COUNTERFEITING OF PHARMACEUTICAL PRODUCTS UNDER THE EU LAW AND RELEVANT JURISDICTIONAL PRACTICE[*)]

Marius Pantea[**)]

Abstract

Throughout the article, the author brings forward the main characteristics of intellectual property law touching the pharmaceutical industry, the provisions of European Union (EU) law and the practical arrangements for the protection of medicines and other pharmaceuticals, international and regional bodies involved in the process of registration and protection of patent in the abovementioned field, important statistical aspects of the counterfeiting of medicines and medical devices. The end of the article highlights the EU strategy in the field of protecting pharmaceutical products and objectives of EU institutions specialized in combating such criminal activities.

Keywords: *intellectual property law; counterfeiting; pharmaceuticals; e-commerce*

Preamble

Inventiveness and creativity are essential features that favoured human differentiation, during its evolution, from all other living creatures. The ability to give these features a productive use remains fundamentally paramount in social and economic structures of human society. Survival of every single man, of each enterprise, organization or even nations clearly depends on the ability to keep permanent contact with the development and progress in all fields.

Intellectual property includes legal rights ensuing from intellectual creation activities in the following areas: industrial, scientific, literary or artistic, and impossibility of protection by mere possession of the intellectual property object stands for the basis of the whole concept of legal regulations on such property, designed to protect creators and other producers of goods and services on account of time-limit assignment of the right to use such works or services[1)]. Intellectual property rights are outlined in Article 27 of the *Universal Declaration of Human Rights*, which stipulates that „everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits ... Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic

[*)] Article translated from the Romanian language by Cerasela Gheorghe (Casa de traduceri).

[**)] PhD, Lecturer – Faculty of Police, „Alexandru Ioan Cuza" Police Academy, Bucharest; email; marius.pantea@academiadepolitie.ro.

[1)] See M. Pantea, *Protecția penală a proprietății intelectuale în era globalizării (Criminal Protection of Intellectual Property in the Era of Globalization)*, Expert Publishing House, Bucharest, 2008, p. 18.

production of which he is the author" and in the *EU Charter of Fundamental Rights*, which clearly stipulates in Article 17 par. 2 that „intellectual property shall be protected"[2)].

In the era of globalization of trade and communications, industry digitization, the unprecedented development of information systems, intellectual property protection is a challenge for democratic governments and international vocation bodies. The various forms taken by the intellectual property were always based and are still based on economic interests and „counterfeiting has become a thriving industry, which may even kill and whose flagship is China", according to the European Commission's statements, which challenged Member States of the European Union (hereinafter EU) to combat this phenomenon[3)].

Large sums of money invested in the industrial logistics by criminal organizations with the view to increase both quality and quantity of current production allow counterfeit products to be manufactured, which are increasingly harder to be detected. In some countries, there were built real industrial parks specialized in the manufacture of counterfeit goods, where the goods sold are actually fake. The price of a counterfeit product can sometimes be higher than the price of an original one, so as not to attract attention of the authorities or holders of rights. At present, involvement of international criminal organizations in global trafficking of counterfeit goods is a certainty, often being used for this purpose all legal instruments for the import and export of such products.

„Counterfeit industry of pharmaceuticals" has become lately more profitable than illegal drug trafficking as organized crime groups operate, generally, similarly with any economic agent provider of services or manufacturer of material goods, aiming to increase their earnings and with the view to reduce the volume of the total gross income expenses. Crime in the area of intellectual property rights has become a global problem, has a strong cross-border character, its negative effects often involving serious violations of human rights and fundamental freedoms, financial losses and economic damage to states, endangering people's life and health, being a threat to national security of states, and potentially having a devastating effect on human society.

1. Agreement on intellectual property rights related to trade. On the subject of pharmaceuticals, it all started from the premise that their protection is an economic incentive to develop research and innovation in the field. Economic reasons behind the rationale of this type of protection justified costs and benefits and led to a proposal for international regulation embodied in the Agreement on

---

[2)] Published in the „Official Journal of the European Union" C 303 / 1 of December 14th, 2007 (see http://eur-lex.europa.eu/ro/treaties/dat/32007X1214/htm/C2007303RO.01000101.htm).

[3)] *European Commission*: *The counterfeiting industry can kill and must be abolished*, article published on the site *Ziare.com*, March 10th, 2008 (see http://www.ziare.com/articole/medicamente-contrafacute).

Trade-Related Aspects of Intellectual Property Rights (TRIPS)[4]. This established at international level a legal mechanism allowing all member countries to have access to both new patent-protected drugs, and especially in generic medicines.

A brief history of the emergence of the Agreement on Trade-Related Aspects of Intellectual Property Rights sends us back to the 80s of last century as starting point, when the acceleration of globalization in the field of intellectual property rights through international trade, foreign direct investment and licensing led to a situation of conflict between protection standards of these rights at the relevant time and needs incurred due to the economic circumstances of the time. This situation worsened during the 90s of the twentieth century, as the need to sell products covering intellectual property rights internationally has become increasingly inappropriate with the arrangements for the protection of inventions and existing trademarks, strictly based on national or regional laws and regulations.

