Counterfeiting and illicit drug sales. Effects on intellectual property rights

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Abstract

The ability of man to be inventive and creative has led to economic development and social progress, but also to the creation of a real danger to his health and life when talking about the counterfeit and falsified drug market[2]*. Ensuring the observance of intellectual property rights is essential worldwide in public health or safety policies, as counterfeiting poses a threat to people. The consequences of medication counterfeiting on health are quite difficult to assess. The methods of counterfeiting and the ways in which such drugs reach consumers are diverse. We are talking about direct sale, import, packaging change (original packaging, but counterfeited drug), falsification of the prospectus or attachment of a leaflet in another language, application of counterfeit (holograms) on packaging, advertisements, on the Internet, by press, fictitious terms of validity. The paper analyzes the national provisions containing regulations related to the sale and counterfeiting of medicines, as well as the European ones in the field, as well as the measures that can be taken to reduce the risk of their use. There are also some examples of this case related to illicit selling and counterfeiting of medicines.*

Keywords*: counterfeiting of medicines, infringement of intellectual property rights, organized crime, public health threat*

JEL Classification: K14, K32, K39

1. Introduction

The usual definition of the verb **to counterfeit** shows that it means *"to reproduce an object, an original preparation for fraudulent purposes, considering it as authentic, to forge"*[3]**.**

Counterfeiting in the field of intellectual property means *the infringement of exploitation rights, infringement of the right to prohibit the use of*

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[2] Law no. 95/2006 on health reform defines the notion of *medicine* in art. 699 „as any substance or combination of substances presented as having properties for the treatment or prevention of diseases in humans; or any substance or combination of substances which may be used or administered to human beings or for the restoration, correction or modification of physiological functions by the conduct of a pharmacological, immunological or metabolic action or for the establishment of a medical diagnosis."

[3] https://dexonline.ro/intrare/contraface/12699, accessed on 06.10.2017.

industrial property rights by a third party, without the authorization or consent of the right holder[4].

Counterfeit goods are defined as "*any commodity, including its packaging, which carries without authorization an identical trademark or which does not differ in its essential aspects from a registered product or service trademark registered for the same type of goods and which, for that reason, violates the rights of the trademark owner; any symbol of a product or service trademark (including logo, label, self-adhesive, brochure, instructions for use or warranty bearing such a symbol), even if presented separately; any packaging bearing counterfeit trademarks"*[5]

Whether we are talking about Law 8/1996 on copyright, Law 64/1991 on patents, Law 84/1998 on trademarks and geographical indications, Law 129/1992 on the protection of industrial designs and models, Law 95/2006 on health reform, Law 11/1991 on combating unfair competition, Law 16/1995 on the protection of topographies of semiconductor products, Law 344/2005 on measures to enforce intellectual property rights in customs clearance, we discover referrals on counterfeiting or counterfeit goods.

The term counterfeiting is used for counterfeit goods or pirated goods, but in a narrow sense we are interested in the violation of intellectual property rights.

There are opinions that, although at first glance, the terms of forged and counterfeit lead us to the same thing, they are different, meaning that the concept of counterfeiting refers to the medicines that are not in compliance with EU law on intellectual and industrial property rights. The terms of counterfeit or pirated are typically identified with fake by the public, and are used to describe illicit activities related to breaking the intellectual property rights (piracy mainly concerns copyright, trademark, patent, drawing, industrial model infringement)[6].

The European Parliament has recommended the adoption of a unitary definition, harmonized at the Community level, of the terms of counterfeiting and piracy.

In this paper we will refer to both situations. Counterfeiting often contains falsifications. Thus, the image of a product and companies investing in these trademarks or patents deteriorates.

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[4] Al. L. Arjoca, *Combaterea contrafacerii medicamentelor în România. O nouă provocare pentru autoritățile române*, Revista Română de Proprietate Intelectuală nr. 2 (27), iunie 2011, p. 131.

[5] A. Lăncrănjan, M. Litvin, M. Pop, *Ghid de investigare a infracțiunilor de proprietate intelectuală săvârșite în mediul digital*, p. 8, the document is available online at http://www.inmlex.ro/fisiere/d_1443/Ghid%20de%20investigare%20a%20infractiunilor%20de%20proprietate%20intelectuala%20savarsite%20in%20mediul%20digital.pdf, accessed on 06.10.2017.

[6] Trade and Counterfeit and Pirated Goods. Maping the economic impact, p. 16, OECD Publishing, Paris, OECD/EUIPO 2016, the document is available online at http://www.keepeek.com/Digital-Asset-Management/oecd/governance/trade-in-counterfeit-and-pirated-goods_9789264252653-en#.WbgOXIqLnUo#page6, accessed on 15.10.2017.

