власника товарного знака імпортером до виведення лікарського засобу на ринок.

Далі в статті автор пропонує системну та детальну класифікацію вимог, які містяться в різних рішеннях судових інстанцій ЄС, відповідно до п'ятьох умов, перерахованих вище, а також вдається до аналізу цих умов.

У результаті проведеного дослідження зроблено висновок про те, що, незважаючи на численні рішення судових інстанцій ЄС з питання перепакування лікарських засобів, залишається занадто багато ризиків нерівномірного застосування прецедентів національними судами держав-членів ЄС. Крім цього, такі рішення здаються більш сприятливими для паралельних імпортерів, аніж для власників товарних знаків, на шкоду захисту прав інтелектуальної власності і, що є набагато серйознішим, на шкоду здоров'ю споживачів.

Ключові слова: товарні знаки, ЄС, лікарські засоби

Introduction. The EU pharmaceutical market has significant differences in drug prices. In fact, based on the EU healthcare policy of keeping drugs available to general public, each EU Member State fixes the prices of drugs sold in its territory which leads to price differences across the EU. These differences, in turn, create business opportunities for parallel importers [1, 783].

Traditionally, the most attractive parallel import markets within Europe were the UK, Scandinavia and Germany, while the predominant exporting markets are Spain and Greece which have generally strict government drug price controls to keep the prices down [2, 489].

In order to parallel import a pharmaceutical product into a country, the importer should obtain an authorization from the relevant national drug control authority to release the product on the market complying with a certain number of conditions (i.e. a parallel import licence). This procedure is similar to obtaining a marketing authorization for placing a drug on the market.

There may exist differing national regulations concerning *e.g.* the box sizes, the number of pills in one box, the information leaflet to be attached to the drug, the language used for the accompanying instructions, etc. The packaging and labelling of pharmaceuticals are strictly regulated on the EU and Member State level. Therefore, in order to import pharmaceuticals in a market that is different from the one where they were originally intended to, their packaging often needs to be altered.

Changes that may be necessary to carry out when importing a pharmaceutical product could generally be grouped into the following categories: *repackaging* — replacing the original container in which the products were sold, and reaffixing the original trademark before marketing; *re-labelling* — replacing the outer packaging and reaffixing another trademark, under which the same product is sold in the importing Member State; *re-boxing* — retaining the original internal packaging but adding a new exterior carton printed in the language of the Member Sate of importation; *over-stickering* — retaining the original internal and external packaging but adding an additional external label printed in the language of the Member State of importation; *de-branding* — selling the goods after their original trademarks have been removed without being replaced [2, 489–490; 3, 12]. Additionally, we may also think of cases where the parallel importer adds an *extra-article* to the product.

The legality, as such, of parallel imports depends on the regime of trademark exhaustion (international, regional, national) that the country of destination applies. Further, even if the regime of exhaustion allows parallel imports, repackaging may still be liable to interfere with the trademark rights of the original manufacturer of the product.

In the EU Article 7(1) of the Directive 2008/95/ECof 22.10.2008 to approximate the laws of the Member States relating to trademarks (TMD) [4] enunciates the principle of regional exhaustion of trademark rights: the owner of a trademark right is not entitled to prohibit its use in relation togoods that have been put on the market in the Community under the trademark by the owner or with his consent (para. 1) unless there are 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 (para. 2). Equivalent provisions exist in the Community Trademark Regulation (Article 13 CTMR).

Thus, in principle, trademark rights of drug manufacturers are regionally exhausted inside the EU and drugs, which have been legally put into commerce in one Member State, can be parallel imported into another Member State and repackaged (which may include reaffix-

ing the mark) even without the authorization of the trademark owner, so long as a specific repackaging does not fall under the exemption of Article 7(2) TMD. The argument advanced by the drug manufacturers that it is only the right to resell which is exhausted under article 7(1) TMD has not been accepted by the Court of Justice of the European Union (CJEU) [5, para. 32–37].