The United States of America initially endorsed at the Ministerial Conference in 1982 the establishment of an international code of counterfeit goods, but the initiative was not viewed with much enthusiasm by the other Member States. Negotiations on the launch of the Uruguay Round lasted almost as long as negotiations for the entire Tokyo Round. The United States of America attempted to launch a round of negotiations since the early 80s, due to unsatisfactory results of the Tokyo Round. Inclusion of new areas, among which pharmaceuticals, in the Uruguay Round was entirely a U.S. initiative, being driven by the interests of multinational companies in this country. In terms of intellectual property area, the main stimuli were brought by the pharmaceutical, software and entertainment industries.

The Agreement sets down general standards in relation to each of the main areas of intellectual property accepted. There are thus established minimum standards of protection that are to be offered by each member, characterized as an agreement allowing members to provide greater protection of intellectual property, in as far as Member States are free to determine the most appropriate implementation method of the agreement, in compliance with their own legal system and relevant policies. It also allows Member States to provide some options for the definition of recipients and national treatment, provided these issues shall be notified to the Council of the *Agreement on Trade-Related Aspects of Intellectual Property Rights*.

Most significant amendments to the above-mentioned document on intellectual property are in the field of patents, given the controversies relating to technology protection. Article 27 of the Agreement provides a broad definition of processes, products likely to be patented: *patents shall be available for any inventions, whether products or processes, in all fields of technology, provided*

[4] The Agreement on Trade-Related Aspects of Intellectual Property Rights is an agreement concluded among all WTO members, establishing protection and enforcement of intellectual property rights. *Trade-Related Aspects of Intellectual Property Rights* is the most comprehensive multilateral agreement on intellectual property to date (see http://www.microsoft.com/romania/antipiracy/informlegale.mspx).

that they are new, involve an inventive step and are capable of industrial application. The Agreement prohibits discrimination in relation to the use of rights conferred by patents between imported and locally produced products. Patents shall be available as to the place of innovation, the field of technology and whether products are imported or locally produced. Therefore, many countries need to expand the level of patent protection in major technological fields, like the pharmaceutical, chemical and food industries. Member States shall enjoy flexibility in defining the conditions for protection, establishment of these conditions standing at the discretion of each country. Developing countries may opt for high standards of novelty and to determine whether an invention can be patented or not, although the usefulness of such excessive demand as compared to usual practice may be extremely low. Authorities in the field can be prepared to recognize only the restrictive demands to promote the ability of competitors to invent around patents. Likewise, there are provided exemptions from patentability, designed to protect public order or morality, to prevent environmental damage, to protect the lives of people and animals and preserve vegetation. These exceptions are limited by the provision under which „members may provide exceptions limited to exclusive rights conferred by a patent, provided that they do not unduly prejudice the normal exploitation of the patent or cause undue harm to lawful interests of patent owner, bearing in mind the legitimate interests of third parties" (Article 30). In practice, it allows states to provide limited use for private and non-commercial purposes, research, experimentation or teaching purposes and for the preparation of certain medicines by pharmacies. It can also be raised in the approval of generic medicines. There can also be excluded from patentability diagnostic, therapeutic and surgical methods. The most controversial is the exception[5)] relating to biotechnological inventions, which in principle are patentable, and patents should be given to micro-organisms and microbiological processes. However, unlike the strong protectionist U.S. approach, the Agreement on Trade-Related Aspects of Intellectual Property Rights permits the exclusion from patentability of essentially biological processes for the production of plants or animals and plants and animals other than micro-organisms.

In addition to expanding coverage of patents, including pharmaceuticals, the agreement strengthens the purpose of rights conferred, recognizes the exclusive right of import, although many experts argue that this right was implicative to the right to offer for sale. Since the obligations on the use of patents in domestic production of medicines are no longer valid, these can not be used to justify compulsory licensing. However, the right of import is explicitly limited.

[5)] Article 27.3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (see http://www.dce.gov.ro/Materiale%20site/texte_ref/ACORD_PRIVIND_ASPECTELE_DREPTURILOR_DE_PROPRIETATE_INTELECTUALA.html).

It is important to note the fact that the holder of a patent in the pharmaceutical area has the opportunity to decide how to use it and submit it. Likewise, the agreement establishes an obligation to disclose this type of invention so that to fulfil the original purpose, namely to boost the innovative process in the health area, resulting in economic growth. This provision ensures that the company fully benefits of the gains of the relevant invention in the pharmaceutical field, as well as of the possible economic implications of that patent. Member States may allow unauthorized use of patented inventions under certain conditions, as long as those exceptions do not unreasonably interfere with the exploitation of patents and do not unreasonably prejudice the legitimate interests of the patent holder. In practice, it allows states to provide limited use for private and non-commercial purposes, research, experimentation or teaching and for the preparation of certain medicines by pharmacies. This provision may also be appealed to in the generic drug approval. There are set new limits on the use of compulsory licenses for patented information, but it is recognized their partly utility as means to stimulate competition with the view to ensure access to technology.