2. Relevant legal regulations and comments

As early as 2006, the Commission warned about the sale of counterfeit medicines on the Internet[7]. There was talk of a medicine against obesity, called *rimonabant*, which was still under evaluation by the European Medicines Agency. This product was to enter the market only after its effectiveness and safety were proved by the Scientific Committee of the Agency. Counterfeiters try to bypass those authorization / licensing paths and regulation by competent authorities. According to a study conducted at that time, approximately 170 drugs were counterfeited, most of them sold via the internet.

Directive 2011/62 / EU[8] of the European Parliament and of the Council (amending Directive 2001/83/EC[9]) dealing with the alarming increase of the sale of fake medicinal products in the EU was published in 2011 and transposed by the Member States in January 2013. It states that *"the illegal sale of drugs to the population through the Internet poses a serious threat to public health, as it can reach the population with fake medicines* (point 21).

A ***false drug*** is in accordance with the Directive, "*any medication for which it is falsely presented*:

- *the identity, including packaging and labeling, the name or composition in respect of any of its ingredients, including excipients and the strength of the ingredients;*
- *the source, including the manufacturer, country of manufacture, country of origin, the holder of the authorization of market introduction; or*
- *the history, including records and documents relating to the distribution channels used".*

According to the same Directive, the Member States may restrict the retail sale only in pharmacies (Decision of 19 May 2009 in the Joined Cases C-171/07 and C-172/07, Apothekerkammer des Saarlandes and Others/Saarland, Rep., 2009, I -4171, paragraphs 34 and 35). It is therefore considered that they should be able to do the same in the case of medicines sold via the Internet (distance selling).

Art.85c par. (3) of Directive 83 provided for the creation of a common logo to be recognized in the European Union and capable of identifying the Member State from which the person is selling the medicine remotely, using the services of the information society. The Implementing Regulation No. 699/2014[10]

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[7] Commission warns about fake drugs on the internet, Brussels, 27 March 2006, The document is available online at http://ec.europa. eu/health/human-use/falsified_medicines/developments_en, accessed on 06.10.2017.

[8] JOUE L 174/74 din 01.07.2011, the document is available online at http://ec.europa.eu/health// sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_ro.pdf, accessed on 06.10.2017.

[9] JO L 311 din 28.11.2001, the document is available online at http://ec.europa.eu/health//sites /health/files/files/eudralex/vol-1/dir _2001_83_cons2009/2001_83_cons2009_ro.pdf, accessed on 20.10.2017.

[10] JOUE L184/5 din 25.6.2014, the document is available online at http://eur-lex.europa.eu/legal-content/RO/TXT /PDF/?uri=OJ: JOL_2014_184_R_0004&from=RO, accessed on 20.10.2017.

of the Commission establishes the design for the common logo for the identification of people offering medicinal products for sale at distance to the public and the technical, electronic and cryptographic requirements for verifying the authenticity of the medicinal product. Thus, the people who would like to buy medicines in the on-line environment will be able to check through this logo the pharmacies accredited in that state for these sales[11].

Each Member State must, in accordance with the Directive, create an Internet site providing information on national legislation applicable to the distance sale of medicinal products through the information society, the supply conditions, the list of people offering medicines meant to be sold at distance, and information on the risks of fake medicinal products sold through the information society. The European Medicines Agency [12] will also create a website that will provide information on EU drug counterfeiting regulations, a site that will have hyperlinks to the national websites mentioned.

Directive 83 also contains a number of provisions on the measures that may be taken by the Member States if they are aware of the marketing of falsified medicinal products. The state competent authority sends a rapid alert notification to all the Member States and to the Member States' supply chains, and if the medicines reach patients, public announcements are urgently made for their recovery.

In 2016, the European Commission published a Delegated Regulation of the Commission (EU) 2016/161, [13] amending Directive 83, which refers to two safety features to be introduced for many medicines meant for the human use (a two-dimensional bar code and a device to protect against any unlawful changes on the packaging). Medicines that will have these two safety features are set out in the Annexes to the Regulation.

Since July 2013, the medicines that are imported into the EU must be accompanied by a written confirmation from the home authority. It must therefore ensure that the standards of good manufacturing practice[14] are equivalent to those existing in the EU[15]. We have here the provisions of Directive 2003/94/EC[16] laying down the principles and guidelines of good manufacturing practice for medicinal products for human use and experimental medicinal products for human use and

[11] Neighboring countries such as Hungary, Bulgaria, Poland, Slovakia, Slovenia have already implemented this logo. Romania has adopted, in this respect, Government Emergency Ordinance 91/2012 for amending and completing some normative acts in the field of health, Official Gazette no. 886 of 27 December 2012.

[12] Established by EC Regulation no 726/2004 of the European Parliament and of the Council of 31 March 2004, laying down the Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, JOUE L136 of 30.4.2004.

[13] JOUE L32/1 din 9.02.2016.

