QUO VADIS UKRAINIAN PATENT REFORM IN THE FRAME OF EU-UKRAINE ASSOCIATION AGREEMENT

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Abstract. The article concerns the issues of harmonization of Human Rights and Intellectual Property Rights in the sphere of Medicine and Pharmacy. In one side, Ukraine is still balancing as a country with the middle and low income and which has legal backgrounds to use TRIPS flexibility provisions. In other side, Ukraine has to keep balance with Ukrainian-EU Association Agreement in the field of protection of Intellectual Property. Ukrainian Government demonstrates the Political Will to provide the National Reforms on the basis of Rule of Law and priority of Human Rights. The reforming in Heath Care is impossible without the ensuring the access to the essential medicines and the mechanisms of Intellectual Property could have the substantial impact into this process. Ukraine is a country-party to the major international treaties in the sphere of Intellectual Property and in particular in International Patent Law: Paris Convention for the Protection of Industrial Property, Patent Cooperation Treaty, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) *etc*. As a country-party of the TRIPS agreement Ukraine was obliged to take the most strength obligations in protection of intellectual property which are determined by the TRIPS-plus. The very important provision for Ukraine is Article 219 of Ukraine–EU Association Agreement which determines that Parties recognize the importance of the Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001. In present time in Ukraine it is enough Political Will to realize patent reform basing on the TRIPS flexibilities' provisions. According to the Report of WIPO in the period of 2000-2015 the share of national patents in the field of medical technologies is near 9.85%, in medicines - 5.5% of all patents in all fields of technology in Ukraine. In comparison, in Germany in the same period the share of patents granted in the field of medical technologies in relation to other sectors of technologies is only 3.89%, in medicines - 3, 64%; in Poland the share of national patents granted in the field of medical technologies is 3.81% (in the field of drugs data available); in Austria in the field of medical technologies - 3.9%; in Spain in the field of medical technologies – near 4.82%. However, this statistic information does not reflect the real situation in Ukrainian Health Care. It reflects the gapes of national patent legislation which allows granting weak patents in the field of medicine and pharmacy. Because of the excessive workload of the patent offices, understaffing and low requirements to the patent granting, pharmaceutical companies obtain unmerited patent monopolies, which do not actually comply to the universally acceptable patentability standards — novelty and innovation level. Thus, the Ukrainian patent reform presumes the following steps. The first one is the excluding from the patentability objects the methods of diagnostic, treatments and surgery and introducing more stringent patentability criteria with regard to pharmaceutical inventions. The draft legislation prohibits to patent new forms of a known from the state of the art medicinal product, including salts, esters, complex ethers, compositions, combinations and other derivatives, polymorphs, metabolites, pure forms, particle sizes, isomers, new dosage forms, or any new property or a new use of a known medicinal product, except those that lead to a significant increase in the therapeutic efficacy of the medicinal product, as evidenced by the research results. Implementing the mechanism of approving the patents on medicines granting by Patent Office (Ukrpatent) by the Sate Expert Center of Ministry of Health of Ukraine could help to patent truly innovative pharmaceutical products and to avoid granting the "evergreening patents". The second one is the implementation of the Bolar regulatory exclusion which allows to generic producer to conduct studies, research and tests for the medicines' regulatory approval and other related acts for preparation to obtain marketing authorisation. Such provision is closely binned with the patent linkage provision which takes place in Ukrainian pharmaceutical legislation. The supplementary protection certificates on inventions (SPC) as a legal instrument of extortion of patent rights is also very sensitive part of patent reform. The main idea of granting such supplementary protection is that the moment when the period that elapses between the filing of a patent application for a new medicinal product and obtaining the marketing authorisation to the same medicinal product makes the period of effective protection under the patent less than 20-years. However, in the international Intellectual Property doctrine the strict connection of such two different procedures are very disputable. However, the obligation to implement of such supplementary protection is directly determine in the Ukraine-EU Association Agreement and Ukraine should keep the balance between TRIPS flexibilities and TRIPS-plus. The other important step of patent

reform is implementing of pre-granting and improvement of post-granting patent oppositions procedures which allows to formally challenge the validity of a pending patent application on the determines by the legislation grounds, such as innovative step, new results in treatments, new efficacy and etc. Such TRIPS instrument as compulsory licensing has never been used in Ukraine because of the gapes of national legislation proper determined procedure, despite that such provisions were declared in the valid legislation.