Relevance of the topic. The issue of drug repackaging carried out by parallel traders — the area where the CJEU developed most of its case law on repackaging for parallel importations-continues to be an actual and recurrent topic before the CJEU [1, 783]. Drug manufacturers strongly oppose repackaging as it can break the link between themselves, their product and their trademark [6, 513]. Since the very first CJEU judgement on the repackaging of pharmaceuticals rendered in 1974 in the Case 16/74 *Centrafarm v Winthrop*, national courts, guided by the CJEU, have been moving towards establishing common practice on this issue and a single comprehensive approach. The CJEU has responded with rulings that are rather complex and at times, create more questions than answers [7, 721]. Even though certain CJEU judgements seemed to crystallize the conditions justifying parallel importations of repackaged products, the so-called pharmaceutical repackaging saga still continues and the most recent CJEU judgement dates 2011[1].

The whole generation of complex legal decisions regarding repackaging and the abundance of conditions provided for in this field set out the **aim** of this research which is to systematically present and discuss the relevant case law applicable in the European Union.

Main part. In the landmark case *Bristol-Myers Squibb v Paranova* the CJEU interpreted Article 7(2) TMD and laid down that a trademark owner could not oppose the subsequent marketing of a repackaged product if five cumulative [8, para. 60] conditions were fulfilled [5, para. 79]:

1) repackaging is *necessary* to market the product in the country of importation (i.e. the exercise by the owner of its trademark rights, having regard to the marketing system he has adopted, should not contribute to the artificial partition of the markets between Member States);
2) it does not affect the *original condition* of the product inside the packaging;
3) the new packaging clearly states the *repackager* of the product and the name of the *manufacturer*;
4) the presentation of the repackaged product is not likely to damage the *reputation* of the trademark or its owner;
5) the importer gives *notice* to the trademark owner before the repackaged product is put on the market.

[1] List of all cases in chronological order: Case 16/74 *Centrafarm BV et Adriaan de Peijper v WinthropBV* (31.10.1974), Case C-102/77 *Hoffman La Roche v Centrafarm* (23.05.1978), Case C-3/78 *Centrafarm BV v American Home Products Corporation* (10.10.1978), Case C-1/81 *Pfizer Inc. v Eurim-Pharm GmbH* (03.12.1981), Joined Cases C-427/93, C-429/93 and C-436/93 *Bristol-Myers Squibb* (11.07.1996), Case C-232/94 *MPA Pharma GmbH v Rhône-Poulenc Pharma GmbH* (11.07.1996), Joined Cases C-71/94, C-72/94 and C-73/94 *Eurim-Pharm Arzneimittel GmbH v. Beiersdorf AG and Others* (11.07.1996), Case C-379/97 *Pharmacia & Upjohn SA v Paranova A/S* (12.10.1999), Case C-443/99 *Merck, Sharp & Dohme GmbH v Paranova Pharmazeutika Handels GmbH* (23.04.2002), Case C-143/00 *Boehringer Ingelheim KG and Boehringer Ingelheim Pharma KG and Others v Swingward Ltd and Others* (23.04.2002), Case E-3/02, *EFTA Court, Paranova AS v Merck & Co., Inc. and Others* (08.07.2003), Case C-348/04, *Boehringer Ingelheim KG and Others v Swingward Ltd and Others* (incl. Dowelhurst) (26.04.2007), Case C-276/05 *The Wel come Foundation v Paranova* (09.10.2008), Joined Cases C-400/09 and C-207/10 *Orifarm A/S and Others v Merck & Co. Inc. and Others* (28.07.2011).

As regards various types of repackaging, according to the CJEU, the concept of repackaging includes *relabeling* (in fact, overstickering), *i.e.* attachment of an additional external label to the original packaging of the imported product without altering the same [8, para. 28, 31–32]. Therefore, the abovementioned five conditions apply to both re-boxing of the product in a new package and to over-stickering [8, para. 32].

The first BMS criterion (necessity test) serves to establish whether the parallel importer is, as a matter of fact in a given case, entitled to repackage the product, while the remaining four conditions determine the framework for the exercise of this right so that the legitimate interests of the trademark owner are safeguarded [9, para. 41].