[14] It means that part of quality assurance which shows that the products are constantly controlled according to the quality standards appropriate to their destination (art. 2 point 6 Directiva 2003/94/CE).

[15] art. 4 paragraph 2 Directive 2003/94/CE.

[16] JOUE L262/22 of 14.10.2003.

the provisions of the Commission's delegated EU Regulation 1252/2014 [17] supplementing the 2001 Directive/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for the active substances used in medicinal products for human use.

The investigation of confirmed incidents of falsification of medicinal products should be stored in an archive system (repertoire system) to allow competent authorities to access them in the future. This provision is introduced by the Delegated Regulation 161/2016 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council laying down detailed rules on the safety features which appear on the packaging of medicinal products for human use, point 36. According to Article 18 of the same Regulation, where a manufacturer considers that the packaging of the medicinal product has been illegally modified or the verification of the safety features indicates that the product may not be genuine, the manufacturer does not place the product on sale or distribution and shall immediately inform the relevant competent authorities. Reports may also be generated to enable competent authorities to verify the compliance by the holders of the authorizationto introduce them on the market, manufacturers, distributors, people authorized to release medicinal products, or to investigate incidents involving falsification. (Article 36, point j). The competent national authorities must notify the Commission, using a special form, of medications issued without a prescription that present a risk to be falsified.

An important role in identifying and demonstrating the development and commercialization of counterfeit medicines is provided by drug manufacturers who can do chemical tests (eg spectroscopic and chromatographic analysis), but also the National Medicines Agency which has data on adverse effects and on the existence of authorization to place them on the market.

One way to reduce the risk of the appearance of counterfeit medicines is to use a short distribution circuit, with ownership transfer performed directly from the manufacturer to the pharmacy. In this case, if counterfeit medicines are found, only those in that pharmacy could be withdrawn, not all of that type on the market[18].

The medicines have been on the list of counterfeit products on the Internet for a number of years, but also on the list of products seized in customs clearance operations. [19] In the second situation, the Council adopted a Regulation no. No 1383/2003[20] on combating counterfeiting and piracy applicable to goods infringing an intellectual property right. This regulation clarifies the arrangements and conditions under which customs authorities may intervene in respect of goods suspected of infringing intellectual property rights, including medicines. That act

[17] JOUE L337/1 of 25.11.2014.

[18] Competition Council, Report on the useful investigation for the knowledge of the pharmaceutical sector in Romania, 2016, p. 388.

[19] 12,354 pieces seized between 1 January 2008 and 30 September 2008, the document is available online at http://www.osim.ro /publicatii/editura/TOATE%20MATERIALELE/BULETIN%20DE%20JURISPRUDENTA%20ONLINE/06_DIVERSE/Protejarea%20drepturilor%20de%20proprietate%20intelectuala.pdf, accessed on 20.10.2017.

[20] The document is available online at http://eur-lex.europa.eu/legal-content/RO/TXT/?uri=URISERV%3Al11018c, accessed on 06.10.2017.

was repealed by Regulation No. 608/2013[21] concerning customs enforcement of intellectual property rights.

It says that the customs authorities should have the power to ensure the observance of intellectual property rights. Practically, securing intellectual property rights at borders is an effective way to grant protection to the rightholder. The marketing of such goods, as it is shown in the regulation, could mislead consumers and in some cases could endanger their health. Where the customs authorities have suspicions that the goods under their control infringe intellectual property rights, they may suspend the release of the goods or withhold the goods, and the persons concerned shall prove that they have infringed the intellectual property right.

We can also exemplify some internal cases.[22]

The Law on Pharmacy 266/2008[23] republished states in art. 2 point 4 that "*the retail distribution of medicinal products is made only through pharmacies, local distribution centers and drugstores."* From the interpretation of this paragraph, corroborated by the following, it follows that the sale on the Internet of at least medicinal products requiring prescription is forbidden in our country. What is interesting, however, is not expressly mentioned in our legislation. That is why the number of online drug vendors has increased considerably lately. There have been several attempts to modify the law to address this issue.

The proposal (made by the College of Pharmacists of Romania) to amend the Law on Pharmacy has established that the sale or release of prescription drugs through information society services is forbidden.

Also, the legislative proposal for completing and amending the Law on Pharmacy has attempted to establish a legal framework for the sale of medicines in the on-line environment. This would only be allowed for community pharmacies and drugstores authorized under the conditions established by order of the Minister of Health. It was proposed that the inspection of the supervision of the drug trade in the on-line environment be carried out by the existing structures within the Ministry of Health.

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[21] JOUE L 181/15 din 29.06.2013, the document is available online at https://www.customs.ro/assets /pdf/infopublice/Reg%20608% 20din%202013_ROM.pdf, accessed on 20.10.2017.