Key words: *patent law, intellectual property, human rights, access to medicines, compulsory license, date exclusivity, EU-Ukraine Association Agreement, TRIPS flexibilities.*

Introduction

Under the EU-Ukraine Association Agreement Ukraine has taken the obligations to harmonize different sphere of national legislation to the European standards. The main sensitive spheres are the Health Care and Intellectual Property. The key point is the legal protection of the Intellectual Property on the market of medicine services and on pharmaceuticals.

The *strategic goal* of the Ukrainian Patent Reform is the implementation of the European standards of medical care by expanding the access to innovative methods of prevention, treatment and diagnosis by the mechanisms of intellectual property legislation. The Ukrainian Government also determine the *social purpose* of the Patent Reform which is to ensure the access to the essential medicines and innovated methods of treatment and diagnosis through the expending of the market of cheaper generic medicines with the identical efficacy to the name-brand medicines for socially vulnerable groups.

Last 10 years the strongest team of national and international experts support the drafting Ukrainian Patent Reform and between of them are Boya Konstantinov (UNDP, USA), Carlos Correa (University of Buenos Aires, Argentine), Muhammed El Said (Lancashire Law School, UCLAN, USA), Tahir Amin (I-MAK, USA), Ellen ‘t Hoen (Medicine Law Policy, MSF, Holland), Pascal Boulet (DNDi, Switzerland), Peter Beyer (WHO, Switzerland), Brook Bayker (Health Gap, USA), Natalya Lukyanova (UNDP, Ukraine), Olena Orlyuk (IP Institute of NALS of Ukraine), Sergiy Kondratyuk (Network PLWH, Ukraine), Viktorya Tymoshevska (Renaissance Foundation, Ukraine), Oksana Kashyntseva (Center for Harmonization of Human Rights and IP Rights, Ukraine). In Ukraine due to the high-powered advocating activities providing by the NGOs, which are focused on protection of Human Rights, Patients' Rights and Intellectual Property Rights, we have changed the government policy in the sphere of insure the access to medicines by the legal mechanisms of intellectual property. It is important to stress that such advocating activities have obtained the support of the National Academy of Law Sciences of Ukraine and in 2012 it was founded the first in the East Europe Center for Harmonization of Human Rights and Intellectual Property Rights of Scientific and Research Institute of Intellectual Property of National Academy of Law Sciences of Ukraine and the expert activity of this Centre is supported by the Network PLWH of Ukraine and by the one of the strongest national expert in IP and access to medicines Sergiy Kondratyuk [1]. The Ukrainian team of expert highly appreciate the expert support of UNDP in Ukrainian Reforms.

In 2017 basing on the cooperation between the Center for Harmonization of Human Rights and IP Rights, UNDP of Ukraine, International Renaissance Foundation, Network of PLWH there were established several working groups in the sphere of Patent Reform in Health Care and access to medicines under the demands on Ukrainian international obligations. In

January 25, 2018 Cabinet of Ministers of Ukraine adopted the Draft Law "On Amendments to Certain Legislative Acts of Ukraine On Improvement of the Legal Protection of Inventions and Utility Models" (hereinafter – Draft Law).

Social background and motivation of the Patent Reform in Health Care

The history of developed countries demonstrates that flexible or balanced patent regime can be more acceptable for developing countries. For example, the Netherlands cancelled the validity of chemical patents for 47 years (1869-1970) for the country to be able to freely imitate the German inventions. Retrospective review of establishing rigid healthcare monopolies via Intellectual Property mechanisms shows that such developed countries as France, Germany, Italy, Japan, Sweden and Switzerland firmly opposed the necessity to implement drug patenting provisions in their national legislation until their national pharmaceutical industries achieved a respective competitive level. France started patenting the medicines in 1960, Germany —in 1968, Switzerland — in 1977, Italy and Sweden — in 1978[2]. Therefore, many developed countries in the process of evolvement used simplified protection systems, often violating the patent rights of other countries[3].