The Agreement provides ample opportunities to specify conditions for the use of compulsory licenses, keeping up a compromise between those who develop technology and potential users. Significantly, compulsory licenses are not territorially limited, so that rights afforded by pharmaceutical patents are not abused. On these lines there may be issued non-exclusive and non-assignable licenses where patent holders have failed within a normal period of time to negotiate voluntary licenses, those interested providing commercially reasonable terms. Licenses shall be used mainly for domestic markets, in order to protect the interests of right holders abroad. Holder by right must be given adequate remuneration, based on economic value of authorized use. Also, authorities can issue compulsory licenses in order to allow use of dependent patents for which operation is related to access to protected technology by virtue of a previous patent. However, such licenses are exclusively allowed when the second patent is an important technological advance, with considerable economic significance to the first patent. Conditions listed above were considered *strict safeguards*[6)]. However, some crucial conditions are totally dependent on the purposes and merits of such agreements. They provide a significant possibility of choice for economic policy makers from developing countries in order to build legal foundations, making sure that these conditions do not become too restrictive. An example is the distribution of patented pharmaceutical products through public hospitals or health centres on non-commercial grounds, ensuring access to those who can not afford buying them, though need them. Pharmaceutical patent legislation in some developed countries

[6)] See Article 31 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (see http://www.dce.gov.ro/Materiale%20site/texte_ref/ACORD_PRIVIND_ASPECTELE_DREPTURILOR_DE_PROPRIETATE_INTELECTUALA.html).

and developing countries contains such provisions, although only Canada actually uses this tool extensively for pharmaceutical products.

The agreement unifies coverage of patent protection granted to pharmaceutical products for a minimum term of protection of 20 years since its first embodiment. Moreover, in case of alleged infringement of pharmaceutical patent holders' rights, the burden of proof is reversed, being placed with the defendant that is to demonstrate that its product or process for obtaining a pharmaceutical product does not infringe patent held by the accuser[7)]. This has lately become the general rule in many industrialized countries, where it is recognized the fact that the demonstration of process violation is difficult and therefore the procedure requires amendment in patent law in many developing countries, but also in some developed countries.

2. *EU legislation in the field of pharmaceuticals protection*, taking over all the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights[8)], includes the following regulations:

- *Protocol amending the TRIPS Agreement*[9)]
- *European Patent Convention* done at Munich in 1973[10)] and its Revision Act, adopted in 2000[11)]. The regulation allows inventors to obtain a single patent, encourages innovation, promotes a unified and clear legal framework and provides financial facilities in the area by reducing the costs of registration. European patent term is 20 years from the actual date of filing the application[12)];
- *Regulations to the European Patent Convention, adopted by the Administrative Council*, setting forth the instituting of the European Patent Office in The Hague and the procedures for obtaining a European patent[13)];

[7)] Under certain conditions, according to Article 34.1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (see http://www.dce.gov.ro/Materiale%20site/texte_ref/ACORD_PRIVIND_ ASPECTELE _DREPTURILOR _DE_PROPRIETATE_INTELECTUALA.html).

[8)] Done at Marrakech on April 15th, 1994, ratified by Romania on December 22nd, 1994 by Law no. 133/1994 published in the „Official Gazette of Romania", Part I, no. 360 of December 27th, 1994 (see http://www.osim.ro/legis/marci/lege133.htm).

[9)] Published in the „Official Journal of the European Union" L 311 37 of November 29th, 2007 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:311:0037:0041:RO: PDF).

[10)] See M. Uban, L. Antoniu, E. Bondar, *Convenția brevetului european* (*European Patent Convention*), OSIM Publishing House, Bucharest, 2004.

[11)] Romania joined by Law 611/2002, published in the „Official Gazette of Romania", Part I, no. 844 of November 22nd, 2002 (see http://www.osim.ro/legis/brevet/leg611.html).

[12)] Date referred to in Article 53 point c of the Convention on the Grant of European Patents (see http:// www.tehimpuls.ro/files/File/Legislatie/conventia%20brevetului%20european%20%28traducere%29.pdf).

[13)] Decision 2011/167/EU of the Council of March 10th, 2011 authorizing enhanced cooperation in the area of the creation of unitary patent protection, published in the „Official Journal of the European Union" OJ L 76/53 of March 22nd, 2011 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:076:0053:0055:ro: PDF).

- *Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions*[14], which establishes patent protection of products consisting of or containing biological material, and processes which produce, process or use biological material. Equally, it protects biological material isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature. Inventions related to plants or animals shall be patentable if the technical feasibility of the invention is not limited to a particular variety of plant or animal. There is also protected an element isolated from the human body or produced in another way through a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element[15];
- *Council Decision of 1975 setting up a Pharmaceutical Committee*[16], which establishes the obligation to consult the Committee for Proprietary Medicinal products when the latter shall draw up proposals for directives in the field;
- *Convention on the elaboration of a European Pharmacopoeia*[17], common to the countries concerned, undertaken by the „Public Health Committee" of the Council of Europe aimed at the preparation and adoption of monographs to be included in the „European Pharmacopoeia";
- *Protocol to the Convention on the elaboration of a European Pharmacopoeia 1994*[18];
- *Regulation (EC) No. 297/95 of the Council on fees payable to the European Agency for the Evaluation of Medicinal Products*[19];
- *Commission Regulation (EC) No. 540/95 of March 10th, 1995 laying down the arrangements for reporting suspected unexpected adverse reactions which are not serious, whether arising in the Community or in a third country, to*

[14] Published in the „Official Journal of the European Union" 'L 213/13 of July 30th, 1998 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:213:0013:0021:EN:PDF).