The CJEU has expressly stated that the *burden of proof* of these conditions lies with the parallel importer [8, para. 52] with, however, certain nuances of application with respect to the 2nd and the 4th conditions where the standard of proof is somewhat lower.

1. Necessity. Imagine a situation where the trademark owner places an identical pharmaceutical product on the market in several EU Member States using various types of packaging and the parallel importer cannot market the product in one Member State in the packaging used in another one because of national regulations. In this case, exercise by the owner of its trademark rights would, in theory, contribute to the *artificial partition* of the markets between Member States [5, para. 52]. That means that the trademark owner may prohibit parallel importation of repackaged products only if the repackaging was not *necessary* in order to market the product in the Member State of importation [5, para. 56]. The condition of necessity is satisfied if, without repackaging, effective access to the markets of the Member State of importation is hindered [10, para. 43–44] by "the conduct of the trademark proprietor, and factual or legal trade barriers" [9, para. 44].

The importer is not required to demonstrate that, "by putting an identical product on the market in varying forms of packaging in different Member States, the trademark owner *deliberately sought to partition* the markets between Member States" [5, para. 57]. By using the term "artificial" the CJEU intended to stress that the trademark owner may always rely on his rights to oppose distribution of the repackaged goods each time it is justified by the need to safeguard the essential function of the mark, in which case the partitioning cannot be considered artificial [5, para. 57]. Thus, the CJEU imposes *objective* interpretation of the necessity condition by national courts in the light of the circumstances prevailing at the time of marketing in the importing Member State [10, para. 45–46].

According to the CJEU, the condition of necessity will *not* be satisfied if marketing the product in the country of destination is possible a) by simply affixing to the original packaging new labels in the language of the Member State of importation[2], or b) by adding new user instructions or information in the language of the Member State of importation, or c) by replacing an additional article not capable of gaining approval in the member state of importation with a similar article that had obtained such approval [5, para. 55]. Another example of absence of necessity would be the case when,by repackaging the products, the parallel importer only attempts to secure a commercial advantage (e.g. charging higher prices, making products more attractive, increasing sales figures, etc.) [10, para. 44; 11, para. 39].

[2] I. e. over-stickering. This is, however, limited by the CJEU's considerations with respect to possible strong resistance to relabelled pharmaceuticals on a given market (see below).

Still, in case there exists on the market or its substantial parta strong resistance from a significant proportion of consumers to relabelled drugs, their repackaging cannot be only explained by the attempt to secure a commercial advantage but rather by achieving an effective market access [12, para. 31] which complies with the objective necessity requirement [12, para. 33]. However, any resistance to relabelled drugs is not automatically sufficient to make repackaging necessary; resistance should be so strong that, without repackaging, the access to the market in the importing country would be hindered [12, para. 30]. The factual circumstances should be determined in each case by national courts [12, para. 32].

Nevertheless, it remains unclear how a decision could be taken as to whether there is a strong enough resistance, how to evaluate a significant proportion of consumers and what is the identity of these consumers (i.e. patient and/or pharmacists) [13, 501–502 ; 7, 740]. The so-called "consumer resistance test" appears to be rather disconnected from the realities of the market [13, 501–502]. Parallel importers could envisage collecting consumer data (e.g. conducting consumer surveys) showing that repackaging is necessary to overcome consumer resistance to relabelled products, i.e. conduct consumer surveys [7, 746] which are however quite expensive.

The CJEU has ruled that, conversely, repackaging passes the threshold of the necessity test if, inter alia, without repackaging marketing of the drug in the Member State of importation is impossible because of a) a rule authorizing packaging only of a certain size or a similar national practice, b) sickness insurance rules making the reimbursement of drugs dependent on the size of their packaging, or c) well-established medical prescription practices based, *inter alia*, on standard sizes recommended by professional groups and sickness insurance institutions [5, para. 53].