Thus, the developed countries, having taken full advantage of the Paris Convention provisions to strengthen the innovative capacities of their pharmaceutical companies, are now denying the same privileges to the developing countries. This is morally unwarranted in a civilized society[4].

Similarly, the Asian economies which have born new "world tigers" in the period of 1960s-1980s supported imitation and reverse engineering. For example, when South Korea introduced patents in 1961, their validity term was limited to 12 years and they were not applicable to nutritional technologies, pharmaceutical industry and chemical industry. India, having the third largest pharmaceutical industry in the world, was compelled to introduce patent protection of drugs only in 2005 because of WTO accession. Therefore, many developed countries in theirs process of evolvement used simplified protection systems, often violating the patent rights of other countries[5].

Key point is that because of the excessive workload of the patent offices and because of low requirements to the patent granting, pharmaceutical companies have obtained unmerited patent monopolies, which do not actually comply to the universally acceptable patentability standards — novelty and innovation level. Patent reforms initiated in 2013 in Brazil and South Africa is an attempt of their national governments to solve the problem of balancing the public health safeguarding with the patent rights protection. The next example for Ukraine is Brazilian experience. Brazil relied on the following key arguments to support patent reform: non-residents were the main group to benefit from patent system functioning (75-80% of the patent applications were submitted by the non-residents); considerable decrease in the number of technology transfer agreements in pharmaceutical industry; the number of international patent applications submitted by the country residents remained on the same level (0.3%) during 10 years of strict patent protection regime; the budget deficiency on foreign payments under IP rights increased by 36 times from 1993 to 2012 – from $86 million to $3.1 billion[5]. It should be noted that in the opinion of international experts the provisions suggested by South African and Brazilian patent reforms fully comply to the international standards, including WTO TRIPS agreement and the Doha

Declaration on the TRIPS Agreement and Public Health, and are supported by the international organizations, including WIPO, WTO, UNDP, UNAIDS, WHO[6].

What is the current situation in Ukraine?

According to the Report of WIPO in the period of 2000-2015 the share of national patents in the field of medical technologies is near 9.85%, in medicines - 5.5% of all patents in all fields of technology in Ukraine[7].

In comparison, in Germany in the same period the share of patents granted in the field of medical technologies in relation to other sectors of technologies is only 3.89%, in medicines - 3, 64%; in Poland the share of national patents granted in the field of medical technologies is 3.81% (in the field of drugs data available); in Austria in the field of medical technologies - 3.9%; in Spain in the field of medical technologies – near 4.82%[7]. However, this statistic information does not reflect the real situation in Ukrainian medicine (health care). It reflects the gapes of national patent legislation which allows granting weak patents in the field of medicine and pharmacy. Because of the excessive workload of the patent offices, understaffing and low requirements to the patent granting, pharmaceutical companies obtain unmerited patent monopolies, which do not actually comply to the universally acceptable patentability standards — novelty and innovation level. Patent reforms initiated in 2013 in Brazil and South Africa is an attempt of their national governments to solve the problem of balancing the public health safeguarding with the patent rights protection. We would like to strength our position by the World Bank Research in 2005 that determined no causal relations where identified between the enhanced Intellectual Property Rights protection and foreign investments[8].

National content, Legal background and Political Will of the Patent Reform in Ukraine

Ukraine is a country-party to the major international treaties in the sphere of Intellectual Property and in particular in International Patent Law: Paris Convention for the Protection of Industrial Property, Patent Cooperation Treaty, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) *etc*. As a country-party of the TRIPS agreement Ukraine was obliged to take the most strength obligations which are determined by this agreement. TRIPS set minimum standards for intellectual property protection that must be observed and enforced by all WTO Member States. At that time Ukraine had to achieve the strategic goal – to be the member of the WTO and Ukraine had to take the TRIPS-plus obligations. However, in the course of time it has become obvious the potentially detrimental effects of various aspects of the TRIPS package on public health and development, particularly in low- and lower-middle-income countries[9]. According to the Article 7 of TRIPS the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. Unfortunately, Ukraine always being in balancing in low- and lower-middle-income countries, which is very sensitive in the Health Care, but the absence of the political did not give a chance for any patent reform from the point not