[15] See C. Voicu et al., etc., *Securitatea Financiară a Uniunii Europene în viziunea Tratatului de la Lisabona* (*Financial Security of the European Union under the Lisbon Treaty*), vol. II, Pro Universitaria Publishing House, Bucharest, 2010, p. 81.

[16] Published in the „Official Journal of the European Union" L 147/23 of June 9th, 1975 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31975D0320:RO:HTML).

[17] Published in the „Official Journal of the European Union" L 158/19 of June 25th, 1994 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:21994A0625%2802%29:RO:HTML).

[18] Published in the „Official Journal of the European Union" L 35 of February 15th, 1994 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995R0297:RO:HTML) as amended by Commission Regulation (EU) No. 301/2011 of March 28th, 2011 amending Council Regulation (EC) No. 297/95 as regards the adjustment of the fees of the European Medicines Agency to the inflation rate (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011R0301:RO:HTML).

[19] Published in the „Official Journal of the European Union" L 158/19 of June 25th, 1994 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995R0297:RO:HTML).

medicinal products for human or veterinary use authorized in accordance with the provisions of Council Regulation (EEC) No. 2309/93[20];

- *Commission Regulation (EC) No. 540/95* laying down the arrangements for reporting suspected unexpected adverse reactions which are not serious, whether arising in the Community or in a third country, to medicinal products for human or veterinary use authorized in accordance with the provisions of *Council Regulation (EEC) No. 2309/93*[21];
- *Commission Regulation (EC) No. 1662/95* laying down certain detailed arrangements for implementing the Community decision-making procedures in respect of marketing authorisations for products for human or veterinary use[22];
- *Regulation (EC) No. 1610/96 of the European Parliament and of the Council* concerning the creation of a supplementary protection certificate for plant protection products[23];
- *Commission Regulation (EC) No. 2141/96* concerning the examination of an application for the transfer of a marketing authorization for a medicinal product falling within the scope of Council Regulation (EC) No. 2309/93[24];
- *Directive 2001/20/EC of the European Parliament and of the Council* on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use[25];
- *Directive 2001/82/EC of the European Parliament and of the Council* on the Community code relating to veterinary medicinal products[26];

---

[20] Published in the „Official Journal of the European Union" L 55 of March 11th, 1995 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995R0540:RO:HTML).

[21] Published in the „Official Journal of the European Union" JO L 214 of August 24th, 1993 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995R0540:RO:HTML).

[22] Published in the „Official Journal of the European Union" L 158/4 of July 8th, 1995 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995R1662:RO:HTML).

[23] Published in the „Official Journal of the European Union" L 198 of August 8th, 1996 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996R1610:RO:HTML).

[24] Published in the „Official Journal of the European Union" L 286 of November 8th, 1996 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996R2141:RO:HTML).

[25] Published in the „Official Journal of the European Union" L 121 of May 1st, 2001 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0001:0066:RO:PDF), as amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council of June 18th, 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny - Adaptation to the regulatory procedure with scrutiny - Part Four, published in the „Official Journal of the European Union" OJ L 188 of July 18th, 2009 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:188:0014:0092:RO:PDF).

[26] Published in the „Official Journal of the European Union" L 311 of November 28th, 2001 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:RO:PDF), as amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council of June 18th, 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with

- *Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use*[27)];
- *Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use*[28)];
- *Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a „European Medicines Agency"*[29)];
- *Commission Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products*[30)];
- *Commission Regulation (EC) No. 2049/2005 laying down, pursuant to Regulation (EC) No. 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the „European Medicines Agency" by micro, small and medium-sized enterprises*[31)];
- *Commission Directive 2006/130/EC implementing Directive 2001/82/EC of the European Parliament and of the Council* as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription[32)];

---

scrutiny – Adaptation to the regulatory procedure with scrutiny – Part Four, published in the „Official Journal of the European Union" OJ L 188 of July 18th, 2009 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:188:0014:0092:RO:PDF).

[27)] Published in the „Official Journal of the European Union" L 311 of November 28th, 2001 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:RO:PDF), as amended by Directive 2010/84/EU of the European Parliament and of the Council of December 15th, 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use, published in the „Official Journal of the European Union" L 348 of December 31st, 2010 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010L0084:RO:PDF).

[28)] Published in the „Official Journal of the European Union" L 262 of October 14th, 2003 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:262:0022:0026:RO:PDF).

[29)] Published in the „Official Journal of the European Union" L 136 of April 30th, 2004 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:RO:PDF).

[30)] Published in the „Official Journal of the European Union" L 91 of April 9th, 2005 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:091:0013:0019:RO:PDF).

[31)] Published in the „Official Journal of the European Union" L 329 of December 16th, 2005 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:329:0004:0007:RO:PDF).

[32)] Published in the „Official Journal of the European Union" L 349 of December 12th, 2006 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006L0130:RO:HTML).