It should be observed that the necessity test concerns only the mere fact of repackaging of the product, as well as the choice between re-boxing and overstickering, and not the manner or style in which it has been repackaged [8, para. 38–39]. The presentation of the repackaged product may be assessed only against the condition of avoiding damage to the reputation of the trademark or its owner [14, para. 29] as long as the repackaging itself proves necessary.

There is no objective difference between reaffixing the same trademark after repackaging and replacing the original mark by another one (under which the drug is sold by the trademark proprietor in another Member state) [10, para. 37] because in both cases there is use by the parallel importer of a trademark which does not belong to him [10, para. 38] and the condition of necessity should also objectively apply to replacement of the trademark used in the exporting Member State. Such replacement may, for instance, be necessary where a consumers' protection rule prohibits use in the Member State of importation of the trademark used in the Member State of exportation on the ground that it is liable to mislead consumers [10, para. 43].

The burden of proving necessity lies with the parallel importer, who is obliged to provide the trademark owner with sufficient and necessary information enabling the latter to determine whether repackaging is necessary [14, para. 37]. Information to be furnished by the parallel importer must include the *disclosure of the exportation Member State* only in case when without disclosure the trademark owner would be prevented from evaluating the need to repackage [14, para. 35].

2. Effect on the original condition of the product. The CJEU has expressly limited the application of this condition to the product inside the packaging [5, para. 58]. The trademark owner may oppose repackaging if there is a real risk

that the product inside the package is exposed to tampering or to influences affecting its original condition, taking into account the nature of the product and the method of repackaging [5, para. 59].

In particular, the CJEU found that the condition of the product is not automatically affected in cases of: a) marketing of the product in a double packaging and the repackaging only affects the external packaging, leaving the internal packaging intact [15, para. 10]; b) replacing the outer packaging without touching the internal one so thatthe original trademark affixed by the owner on the internal packaging be visible through the new external wrapping [16, para. 10]; c) inspection of the repackaging by a public authority for the purpose of ensuring that the product was not adversely affected [15, para. 10]; d) removal of blister packs, flasks, phials, ampoules or inhalers from their original external packaging and their replacement in new external packaging [5, para. 61]; e) fixing of self-stick labels on the inner packaging of the product (e.g. on flasks, phials, ampoules or inhalers) [5, para. 64]; f) addition to the packaging of new user instructions orinformation in the language of the Member State of importation [5, para. 64]; g) insertion of an extra article from a source other than the trademark owner (e.g. a spray) [5, para. 64, 79]; h) insertion in the external packaging of a leaflet containing information of the pharmaceutical product [16, para. 12].

In this manner, the CJEU has introduced a presumption of absence of *direct* affectation of the product's condition in the above-mentioned situations [3, 13]. Such activities may, nevertheless, in practice present danger to public health because they are prejudicial to the traceability and quality of drugs [17, 12].

The original condition of the product inside the packaging might be *indirectly* affected where, for example: a) the external or inner packaging of the repackaged product (or a new set of user instructions or information) either omits important information or gives inaccurate information concerning the nature, composition, effect, use or storage of the product[5, para. 65]; b) an extra article inserted into the packaging by the importer and designed for the ingestion and dosage of the product does not comply with the method of use and the doses envisaged by the manufacturer [5, para. 65].

In any case it is for the national court to assess the above-mentioned facts (with respect to both direct and indirect affectation of the product's condition) by making a comparison of the repackaged product with a product marketed by the trademark owner in the Member State of importation [5, para. 66]. The parallel importer may be requested to provide additional information facilitating the comparison; this information should be taken into consideration if it does not contradict the one provided by the trademark owner in the importing Member State [5, para. 66].

As it is the case with the rest of the conditions, it is for the parallel importer to prove that the original condition of the product is not affected by repackaging. However, it is sufficient to furnish evidence leading to the "reasonable presumption" that the requirement has been met [8, para. 53]. Practically, this appears relatively easy to fulfil [18, p. 19].

3. Identification of the manufacturer and importer. This requirement isaimed at protection of the trademark owner's interest that the consumer or end user should not be led to believe that the trademark owner is responsible for the repackaging [5, para. 70].