[22] "*On March 14, 2008, at the Otopeni customs office, as a result of the risk analysis, the customs workers discovered 6,000 pieces of VGR 100 PFIZER medicines proven to violate the ownership rights of VGR 100 trademark owners. The goods were originally from China and were intended for a natural person domiciled in Buzău. The customs authority notified the owner of the intellectual property right in accordance with art. 9 of the Law no. 344/2005. The owner of the intellectual property right informed in writing the Customs Authority, according to art.10 of the Law no. 344/2005 that the detained goods infringe the intellectual property right of VIAGRA and are to be destroyed ",* the document is available online at http://www.osim.ro/publicatii/editura/TOATE MATERIALELE/BULETIN DE JURISPRUDENTA ONLINE/06_DIVERSE/Protejarea drepturilor de proprietate intelectuala.pdf, accessed on 28.10.2017 *"On 16.02.2009 at D.J.A.O.V. Bihor, as a result of the risk analysis, the customs workers discovered 1,960 pieces of medicines proven to violate the intellectual property rights of the Viagra trademark. The goods were originally from China, the estimated value of the goods being 58,800 EURO", in the Newsletter, no. 2/2009, Intellectual Property Rights,* the document is available online at *https://www.customs.ro/assets/pdf/info-publice/buletin_2_2009.pdf*, accessed on 28.10.2017.

[23] Official Gazette no 85/2 February 2015.

The justification for introducing this possibility of selling drugs on the Internet only through specialized institutions is also related to the increase of revenues to the state budget by eliminating the illegal activities that are done in this respect[24].

The Legislative Council gave a negative opinion to this proposal[25], justifying the need to take into account the provisions of Directive 2001/83 / EC laying down the conditions under which medicinal products can be sold remotely, to the public, through the information society. Similarly, in the same proposal, it is required the need for campaigns to inform citizens about the dangers they are exposed to when buying medicines from the Internet. Also, the proposal to sanction by suspending the site is not clear enough, not specifying the length and procedure for enforcement of this sanction. Any change to the law in this respect must be correlated with the EU provisions, especially of the Directive that we have referred to.

In a file settled by the Iaşi Court of Appeal in 2010, both the creator of the site and those who marketed the medicines via the Internet were sanctioned for the sale of counterfeit medicines through a website (suspended sentence and payment of damages to one of the owners of the trademark of counterfeit medicines).[26]

Law no. 95/2006 on health reform sets the sanction *in Art. 834 the counterfeiting or putting into circulation of drugs without observing the law of imprisonment from 3 months to 3 years. If counterfeited medicines or put into circulation without observing the provisions of this title are injurious to health, the offense is punished by imprisonment from one year to 8 years. If these facts resulted in the illness or aggravation of a person's illness, the punishment shall be imprisonment from 2 to 8 years of age, and if death has resulted, the sentence shall be imprisonment from 5 to 15 years.*

The criminal action will start automatically.

In order to obtain the marketing authorization for a medicinal product for human use, both time and money is needed. Some substances must first be patented, for othersthe trademark must be promoted. Thus, we are talking about both the infringement of the right to the patent and the infringement of the trademark right.

The **counterfeiting industry** is not of a recent date.[27]

Trademark counterfeiting and counterfeiting of medicinal products are considered to be similar in particular because *there is counterfeiting of the drug through reproduction, regardless of its circulation, which is a distinct act*[28].

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[24] Pesentation of Reasons, Draft amendment to the Law on Pharmacy, the document is available online at http://www.cdep.ro/ proiecte/2015/800/00/4/em1015.pdf, accessed on 28.10.2017.

[25] The document is available online at http://www.cdep.ro/proiecte/2015/800/00/4/cl1015.pdf, accessed on 28.10.2017.

[26] Criminal Decision no 43/18.03.2010, criminal section, Iaşi Court of Appeal, in Al. L. Arjoca, *op. cit.*, p. 141.

[27] For details on the history of trademark counterfeiting, see V. Roş, A. Livădariu, *Probleme privind acțiunea în contrafacerea mărcilor și evaluarea prejudiciului*, 2015, the document is available online at https://www.juridice.ro/357644/probleme-privind-actiunea-in-contrafacerea-marcilor-si-evaluarea-prejudiciului.html, accessed on 28.10.2017.

[28] Al. L. Arjoca, *op. cit.*, p. 132.

According to **Law 84/1998 on trademarks and geographical indications**, art. 90, the counterfeiting of a trademark constitutes an offense, therefore it is a criminal offense and it is punished by imprisonment from 3 months to 2 years or by fine.