- *Commission Regulation (EC) No. 507/2006* on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No. 726/2004 of the European Parliament and of the Council[33)];
- *Regulation (EC) No. 816/2006 of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems*[34)];
- *Commission Regulation (EC) No. 1950/2006*[35)] establishing, in accordance with *Directive 2001/82/EC of the European Parliament and of the Council* on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae[36)];
- *Commission Regulation (EC) No. 658/2007* concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under *Regulation (EC) No. 726/2004 of the European Parliament and of the Council*[37)];
- *Regulation (EC) No. 1394/2007 of the European Parliament and of the Council* on advanced therapy medicinal products and amending *Directive 2001/83/EC and Regulation (EC) No. 726/2004*[38)];
- *Commission Decision 2008/911/EC establishing a list of herbal substance, preparations and combinations thereof for use in traditional herbal medicinal products*[39)];
- *Commission Regulation (EC) No. 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products*[40)];

[33)] Published in the „Official Journal of the European Union" L 92 of March 30th, 2006 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R0507:RO:HTML).

[34)] Published in the „Official Journal of the European Union" L 157 of June 9th, 2006 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R0816:RO:HTML).

[35)] Published in the „Official Journal of the European Union" L 367 of December 22nd, 2006 (a se vedea http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1950:RO:HTML).

[36)] Solipeds *(odd-toed ungulate)* mammal family, including horse, donkey, zebra, etc., (In sg.) animal in this family. [Sg. ecvideu. / <Fr. équidés, cf. Lat. equus – Horse], see http://dexonline.ro/definitie/ecvideu.

[37)] Published in the „Official Journal of the European Union" L 155 of June 15th, 2007 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007R0658:RO:HTML).

[38)] Published in the „Official Journal of the European Union" L 324 of December 10th, 2007 amended by Commission Regulation (EU) No. 1235/2010 of the European Parliament and of the Council of December 15th, 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No. 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No. 1394/2007 on advanced therapy medicinal products (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX: 32010R1235:RO:NOT).

[39)] Published in the „Official Journal of the European Union" L 328 of December 6th, 2008 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008D0911:RO:HTML).

[40)] Published in the „Official Journal of the European Union" L 334 of December 12th, 2008 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008R1234:RO:HTML).

➢ *Directive 2009/35/EC of the European Parliament and of the Council on the colouring matters which may be added to medicinal products*[41];

➢ *Regulation (EC) No. 469/2009 of the European Parliament and of the Council concerning the supplementary protection certificate for medicinal products*[42];

➢ *Commission Regulation (EC) No. 668/2009* implementing *Regulation (EC) No. 1394/2007 of the European Parliament and of the Council* with regard to the evaluation and certification of quality and non-clinical data relating to advanced therapy medicinal products developed by micro, small and medium-sized enterprises[43];

➢ Protocol amending the Agreement on Trade-Related Aspects of Intellectual Property Rights, which specifies important pharmaceutical regulations, reaffirmed by the Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health[44]. Annex to this protocol defines the „pharmaceutical product" as *„any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems"*.

3. International and regional bodies. Among international and regional vocation organizations with authority in managing issues on the patent granted for pharmaceuticals range:

3.1. World Trade Organization (WTO), which was created on January 1st, 1995 to implement the „Agreement on Trade-Related Aspects of Intellectual Property Rights" and to replace the „General Agreement on Tariffs and Trade" (GATT)[45], which included a series of commercial treaties concluded at the end of World War II in order to facilitate free trade. Principles of the „General Agreement on Tariffs and Trade" were adopted by the World Trade Organization, which was responsible for administering and expanding them. Unlike the „General Agreement on Tariffs and Trade", World Trade Organization has a substantial institutional structure. Effectively, the World Trade Organization is the successor of the much delayed *International Trade Organization* (ITO), which was originally planned to be successor of the General Agreement on Tariffs and Trade. The International Charter for the International Trade Organization was

---

[41] Published in the „Official Journal of the European Union" L 109 of April 30th, 2009 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009L0035:RO:HTML).

[42] Published in the „Official Journal of the European Union" L 152 of June 16th, 2009 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009R0469:RO:HTML).

[43] Published in the „Official Journal of the European Union" L 194 of July 25th, 2009 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009R0668:RO:HTML).

[44] Text adopted by the European Parliament in Strasbourg in 2007 (see http://www.europarl.europa.eu/sides/).

[45] General Agreement on Tariffs and Trade.

established in the United Nations conference on trade and occupation, held in Havana in March 1948, but was blocked by the U.S. Senate. Some historians have assumed that failure may have resulted from fears coming from within the U.S. business community, that the „World Trade Organization" could be used to regulate, rather than liberate, big business.

World Trade Organization promotes economic globalization and free trade, which are considered by many to be two topics of concern. World Trade Organization treaties have been accused of bias tendency toward multinational corporations and rich countries. While partnership is voluntary, critics believe that non-joining places non-participant nation under embargo, creating an international system of constrained economic rules and discouraging exchange and experimentation.

The decision-making process within the organization and in terms of organization was also subject to criticism. The three major members – the United States of America, the European Union and Japan – have been accused of using the World Trade Organization to exert undue influence over the less-powerful Member States. In addition, some believe that Member States have adopted treaties undemocratically or to the detriment of their citizens or the environment.

3.2. The European Patent Office (EPO), based in Munich, part of the European Patent Organization, established by the European Patent Convention, is basically aimed to issue the European patent for invention. Official working languages of the European Patent Office are English, French and German. World Intellectual Property Organization (WIPO) is an observer of the works of the European Patent Office Board of Directors, according to an agreement signed by the two institutions. A European patent is valid up to 20 years from the date of filing the application. The European Patent Convention formally stipulates that „any infringement of a European patent shall be dealt with by national law" in the area.