business but society priorities. Let to stress that the necessity to look for the balance between social interest and business is the strategy of WHO and WIPO. The World Health Organization has taken several measures to counteract the potentially adverse health impact of IP protection[10]. Thus, the sixty-first World Health Assembly adopted Resolution 61.21, which endorsed the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property in 2008[11]. This Global Strategy aims are to improve the delivery of and access to health products and medical devices by effectively overcoming barriers to access. Adoption of the Global Strategy followed an 18-month period of deliberations and meetings of the WHO Intergovernmental Working Group on Public Health[12].

More recent measures by the WHO include an intensive study on access to medical technologies and innovation, conducted in collaboration with the WIPO and the WTO[13]. There various forms of technical assistance have been provided by WIPO to low- and lower-middle-income countries in formulating IP laws and policies using the TRIPS flexibilities[14].

In October 25, 2017 it was provided the High-Level Meeting in IP and Access to Medicines under the experts support of WHO. The main experts' recommendations lay along the TRIPS flexibilities provisions. Moreover, during the meeting it has been stressed that Ukraine should widely use the provision of Article 219 of Ukraine–EU Association Agreement which determines that Parties recognize the importance of the Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001 (hereinafter referred to as the "Doha Declaration") by the Ministerial Conference of the WTO. In interpreting and implementing the rights and obligations under this Chapter, the Parties shall ensure consistency with the Doha Declaration. The Parties shall contribute to the implementation of, and shall respect, the Decision of the WTO General Council of 30 August 2003 on paragraph 6 of the Doha Declaration.

The scope of Ukrainian Patent Reform in a Health Care - Introducing more stringent patentability criteria with regard to pharmaceutical inventions

The important part of the patent reform is the increasing of the invention level standards, the strictest application of absolute novelty and invention level criteria in order to prevent granting patents which are not really innovative and to facilitate for their innovations and the prohibition of patents for the new forms of substances which do not enhance their therapeutic efficacy. Thus, the Draft Law prohibited to patent new forms of a known from the state of the art medicinal product, including salts, esters, complex ethers, compositions, combinations and other derivatives, polymorphs, metabolites, pure forms, particle sizes, isomers, new dosage forms, or any new property or a new use of a known medicinal product, except those that lead to a significant increase in the therapeutic efficacy of the medicinal product, as evidenced by the research results.

To impalement such provision into the national practice of granting patents it is necessary to work out new Rules of Examination of the Patent Application in the field of Medicine and Pharmaceuticals basing on the recommendations of WHO's Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective and UNDP's Guidelines for the Examination of Patent Applications Relating Pharmaceuticals.

Excluding from the patentability objects the methods of diagnostic, treatments and surgery

Under the Constitution of WHO one of the main principle is the extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health. We have to stress that TRIPS and Ukrainian-EU Association Agreement do not demand to grant patents to the diagnostic methods, treatments and sugary, such decision should be making on the national level of country-party as well as the legal regime of arts in the sphere of biotechnologies.

Thus, under the Draft Law shall not be granted to the followings:

- varieties of plants and breeds of animals;
- processes of reproduction of plants and animals, being biological by their nature, that are not related to non-biological and microbiological processes, as well as the product of such a process;
- surgical or therapeutic methods of treating a person or an animal;
- methods of diagnostics of an organism of a person or an animal;
- human cloning processes;
- processes of changing genetic identity of people through the embryonic line;
- use of human embryos for industrial or commercial purposes;
- the processes of altering the genetic identity of animals that may cause their suffering without any significant medical benefit to humans or animals, as well as animals derived from such process;
- the human body at various stages of its formation and development, as well as the simple discovery of one of its elements, in particular the sequence or part of the gene sequence. This provision does not affect the legal protection of the invention being an object of the human organism outside the body or obtained in another way, using the technical process, including a gene sequence or a fragment of gene sequence, even if the structure of this element is identical to the structure of the natural element;
- a product or process involving a plant or animal if its use is restricted to a certain variety of plants or certain breeds of animals; a product or process that relates to a natural biological material which is not detached from its natural environment or is not a product of a technical process.