"Counterfeiting a trade mark means making or using, without the consent of the proprietor, by third parties, in the course of trade, a sign which is identical with the trademark for goods or services identical to those for which the trademark has been registered; which, given the identity or similarity with a trademark or given the identity or similarity of the goods or services to which the sign is affixed with the goods or services for which the trademark was registered, would give rise to a likelihood of confusion on the part of the public, including the association of the trademark with the sign; which is identical with or similar to the trademark for goods or services other than those for which the trademark is registered when it has acquired a reputation in Romania and whether by using the sign without due cause could take advantage of the distinctive character or the reputation of the trademark or the use of the sign would cause the trademark owner an injury".

The holder of the breached industrial property right may choose between pursuing the criminal action for counterfeiting, punishing the perpetrator, within which to exercise the civil action for compensation for the damage suffered, or to exercise separately the civil action for counterfeiting[29]. Counterfeiting is being considered by some of our specialists as a type of action for civil liability, with a legal regime derogating from that established by common law, while others consider it to be out of the question.[30] In fact, the occurrence of a damage is not a constituent element of counterfeiting offenses, hence the evidence of the existence and extent of the damage falls to the party exercising the civil action.

Relevant in this area are also the 2015/2436 Directive on the approximation of the laws of the Member States relating to trademarks[31] and Regulation No. 2015/2424 on the European Union trademark.[32] The Directive states: *"Counterfeiting a trademark can be established only if it is found that the trademark or the counterfeit sign is used in the course of trade to differentiate the goods or services. The use of the sign for purposes other than the differentiation of goods or services should be governed by national law.*[33]*"" Counterfeiting an EU trademark should also include the use of a sign as a trade name or a similar*

[29] S. Florea, *Acțiunea în contrafacere în dreptul intern (II). Reglementarea și natura juridică a acțiunii în contrafacere,* the document is available online at https://www.universuljuridic.ro /actiunea-contrafacere-dreptul-intern-ii-reglementarea-si-natura-juridica-actiunii-contrafacere/, accessed on 28.10.2017.

[30] S. Florea, *Acțiunea în contrafacere în dreptul intern (III). Specie a acțiunii în răspundere civilă delictuală. Acțiune în revendicare* the document is available online at https://www.universuljuridic. ro/actiunea-in-contrafacere-in-dreptul-intern-iii-specie-a-actiunii-in-raspundere-civila-delictuala-actiune-in-revendicare/, accessed on 28.10.2017.

[31] JOUE L336 of 23.12.2015.

[32] JOUE L341 of 24.12.2015.

[33] For details on these acts, see S. Florea, *Impactul reformei dreptului european al mărcilor asupra legislației române în materie*, Revista Română de Dreptul Proprietății Intelectuale nr. 2(47), Ed. Universul Juridic, București, 2016, pp. 112-130.

designation, as long as the use is intended to differentiate the goods or services ", the Regulation mentioned above states.

Over time, there has been the problem that pharmaceutical products are not protected by **patents** because there is no originality from those who extract them. In many countries like Germany, France, Switzerland, Japan, these were not patented until around the 1960s-1970s. Before the TRIPS Agreement, most developing countries did not offer patents to pharmaceutical products[34].

WTO - World Trade Organization (GATT - The General Agreement on Tariffs and Trade) has succeeded in creating a link between trade and intellectual property through the TRIPS[35] (Trade Related Aspects on Intellectual Property Rights) agreement. *Trade related Aspects of Intellectual Property – TRIPS*[36] is an integral part of the World Trade Organization (WTO) Agreement, which was concluded at Marrakesh in 1994. Annex IC[37] of the Agreement provides minimum standards for certain intellectual property regulations (including the trade with counterfeitproducts). Practically, this Agreement has a role in the globalization of regulations in this area (all signatory states must comply with these rules).

By virtue of this agreement, the prerequisites for the access of states to new patents protected by the invention patent and to the generic ones have been created. [38] The agreement prohibits in Article 27.1 the discrimination on the "rights conferred by patents between imported and locally produced products".[39]

Article 46 of Law 64 of 1991 on ivention patents[40] refers to compulsory licenses that may be authorized in certain situations by the Tribunal of Bucharest. And internationally, when the owners of intellectual property rights are in conflict with the public interest, these mandatory licenses are invoked. Due to the fact that the manufacturers, the intellectual property holders keep very high prices for vital medicines, counterfeit products make it much easier on the market[41]. Many pharmaceutical companies holding patent rights for medicines claim that such compulsory licenses or the approval of parallel imports are contrary to the TRIPS

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[34] Ha-Joon Chang, *The Wicked Samaritans. The Myth of Free Exchange and the Secret History of Capitalism*, Polirom, Bucharest, 2012.

[35] This agreement has diminished the distance between the way world states protect intellectual property rights and has subjected them to common international rules, in O-M. Florescu, *The TRIPs Agreement, Important Multilateral Agreement WTO Treaty*, Journal of Theoretical and Applied Economics No. 6 / 2006 (501), p. 62.