The indication must be clearly shown on the external packaging of the repackaged product [15, para. 12; 16, para. 11]. This implies that the identification should be printed "in such a way as to be understood by a person with normal eyesight, exercising a normal degree of attentiveness" [5, para. 71].

It is not necessary to make a further express statement on the packaging that the repackaging was carried out without the authorization of the trademark owner as such a statement could be viewed as an indication of a not entirely legitimate product [5, para. 72].

Further, if the parallel importer has added to the packaging an extra article from a source other than the trademark owner, he should indicate the origin of this article so as to avoid creating the impression that the trademark owner is responsible for it [5, para. 73].

In the recent case of 2011, the ECJ held that the trademark owner cannot oppose parallel importations of a repackaged product just because the new packaging indicates as the repackager not the undertaking which actually carried the repackaging further to the parallel importer's instructions, but the undertaking holder of the marketing authorisation which has instructed the repackaging and which assumes liability for it [19, para. 36]. In particular, the undertaking indicated as the repackager is responsible for any damage caused by the entity which actually repackaged the products, even if the latter acted contrary to the instructions [19, para. 30].

4. Protection of the reputation of the trademark and its owner. Generally, in assessing the risk of damage to reputation of the trademark and its owner, account should be taken of the nature of the product and the market to which it is intended [5, para. 75]. The CJEU has stated that pharmaceuticals are "a sensitive area in which the public is particularly demanding as to the quality and integrity of the product, and the presentation of the product may indeed be capable of inspiring public confidence inthat regard" [5, para. 76]. Therefore, defective, poor quality or untidy carton or label can be opposed by the trademark owner [5, para. 76].

The CJEU has drawn a distinction between products sold to hospitals and those sold to consumers through pharmacies. In hospitals drugs are administered to patients by medical professionals and in this case the presentation of the product is less important [5, para. 77]. However, the presentation of the product is more important to consumers, even though prescription of drugs by a doctor gives them more confidence in the quality of the product [5, para. 77]. Still, we do not see any objective reason to justify such distinction as presentation of drugs should be viewed as of equal importance to all consumer circles.

The CJEU has clarified the scope of this condition by giving the following examples of activities which are, in principle, liable to damage the trademark's reputation: a) failing to affix the trademark to the new exterior carton ("de-branding"); b) applying the parallel importer's own logo or a house-style, or a get-up used for a number of different products ("co-branding"); c) positioning the additional label which wholly or partially obscures the owner's trademark; d) failing to state on the additional label that the trademark belongs to the owner; or e) printing the name of the parallel importer in capital letters [8, para. 47]. These are however mere examples, as the reputation of the trademark or its owner may also be damaged if, due to the presentation of the repackaged product, the trademark's value is affected 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" [8, para. 41–43].

The assessment of whether any of the above activities actually damages the trademark's reputation is a question of fact and is carried out by national courts on a case-by-case basis [8, para. 46] which might lead to a further litigation and divergence of opinion. There is no requirement of minimum intervention with respect to the presentation of the new packaging [14, para. 27]. This, however, may sound contradictory to the principle of proportionality and appears

more favourable to parallel importers than to trademark owners [17, 13].

Apart from the packaging itself, the damage to the reputation of the mark or its owner may be caused by "circumstances outside the actual package design such as advertisements" promoting the repacked product [9, para. 52].

As regards the burden of proof, here again the parallel importer may limit itself to establishing a "reasonable presumption" that the condition relating to the reputation of the trademark owner and its proprietor is fulfilled [8, para. 53]. If the importer furnishes such initial evidence, the burden of proof shifts to the trademark proprietor as he is best placed to assess whether the repackaging is likely to damage his reputation and that of the trademark [8, para. 53].

5. Prior notice. The fifth BMS condition was first established by the CJEU in the *Hoffman-La Roche* case [15, para. 14] and further clarified in the *Bristol-Myers Squibb* and other cases.