The mentioned novelties lay along the European standards of protection of biotechnologies, but it is still the discussion that it is necessary to work out separate legislation on protection of biotechnologies like the intellectual property objects.

Implementing the mechanism of approving the patents on medicines granting by Patent Office (Ukrpatent) by the Sate Expert Center of Ministry of Health of Ukraine

Such legal instrument helps to strength the control of the state through the Ministry of Health of Ukraine for the patenting granting procedure and patent monopoly in the field of health care from the balance of public interests.

According to the national legislation all medicines are approved for use in Ukraine after their registration by the Ministry of Health of Ukraine, and such registration is based on the decision of State Expert Center of the Ministry of Health of Ukraine, which researches the safety and efficacy of the pharmaceutical products. The problems arise during the

examination of applications on inventions in the sphere of medicine and pharmacy in the State Patent Office: for the expert of the State Patent Office the efficacy and safety could not be obviously. The expert of the State Patent Office examines the application from the point of novelty and new inventive step. The issues of efficacy and safety are not in their competence.

The research of the international experience of granting the patent in the sphere of healthcare shows us that the ANVISA's (Brazilian Health Regulatory Agency) experience is the most applicable for Ukraine. For this purpose, the involving to the procedure of the examination of the patent application in the field of medicine additional experts of the Ministry of Health of Ukraine for the improvement of technical level (therapeutic effect) of invention in the sphere of medicine shall be very effective.

Implementation of the Bolar regulatory exclusion provision

In Europe and in USA, the Bolar provision (also known as the Roche-Bolar provision) allows other parties to conduct studies, research and tests for the medicines' regulatory approval and other related acts such as manufacturing the pharmaceutical products. This provision or exemption originated in the U.S. by virtue of the *Roche Products vs. Bolar Pharmaceuticals* judgment.

Under this exemption, the producer of the generics has the advantage of producing or making serious preparations to produce the generics before the patent expiration of the original product, without the risk of being accused of patent infringement. Most countries adopt this provision, which is part of the TRIPS agreement, allowing researchers and scientists to utilize information from a patented invention to further understand the invention for the purpose of manufacturing the generics and perhaps developing or manufacturing new and innovative pharmaceuticals and to make preparations for the registration of generic products. However, Ukrainian legislation had not yet such provision and the preparation to the registration of the generic product is considered as the violation of patent's rights. Such situation caused because the patent linkage provision in Ukrainian pharmaceutical legislation. However, such scope of infringement does not exist in EU legislation as well as in USA legislation. To exclude such provision is one of the substantial part of patent reform.

Limiting the applicability of registration data exclusivity

Very close to the mentioned below issued is the provision of Article 9 of the Law of Ukraine "On Pharmaceuticals" which determines data exclusivity regime and patent linkage which has strengthened data exclusivity. There is a widespread practice when the manufacturers of brand medicines prevent competition by evergreening[1] patents. The Ukrainian laws also allow the five-year extension of the patent validity. The data exclusivity regime (5+1 year) also fences off the market from the generics. Thus, in Article 31 of Draft law the actions which are not considered to be infringement of rights beyond others is the use of the invention (utility model) in studies aimed to prepare and submit information for the registration of a medicinal product, a product for animal protection, a product for plant protection.

[1] The practice of "evergreening" is when the manufacturer introduces minor modifications to the already known substance to extend the patent protection of the drug beyond the legally approved term (20 years).

Implementing of pre-granting and improvement of post-granting patent opposition procedures in the Sate Patent Office (Ukrpatent)

Opposition proceeding is an administrative process available under the EU Patent Law and in many national jurisdictions which allows third parties to formally challenge the validity of a pending patent application ("pre-grant opposition") and of a granted patent ("post-grant opposition"). Actually, Ukrainian Law "On Protection of Inventions and Utility Models" does not allow the third parties to provide the arguments against the satisfaction of a patent application on the stage of its examination. According to the Draft Law within six months since the publication of the information on the application for an invention, any person may file a reasoned opposition to the application to the examination facility. The Draft also determines the following grounds for the pre-grant opposition:

- the declared object does not meet the requirements of parts 1, 2 or 3 of Article 6 of Draft law which mean that invention contradicts to the public order, generally accepted morality principles and it does not meet the patentability requirements;
- and the invention does not meet the requirements for patentability also established by Article 7 of Draft Law and which were means between the object excluded from the patent objects.