4. Counterfeiting of pharmaceuticals and medical devices. Practical approaches. Competition and innovation activities in the pharmaceutical area are global, and unfair competition practiced by pharmaceutical trusts that unreasonably delay market entry of generic medicines has been the subject of an „Antitrust Report on shortcomings in pharmaceutical sector"[46)] at EU level. According to the report in the European community, there were spent about *214 billion euros* in 2010, (about 2% of European GDP) for pharmaceutical products, about 430 euros per EU citizen[47)]. It was also found that, unaccountably, during the period 1995-2000 there was registered a decline of new drugs entering the market from 40 to 27 new pharmaceuticals, which in conjunction with trusts'

[46)] Presented in Brussels on July 8th, 2009 (see http://europa.eu/rapid/pressReleasesAction.do?reference= IP/09/1098&language=RO).

[47)] See Antitrust Report on shortcomings in pharmaceutical sector in the European Union (http://europa.eu/rapid/ pressReleases Action.do?reference= IP/09/1098&language=RO).

attempts to extend their market penetration, as generic drugs, has led to major losses of public health systems of member countries and therefore on consumers.

A justification of the big drug manufacturers, for manoeuvres mentioned above, is the loss of 45 billion euros due to counterfeiting of pharmaceuticals[48]. According to the World Health Organization., in 2010, the counterfeit medicines and medical devices market ranged at approximately $ 75 billion, 90% more than in 2005, and for 2011 experts in the specialty industry forecast an increase by 13%[49].

In Europe, counterfeit drugs market ranged at about 10.5 billion euros in 2010, the EU average of consumers of such pharmaceutical products amounting to 20% of the total community population[50]. An impressive number if we consider that, in France, nearly 7 million people made already use of counterfeit drugs, and the German and British citizens have bought in 2009, counterfeit swine flu antiviral drugs worth many million of euros, generating a profit of about 60,000 pounds per day to Russian criminal organizations[51]. Over 2 million people in the United Kingdom have consumed, in 2007, counterfeit „Prozac" and „Viagra" purchased online from the Internet[52], which prompted the European Commission to initiate relevant legislation in order to regulate virtual pharmacies' status[53].

A check carried out by European authorities in December 2009 revealed that 62% of pharmaceuticals purchased online are counterfeit in whole or fall below the standards required (the active substance does not meet requisite dosage)[54]. Champions of the consumption of counterfeit pharmaceutical products are Germans

---

[48] M. Botezatu, *Chirac, Campaign against Counterfeit Drugs*, article published in the daily newspaper „Evenimentul zilei" of October 12th, 2009 (see http://www.evz.ro/detalii/stiri/chirac-campanie-impotriva-medicamentelor-contrafacute-871412.html).

[49] See R. Collia-Suzuki, *The War against Counterfeit Drugs*, *„The Pharma Packaging and Labeling USA 2011"* Conference, which took place on April 12th – 13th, 2011 in Washington DC, Columbia, (see http://www.pharmaceutical-technology.com/features/feature114721/).

[50] See A. Bardas, *Cumperi medicamente contrafăcute? (Do you buy counterfeit drugs?)*, article published on the site *Ziare.com*, on February 28th, 2011, (see http://www.ziare.com/economie/stiri-economice/cumperi-medicamente-contrafacute-996235).

[51] See I. Ursu *Pe internet se vând medicamente contrafăcute împotriva gripei porcine* (*Counterfeit swine flu drugs sold on the Internet*), article published on the site *Ziare.com*, on November 16th, 2009 (see http://www.ziare.com/stiri/gripa-porcina/pe-internet-se-vand-medicamente-contrafacute-impotriva-gripei-porcine-951761).

[52] *Nu consumați medicamente de pe Internet*, (*Stop consuming drugs on the Internet*), article published on the site *Ziare.com* on January 11th, 2008 (see http://www.ziare.com/articole/medicamente-contrafacute).

[53] See Opinion of the Economic and Social Committee on the Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source of 2009 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0083:RO:HTML).

[54] See A. Serghescu, *Pilulele de slăbit false sunt cel mai des cumpărate medicamente pe piața neagră (Counterfeit weight-loss pills are most often bought drugs on the black market)*, article published on the site Ziare.com, on February 16th, 2010, (see http://www.ziare.com/articole/medicamente-contrafacute).

38%, Italians 37% English 12% and Dutch 10%, the „favourite" products being weight-loss drugs, „Tamiflu" influenza drug, „Viagra" and „Liptor".

According to statistics of the World Customs Organization, counterfeiting of pharmaceuticals brings to organized crime proceeds of approximately $ 200 billion annually[55)], trade in such products becoming more profitable than drug trafficking. At this point we argue that trade in counterfeit pharmaceuticals turned into a global issue, and for its solution it appears *a fortiori* the effective cooperation between relevant industry and national and international authorities. A top of counterfeit pharmaceuticals, provided by the World Customs Organisation, places in top five weight-loss drugs, anti-infective, cardiovascular, for the central nervous system protection and anticancer drugs. We may illustrate in this regard reports drafted by „GlaxoSmithKline" and „Pfizer" which show that approximately 50% of drugs sold online are counterfeit, being identified pills where the active substance was not sufficient to produce health effects and in the contents there were identified impurities, unauthorized substances and even other drugs[56)].