The parallel importer must give prior notice to the trademark owner of the repackaged products being put on sale [15, para. 14; 5, para. 78]. The owner may also require a specimen of the repackaged product before it goes on sale, so that he can check that neither the original condition of the product is directly or indirectly affected by repackaging, nor his reputation risks being damaged [5, para. 78]. This requirement also provides the trademark owner with a better possibility of protecting himself against counterfeiting [5, para. 78]. Trademark owners should react within a reasonable time to the notice and both parties are supposed to make sincere efforts to respect each other's legitimate interests [11, para. 62].

The CJEU has stressed that the requirement to give notice must be fulfilled "in any event" and by the parallel importer itself, even if the trademark owner might receive notification from other sources such as the authority issuing parallel import licences to the importers [11, para. 58, 63–64].

The notice should be given with a reasonable time before the sale of the product so that the trademark owner can carry out necessary examination of the product [11, para. 66]. The CJEU has held that a period of 15 working days appears reasonable provided that the parallel importer simultaneously supplies the manufacturer with a sample of the repackaged product [11, para. 67]. This term is only indicative and can be assessed by national courts [11, para. 67]. From our point of view, if the notification is given without sending a specimen of the product, there should be an additional period allowing the trademark owner to request and receive a sample, as was advanced by the EU Commission in one of the cases [11, para. 60].

The failure to give prior notice has as consequence that the parallel importer infringes trademark rights of the owner on the occasion of any subsequent importation of that product, s*o long as the notice is not given* [8, para. 56].

Conclusion. Undoubtedly, clearer framework conditions of drug repackaging legality have been set down in the above-discussed CJEU rulings. However, even after such a high number of legal decisions there appears to be still too much room for national courts to decide, which might lead to non-uniform application of the CJEU's case law across the EU differing from one Member State to another [18, 19]. The CJEU will likely have to address in future a number of issues which still remain unanswered [7, 745]. Further, the CJEU appears to be more favourable to parallel importers than to trademark owners and shows itself too much preoccupied by the free movement of goods within the Community, at the expense of IP rights and, what is more serious, public health [17, 10]. ♦

List of references

1. *Armengod H. The Repackaging of Pharmaceutical Products and Parallel Trade in the EU [Electronic resource] / Héctor Armengod, Laura Melusine Baudenbacher // RAJ Pharma. — 2009. — December — p. 783. — Access mode : http://www.lw.com/.*
2. *Feros A. Free Movement of Pharmaceuticals Within the EU — Should Rights Be Exhausted Regionally?/ Anna Feros // European Intellectual Property Review. — 2010. — No. 32 (10) — P. 486.*
3. *Henin C. Importations parallules de médicaments et droit des marques/ Christophe Henin, Anne-Catherine Maillois-Perroy // Propriété industrielle. — 2007. — September — P. 11.*
4. *Directive 2008/95/EC of the European Parliament and of the Council of 22 October 2008 to approximate the laws of the Member States relating to trademarks (Codified version)[Electronic resource]. — Access mode : http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1402657157294&uri=CELEX:32008L0095.*
5. *CJEU Judgement of 11 July 1996 in Joined Cases C-427/93, C-429/93 and C-436/93 (Bristol-Myers Squibb v Paranova A/S (C-427/93) and C. H. Boehringer Sohn, Boehringer Ingelheim KG and Boehringer Ingelheim A/S v Paranova A/S (C-429/93) and Bayer Aktiengesellschaft and Bayer Danmark A/S v Paranova A/S (C-436/93)) [Electronic resource]. — Access mode : http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=en&numdoc=61993J0427.*
6. *Grassie G. Parallel Imports and Trade Marks: Part 2: the Repackaging Cases / Gill Grassie // European Intellectual Property Review. — 2006. — No. 28(10) — P. 513.*
7. *Bird R. C. Pharmaceuticals and the European Union: Managing Gray Markets in an Uncertain Legal Environment/ Robert C. Bird, Peggy E. Chaudhry // Virginia Journal of International Law. — 2010. — No. 50 (3) — P. 719.*
8. *CJEU Judgement of 26.04.2007 in Case C-348/04 (Boehringer Ingelheim KG and Others v Swingward Ltd and Others (incl. Dowelhurst)[Electronic resource]. — Access mode : http://curia.europa.eu/juris/liste.jsf?language=en&num=C-348/04.*
9. *EFTA Court Judgement of 08/07/2003 in Case E-3/02 (Paranova AS v Merck & Co., Inc. and Others) [Electronic resource]. — Access mode : http://www.eftacourt.int/cases/detail/?tx_nvcases_pi1%5Bcase_id%5D=62&cHash=38eff06431e61d80dc37cb3432278127.*
10. *CJEU Judgement of 12.10.1999 in Case C-379/97 (Pharmacia & Upjohn SA v Paranova A/S)[Electronic resource]. — Access mode : http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=en&numdoc=61997J0379.*
11. *CJEU Judgement of 23.04.2002 in Case C-143/00 (Boehringer Ingelheim KG and Boehringer Ingelheim Pharma KG and Others v Swingward Ltd and Others) [Electronic resource]. — Access mode: http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1402676816242&uri=CELEX:62000CJ0143.*
12. *CJEU Judgement of 23.04.2002 in Case C-443/99 (Merck, Sharp & Dohme GmbH v Paranova Pharmazeutika Handels GmbH) [Electronic resource]. — Access mode : http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1402677814527&uri=CELEX:61999CJ0443.*
13. *Harrold L. Fighting for Pharmaceutical Profits / Lucy Harrold, Naomi Gross // European Intellectual Property Review. — 2002. — No. 24 (10) — P. 497.*