[36] Romania has adhered to the TRIPs Agreement by Law no. 133/1994, M. Of. nr. 360 din 27 decembrie 1994, the document is available online at http://www.orda.ro/default.aspx?pagina=208, accessed on 29.10.2017.

[37] The document is available online at https://www.wto.org/english/docs_e/legal_e/27-trips.pdf, accessed on 28.10.2017.

[38] M. Pantea, C. Voicu, *"Industria contrafacerilor" în domeniul produselor farmaceutice*, Revista Română de Dreptul Proprietății Intelectuale nr. 4(29), Ed. Universul Juridic, Bucharest, 2011, p. 121.

[39] M. Pantea, C. Voicu, *op. cit.*, p. 122.

[40] Official Gazette no 541/8 August 2007.

[41] In 2001, during the anthrax epidemic, the US used this provision on public interest and compulsory licensing and determined Bayer to grant an 80% reduction to the patent-protected drug, Cypro.

Agreement. Moreover, in these situations, the companies would no longer be interested in investing in obtaining patents.

As regarding the infringement action, it should be pointed out that the remedies refer to the recognition of the prerogatives belonging to the holder of the intellectual property right infringed, even if the patrimonial or non-patrimonial nature of the property is concerned. The destruction, confiscation, withdrawal from the sale of goods obtained through counterfeiting are some of the few consequences of the infringement action. The holder of the violated right may also obtain damages for the moral or material damage he has suffered.

EUIPO (European Union Intelectual Property Office) has shown in a number of studies[42] that over 48 billion euros (7.4% of total sales) are lost each year in 9 sectors of activity due to counterfeit goods sold on the European market. At national level (compared to the European one where the biggest loss caused by counterfeiting is clothing), 444 million euros (16.6%) are lost annually in the medicine industry, 4 times more than the EU average.

Counterfeiting of medicines has received a definition from the World Health Organization (WHO), namely pharmaceutical products whose origin or specifications have been deliberately and fraudulently altered. Counterfeiting may concern both branded and generic products, as shown in the European Parliament resolution of 18 December 2008 on the impact of counterfeiting on international trade[43].

This meaning fits into the broader concept of *sub-standard drugs*. These are products containing the same active ingredients as the original product, packaged and labeled correctly but illegally imported. Also, there are products that contain incorrect amounts of ingredients, products that do not contain active substances, products that contain instead of active substances, harmful ingredients, counterfeit packaging containing either correct quantities of active substances or no active substances at all. Counterfeiting of medicinal products may also apply to an authentic product on whose packaging a larger quantity of active substance is added to increase considerably the price or an authentic product that has another expiry date on the packaging.

Since they do not go beyond the necessary assessment of the quality, safety and effectiveness required by EU rules, they are a real threat to health[44].

The threat to public health has been recognized by the WHO (World Health Organization), which has set up the IMPACT (International Medical Products Anti-*Counterfeiting* Taskforce) for this purpose.

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[42] Extract from the EUIPO Press Release of 5 December 2016, at www.osim.ro. These studies were conducted by EUIPO between March 2015 and September 2016 to create a more complete picture of the economic costs of counterfeiting and piracy in the EU.

[43] JOUE CE 45/47 of 23.02.2010, the document is available online at http://eur-lex.europa.eu/legal-content/RO/TXT/HTML/?uri =CELEX:52008IP0634&from=RO, accessed on 21.10.2017.

[44] European Commission, *Q&A: Directive on falsified medicines*, MEMO/11/91, Brussels, 16 February 2011.

Why buy counterfeit medicines on the Internet? Because they are probably illegal because we do not have a prescription for certain types of medicines, because we are ashamed to buy them from pharmacies or go to a doctor for a prescription (eg forillnesses considered taboo: psychological or sexual), because they aree cheaper, because it is more convenient to get them at home.

Even if the Internet has created new opportunities for consumers, it is also the place where illicit business can take place. Criminals on the Internet have found a growing market here[45].

The explosion of counterfeit online drug trafficking has led to big losses from major drug manufacturers (who are often discouraged to make investments) and also the consumer's lack of confidence in online pharmaceuticals (online there is the largest market but also the least regulated). Because this sale action is illegal, no taxes or charges are paid, therefore the negative impact is also reflected in the tax revenues of those states.

According to the study by EUIPO, *The economic cost of the IPR infringement in the pharmaceutical industry*, Romania ranks the second after Bulgaria, out of a total of 19 EU Member States, on the negative impact of drug counterfeiting on sales revenue only in the case of producers and wholesalers, and not retailers (over 15%, an average for 2008-2013, at country level the loss being 444 million Euros).

In addition to counterfeiting, money laundering and tax evasion and organized crime are closely related to drug trade. The infringement of intellectual property rights is also linked to the rapid development of the Internet, the impossibility of achieving effective control over the quality of products.

The drug counterfeiting market is unfortunately growing according to the WHO in 2010 it was about 75 billion dollars, with 90% more than in 2005[46].