In May cy, Hazim Gaber, Canadian citizen, pleaded guilty in Phoenix (USA) for Internet sales of counterfeit medicines used to treat cancer. He sold common white powders, such as starch, dextrin, dextrose or lactose, as „sodium dichloroacetate"[57)] to 65 patients from North America and Europe. In another case, thousands of patients in the UK have purchased counterfeit „Casodex", prostate cancer medicine.

In late 2008, the border police of several European countries managed to capture 34 million counterfeit pills. In the context of „Medi-Fake" operation, Belgian customs at the airport in Brussels made the biggest catch of illegal drugs in Europe, namely 2.2 million tablets, of which 1.6 million analgesic drugs and 600,000 pills against malaria. Also, the French authorities made a stunning catch in the town of Le Havre, 11 million pseudo-ephedrine tablets, an extremely dangerous precursor used for drug production[58)].

Relevant examples are thrilling if we keep in view that there are sold counterfeit drugs and medical devices to treat cancer, AIDS and other diseases and that 200,000 people die annually due to consumption of counterfeit

---

[55)] See G. Miller, E. Duggan, *Top Counterfeit Drugs Report*, article published on the site www.sproxil.com on August 16th, 2010 (see http://www.fiercepharmamanufacturing.com/node/8843/Chart%20courtesy%20 of%20PSI).

[56)] See http://www.fiercepharmamanufacturing.com/signup?sourceform=Viral-rTynt-Fierce PharmaManufacturing-FiercePharma Manufacturing.

[57)] Medicine used to treat cancer that decreases proliferation and inhibits tumour growth, without apparent toxicity (see http://en.wikipedia.org/wiki/Dichloroacetic_acid).

[58)] *Captură de 34 de milioane de medicamente pe teritoriul U.E. în 2 luni* (*Capture of 34 million of drugs across the EU in two months*), article published in daily newspaper „Romania Libera" of December 16th, 2008 (see http://www.romanialibera.ro/actualitate/eveniment/34-de-milioane-de-medicamente-ilegale-capturate-pe-teritoriul-ue-141904.html).

medicines[59]. The U.S. has seen an increase by 800% in the number of cases of counterfeit pharmaceutical products between 2000 and 2006. In the early 2009, a U.S. federal police operation led to the seizure of counterfeit drugs worth 20 million dollars, being seized: antibiotics, anti-malarial drugs, contraceptives, anti-tetanus vaccines, aspirin and medicines for erectile dysfunction treatment.

Unfortunately, not only drugs are target for counterfeiters. In 2009, 2 million counterfeit insulin needles were found in Great Britain and on the Dutch market. In the Netherlands, the discovery came after the manufacturer received a complaint from a patient who acquired a set of needles that did not fit properly on the insulin pen. A total of 200,000 counterfeit needles were found on the Dutch market, 500,000 in Great Britain and needles worth over 1.3 million in Poland. Right now, 30,000 counterfeit needles are still in circulation in the Netherlands[60].

French police discovered in 2008 in the town Messimy, near Lyon, the largest clandestine laboratory to produce illegal drugs. The laboratory was identified after several weeks of investigation undertaken by French police throughout the country, it was located on the ground floor of a two-floor apartment building, and counterfeit medicines were in the form of pills, suppositories or creams. After their manufacture, pharmaceutical products were packed and sent by mail, recipients being especially cancer patients. The total amount of drugs found at the site was some cubic meters, investigators also discovering lists of recipients and invoices allowing the location of patients and thus getting important evidence in the investigation. Nine people were detained and dozens of searches were conducted to determine „the whole channel" of distribution and manufacturing of drugs, investigators adding that they shall continue their investigation in order to „determine their responsibilities in the network activity, as well as the precise extent of traffic"[61].

5. *EU Strategy in the area of population protection against counterfeit medicines and medical devices*. Since the „counterfeit pharmaceuticals' industry" seriously affects public health, the EU adopted a strategy on population protection against counterfeit medicines and medical devices, which envisages, *inter alia*[62]:

- better regulation of the pharmaceutical market;
- products cheapened by the manufacturer, wholesaler and pharmacy;
- tightening rules on the inspections in the pharmaceutical field;

---

[59] M. Botezatu, *op. cit.*

[60] R. Collia-Suzuki, *op. cit.*

[61] *Vast laborator de medicamente contrafăcute, descoperit lângă Lyon (Large counterfeit drugs laboratory*, found near Lyon), article published on the site *Ziare.com*, on March 10th, 2008, (see http://www.ziare.com/stiri/frauda/vast-laborator-de-medicamente-contrafacute-descoperit-langa-lyon-324742).

[62] See http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformation forconsumers/Counterfeitmedicinesanddevices/index.htm.

- introduction of a unique seal for pharmaceuticals and reseal lock-out;
- the ability to identify batches of products throughout the entire production-distribution channel;
- increasing transparency by building a common database under which a product can be identified;
- tightening rules on the import, export and transit of drugs across the EU;
- introduction of the notification procedure for manufacturers or importers of active substances.

The European Security Strategy provides important measures in intellectual property, considering, in the first place, promotion of innovation and creativity, labour market development and improvement of competitiveness, but at the same time protecting the EU interests in the area.