14. *CJEU Judgement of 09.10.2008 in Case C-276/05 (The Wellcome Foundation Ltd v Paranova Pharmazeutika Handels GmbH) [Electronic resource]. — Access mode : http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1402683816301&uri=CELEX:62005CJ0276.*
15. *CJEU Judgement of 23.05.1978 in Case C-102/77 (Hoffmann-La Roche & Co. AG v Centrafarm Vertriebsgesellschaft Pharmazeutischer Erzeugnisse mbH) [Electronic resource]. — Access mode : http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1402681589345&uri=CELEX:61977CJ0102.*
16. *CJEU Judgement of 03.12.1981 in Case C-1/81 (Pfizer Inc. v Eurim-Pharm GmbH)[Electronic resource]. — Access mode : http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:61981CJ0001.*
17. *Chemtob Concé M.-C. La nécessité d'établir des exigences plus strictes pour le reconditionnement des médicaments importés parallèlement/ Marie-Catherine Chemtob Concé/ / Propriété industrielle. — 2009. — September. — P. 10.*
18. *Curley D. Swings and Round Abouts for Brand Owners / Duncan Curley, Shona Harper // Trademark World. — 2007. — No. 198 — P. 18.*
19. *CJEU Judgement of 28 July 2011 in Joined Cases C-400/09 and C-207/10 (Orifarm A/S and Others v Merck & Co. Inc. and Others) [Electronic resource]. — Access mode : http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1402682477516&uri=CELEX:62009CJ0400.*

Надійшла до редакції 27.05.2014 року

О. Ямпольская. Вопросы права товарных знаков, связанные с переупаковкой лекарственных средств в Европейском Союзе. В статье исследованы вопросы права товарных знаков, связанные с параллельным импортом переупакованных лекарственных средств в ЕС. На основе анализа многочисленных решений судебных инстанций ЕС и публикаций по данному вопросу, автор системно классифицирует условия правомерности переупаковки лекарственных средств для их последующего параллельного импорта в границах стран-членов ЕС.

Ключевые слова: товарные знаки, ЕС, лекарственные средства

O. Yampolska. Trademark law issues related to repackaging of pharmaceutical products in the European Union. This article examines trademark law issues related to parallel imports of repackaged medicines in the EU. Further to the analysis of numerous decisions rendered by the EU courts and publications on this subject, the author systematically classifies the conditions applying to legality of drug repackaging-with a view of subsequent parallel imports thereof in the EU Member States.

Key-words: trademarks, EU, pharmacutical products