In 2007, the volume of goods seized by the EU customs authorities infringing IPR rose by 17% in one year, this increase being of 264% in the case of cosmetic and personal hygiene products, of 98% in the case of toys and of 51% for medicines, says the European Parliament resolution of 18 December 2008 on the impact of counterfeiting on international trade.

WCO and IRCM (the World Customs Organization and the International Institute for Research against Counterfeit Medicines) had the fourth initiative in September 2016 in the programme of fight against counterfeit medicines in Africa, with 113 million counterfeit pharmaceuticals confiscated.

The International Health Organization estimates that more than 50% of medicines marketed via the Internet are counterfeit[47].

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[45] Counterfeiting: a global spread a global threat, p.89, UNICRI (United Nations Interregional Crime and Justice Research Institute) 2007, the document is available online at http://www.unicri.it/news/article/0712-1_counterfeiting, accessed on 21.10.2017.

[46] M. Pantea, C. Voicu, *op. cit.*, p. 131.

[47] Presentation of Reasons, Draft amendment to the Law on Pharmacy, the document is available online at http://www.cdep.ro/ proiecte/2015/800/00/4/em1015.pdf, accessed on 28.10.2017.

Among the most counterfeited products are drugs, an example being the one reported by the World Customs Organization (WCO) in the Ilicit Trade Report (2012), namely Cialis, a medicine against erectile dysfunction that was falsified in 1604 of cases in 2012; 7.16% of the total.[48]

Counterfeit drugs often contain substances such as mercury, rat poison or paint[49].

Unfortunately, from counterfeiting expensive drugs, such as those for weight loss, for erectile dysfunction or steroids, has led to the falsification of medicines that not only endanger human life but also prevent life saving, such as oncology, antibiotics or diabetes products[50].

Drug counterfeiting may also refer to the fact that although the quantities of substances are observed, there is the same active substance, the same weight, the manufacturing method is not complied with because it does not comply with Good Manufacturing Practices (GMP) standards. Another variation is the total lack or a much lower amount of the active substance, which is however included on the package. Another common occurrence, especially when selling on the Internet, is the improper packaging that can lead to degradation, evaporation of the drug.

Usually, the space in which the medication is stored is improper, the manufacturer's instructions, the hygiene conditions are not observed during transport, it is not known whether the persons handling / making them have any training in the field.

Acquiring drugs from the Internet is almost always without a specialist medical checkup, therefore the risk of doing more harm than good is higher. Yet people prefer to buy medicines online because they are much cheaper.

One element that leads to the development of this online counterfeit drug trade is that websites are disconnected very quickly, and transfers are made in very short periods of time. That is why it is difficult for the authorities to intervene on time.

In Romania, there are several actions of the Romanian Police that investigated cases of illegal drug sales in the on-line environment. Tax evasion, putting into circulation of a product bearing an identical or similar trademark with a registered trademark for identical or similar products are some of the investigated

[48] the document is available online at http://www.wcoomd.org/~/media/wco/public/global/pdf /topics/enforcement-and-compliance/ activities-and-programmes/illicit-trade-report/wco-report-2013-_-br.pdf?db=web, accessed on 28.10.2017.

[49] In Southeast Asia and Southeastern Africa, 35% of antimalarial drugs did not pass the chemical analyzes test. More than 120,000 die annually in Africa as a result of antimalarial drug counterfeiting, according to the World Health Organization, cited by M. Wall, in the BBC article *Counterfeit drugs: 'People are dying every day'*.

[50] In addition to these drugs, counterfeiting also applies to narcotic substances, among them hypnotic sedatives. Thus, it appears in the 2005 report of the International Narcotics Control Board, United Nations, New York, 2006, that the information provided by the Swedish customs officers shows that almost all of the seized Rohypnol tablets are counterfeit. The illicit raw material was brought from China. Lithuanian authorities have confirmed the smuggling of large quantities of counterfeit tablets from the Lithuanian territory into the Scandinavian countries as smuggled goods. In Norway, most of the 360,000 Rohypnol tablets seized in 2004 were counterfeit goods.

offenses. An example is the one from 2012-2016, when suspects set up 10 sites through which they sold counterfeit medicines in the EU. The estimated damage is 300,000 euros, in addition to the gain of approximately 1,000,000 Euro[51].

Another case related in the Romanian media[52] is that of prosecuting by the Prosecutor's Office at the ICCJ of three men who sold (in 2007-2010) on various sites, counterfeit medicines (about 2500 pieces of different brands were discovered).