During the last decade, statistics recorded worrying extension of the counterfeiting and piracy phenomenon, which actually turned into a „*super profitable industry*", with direct links to cross-border organized crime, which prompted the European Commission to propose, on September 25th, 2008 the establishment of the *European Observatory on Counterfeiting and Piracy* (hereinafter called the Observatory). The main objectives of the Observatory are:

- Improving the quality of information related to counterfeiting and piracy;
- The establishment of statistical database enabling rapid identification and stopping imports of counterfeit and pirated products in the EU;
- EU implementation of the best strategies to fight against the phenomenon, and also use of the latest techniques for detecting counterfeits and their popularization within the Union;
- Implementation of a uniform strategy in preventing and fighting against the phenomenon;
- Interconnection of public and private system for an effective fight against piracy and counterfeiting;
- Awareness of European public opinion, in order to limit the harmful effects of consumption of counterfeit goods.

Three working groups have been created within the Observatory, whose initial topics are: surrounding data gathering, assessing the European and Member States' legal framework and European public awareness.

The Observatory is composed of members from both the public sector (the existing structures of the European Commission) and the private sector (industry representatives, European and national associations, etc.) and experts participating in regular meetings focused on timely issues embodied in specific reports, which reflect the real situation of piracy and counterfeiting in the EU. Also, the Observatory will prepare a detailed annual report with the identified problems and proposed measures in the production and marketing of counterfeit products.

2008 Council Resolution on a comprehensive European anti-counterfeiting and anti-piracy plan[63] provides in section 9 data of the Organization for Economic Cooperation and Development report on the economic impact of counterfeiting and piracy, particularly its estimate that international trade in counterfeit and pirated goods may have been some USD 200 billion in 2005. Data provided by the customs authorities of member countries of the Organization for Economic Cooperation and Development indicate that „the total value of trade in counterfeit or pirated products could exceed this amount by several hundred billion dollars ..." in 2010[64].

Conclusions

Given those depicted above, we may argue that the protection of intellectual property rights in the information society is an important element of economic development of the internal market. Information Society opens new opportunities under which protected works or products can be exploited via computer, Internet and interactive services. Copyright, related rights and industrial property rights are not just an *ex post* reward for the creators' work, but also a means to encourage them to create more. Holders must be eligible for protection of rights, regardless of national borders or methods of use during the entire period of validity.

In the information society, piracy and trade in counterfeit products prevent the continuation of creative activities that would be financially profitable. We should bear in mind that information assets carry an atypical cost structure, in which most expenses are in the design and production phase.

Economic justification of patent-protected new pharmaceutical products lies not only in paying research teams for their work, but also in ensuring adequate incentives for researchers to continue their creative work, with the view to provide the population with tools to fight against serious disease and similar other challenges to come.

References

Bardas, A., *Cumperi medicamente contrafăcute (Do you buy counterfeit drugs?),* article published on the site Ziare.com, on February 28th, 2011;

Botezatu, M., *Chirac, campanie împotriva medicamentelor contrafăcute (Campaign against Counterfeit Drugs),* article published in the daily newspaper „Evenimentul zilei", October 12th, 2009;

Collia-Suzuki, R., *The War Against Counterfeit Drugs*, „*The Pharma Packaging and Labeling USA 2011*" Conference, April 12th-13th, 2011, in Washington DC, Columbia;

[63] Published in the „Official Journal of the European Union" C 56/1 of March 6th, 2010 (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:056:0001:0004:RO:PDF).

[64] See http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:056:0001:0004:RO:PDF.

Miller, G. & E. Duggan, *Top Counterfeit Drugs Report*, article published on the site www.sproxil.com, 2010;

Pantea, M., *Protecția penală a proprietății intelectuale în era globalizării (Criminal Protection of Intellectual Property in the Era of Globalization)*, Expert Publishing House, 2008;

Serghescu, A., *Pilulele de slăbit false sunt cel mai des cumpărate medicamente pe piața neagră (Counterfeit weight-loss pills are most often bought drugs on the black market)*, article published on the site Ziare.com, February 16th, 2010;

Sherwood, R., *The TRIPs Agreement: benefits and costs for developing countries*, International Journal of Technology Management, vol. 19, no. 1-2/2000;

Uban, M. & Antoniu, L. & Bondar E. (2004). *Convenția brevetului European (European Patent Convention)*, OSIM Publishing House, Bucharest;

Ursu I., *Pe internet se vând medicamente contrafăcute împotriva gripei porcine (Counterfeit swine flu drugs sold on the Internet)*, article published on the site Ziare.com, November 16th, 2009;

Voicu, C. et al. (2010). *Securitatea Financiară a Uniunii Europene în viziunea Tratatului de la Lisabona (Financial Security of the European Union under the Lisbon Treaty)*, vol. II, Pro Universitaria Publishing House, Bucharest;

Watal, J., *Access to Essential Medicines in Developing Countries: Does the WTO TRIPs Agreement Hinder It?*, Science, Technology and Innovation Discussion Paper no. 8, Cambridge, MA, USA, 2000;

Watal, J., *Pharmaceutical Patents, Prices and Welfare Losses: A Simulation Study of Policy Options for India under the WTO TRIPs Agreement*, The World Economy no. 23, 2000.