Operation Pangea VIII[53], organized by Interpol (alongside other operations aimed at protecting the population from non-compliant and potentially dangerous goods) has dealt with combating the sale of counterfeit and illegal drugs online. These are annual activities, one week in which the customs authorities, health regulators, national police and private institutions are launching actions to combat the sale of counterfeit medicines. In 2015, 115 states were involved in the Operation and 20.7 million counterfeit medicines (including oncological drugs, for blood pressure or erectile dysfunction) were seized. The estimated value is $ 81 million. The operation was also attended by Google, one of the largest Internet companies in the world, which underlined the importance of cooperating in this area and hindering the businesses made by these on-line pharmacies.

Operation Pangea IX, which also targeted online sales, led to the discovery of counterfeit medicines worth $ 53 million. There were 4932 websites selling counterfeit medicines. Of the 12.2 million counterfeit medicines, most were weight loss pills, antimalarials, cholesterol pills, for erectile dysfunction or hair loss medications[54].

The substances placed under international control such as drugs (methadone, oxycodone, codeine) and psychotropic drugs (amphetamines) are marketed through cyberfarmacies. The shipping method is also intelligent and discreet, being made in the form of mailboxes, thus keeping the customer anonymity. Unfortunately, these methods lead to drug abuse by adolescents. In the US and Latin America, the first cyber-pharmaceuticals of this kind appeared, followed by Mexico, Asia, China, India, Thailand. Very interesting is the fact that most of the customers are European and American. Statistics show that more sales

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[51] the document is available online at http://www.ziare.com/social/medicamente/steroizi-hormoni-si-medicamente-contrafacute-la-vanzare-pe-internet-afacere-de-un-milion-de-euro-1425486, accessed on 21.10.2017.

[52] The document is available online at http://www.ziare.com/stiri/justitie/medicamente-de-potenta-contrafacute-3-persoane-trimise-in-judecata-1304186, accessed on 21.10.2017.

[53] The document is available online at https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Pangea, accessed on 28.10.2017 The investigations in the US aimed at raising the awareness of people using counterfeit medicines, such as silicone injections for cosmetic purposes, which can lead to serious medical complications. Another case is the one in the UK where an online pharmacy was found selling counterfeit medicines and unlicensed medicines from other countries. The seized drugs were worth $ 2.4 million.

[54] The document is available online at http://www.wcoomd.org/en/media/newsroom/2016/june/wco-participates-in-operation-pangea-ix-against-fake-and-illicit-medicines.aspx, accessed on 28.10.2017.

are made through these organizations than in a regular pharmacy[55]. 95% of the operations are done with substances placed under international control (statistics show that in the United States there is a case of illicit cyberpharmacy selling about 6 millions of annual doses of diazepam and hydrocodone). Estimating, the volume of these operations brings millions of dollars. The chances for a customer to buy a genuine product are minimal.

In 2005, Cyber Chase was launched in the US to stop a chain of drug dealers. They distributed over 200 websites 2.5 million doses of controlled substances.

There are states that have taken steps to stop this phenomenon, but given the different legislation and how these sites act, the interventions have to be made at the international level. In the US, a legal regulation has been adopted: *"Ryan Haight Online Pharmacy Consumer Protection Act of 2008"*[56] which establishes that medicinal products cannot be marketed on the Internet without a prescription. This law also defines the concept of an on-line pharmacy that would represent any person, entity or website, whether it is in the US or elsewhere, which deliberately distributes, releases a controlled substance with the help of the Internet. Each pharmacy selling drugs, especially controlled substances, via the Internet, must report to the Attorney General at time intervals specified in the legislation, the amount and type of controlled substances distributed over a month. Any online pharmacy must visibly and clearly display on its page a statement that it complies with the legal requirements for the sale of products, including a statement of compliance.

In 2014, the German Federal Institute for Medicines and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte*, *BfArM*) requested the examination of the stocks of Sutent produced by Pfizer (used to treat intestinal or kidney cancer) which came from parallel imports. One of the buyers returned the product to the pharmacy because it did not seem to contain the original medicine. The drug was provided by Orifarm, a supplier of parallel medicines imported to Europe that could sell at lower prices than the manufacturer. It turned out that the medicine came from a Romanian supplier and thus stopped importing the medicine from Romania and then from Bulgaria, Poland and Hungary for the same reasons[57].

[55] Report of the International Narcotics Control Board for 2005, United Nations, New York, 2006, p. lxxviii.

[56] The document is available online at https://www.govtrack.us/congress/bills/110/hr6353/text, accessed on 22.10.2017.

[57] EUIPO, the study *The economic cost of the IPR infringement in the pharmaceutical industry*, p. 12, the document is available online at https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/observatory/resources/research-and-studies/ip_infringement/study9/pharmaceutical_sector_en.pdf, accessed on 28.10.2017.

3. Conclusions

The trade with counterfeit products generally makes patent or trademark authors no longer interested in protecting their creative activity due to financial losses. Protecting them also means protecting the population because their work will generate new drugs that will lead to the eradication of serious or even fatal diseases.

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