The opposition is considered within the scope of the motives set forth therein and taking into account the respondent's reply if it is provided within the established deadline. The result of consideration of the opposition are reflected in the substantiated opinion on the examination on the application. A copy of the decision of the State Patent Office, together with a substantiated conclusion, shall be sent to the submitter of the opposition. The important novelty of the Draft Law is that after the publication of the information about the application for an invention, any person may file an application for an information search by the invention formula and the drawings available to the examination facility. The report on the results of the information search is forwarded to the person who filed the petition within two months from the date of the submission. The applicant in the course of the qualification examination of an application for an invention has the right to amend the formula of the invention which could has the impact into the final result? Because of this, it is necessary to stress that such changes shall not extend the scope of the invention disclosed in the application, change the object of the invention, and enhance the scope of rights compared to the formula, which was published on the date of filing an application for a qualification examination.

Supplementary protection certificate on invention and public interests

Analising mentioned above TRIPS flexibilities and possible balance with the provisions of Ukraine-EU Association Agreement the attention should be paid also to the TRIPS-plus provisions which is strictly demanded by the Ukraine-EU Association Agreement. One of them is supplementary protection certificates on inventions (SPC) as a legal instrument of extortion of patent rights. Such provision has been implemented into the all association agreements which have been signed by each country which established such relationships with EU: Article 186 of Georgia-EU Association Agreement and Article 314 Moldova-EU Association Agreement. The rule of extortion of patent rights was transferred to the mentioned agreements from the Regulation (EC) No 469/2009 of the European Parliament

and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products[15] (hereinafter - EU Regulation on SPC).

The main idea of granting such supplementary protection is that the moment when the period that elapses between the filing of a patent application for a new medicinal product and obtaining the marketing authorisation to the same medicinal product makes the period of effective protection under the patent less than 20-years. However, in the international Intellectual Property doctrine the strict connection of such two different procedures are very disputable. Despite that, the same connection is determined in USA legislation. The right to a patent term extension based upon regulatory review is the result of the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417, 98 Stat. 1585 (codified at 21 U.S.C. 355(b), (j), (l) (Hatch-Waxman Act). The act sought to eliminate two distortions to the normal "patent term produced by the requirement that certain products must receive premarket regulatory approval." *Eli Lilly & Co. v. Medtronic Inc.,* 496 U.S. 661, 669, 15 USPQ2d 1121, 1126 (1990). The first distortion was that the patent owner loses patent term during the early years of the patent because the product cannot be commercially marketed without approval from a regulatory agency. The second distortion occurred after the end of the patent term because competitors could not immediately enter the market upon expiration of the patent because they were not allowed to begin testing and other activities necessary to receive FDA approval before patent expiration.

The EU Regulation on SPC also declares that a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the functioning of the internal market.

For Ukraine it is very important to implement into the national legislation the provision of Article 1 of the EU Regulation on SPC, that determines for the purposes of this Regulation, the following definitions:

1) 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;
2) 'product' means the active ingredient or combination of active ingredients of a medicinal product;
3) 'basic patent' means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate.

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use or Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products may,

under the terms and conditions provided for in this Regulation, be the subject of a certificate.

Such mentioned above territorial principle is used in the Legislation of United Kingdom keeping in a mined domestic interest: it is necessary to have a valid UK patent that protects the active ingredient and a marketing authorisation to place the active ingredient on the UK market as a pharmaceutical or plant protection product must have been granted[16]. The SPC is granted to the holder of the patent protecting the active ingredient, not to a licensee or a manufacturer of a pharmaceutical or plant protection product. The patent can protect: the active ingredient, a process to obtain the active ingredient, an application of the active ingredient. However, if you have several patents, protecting the same active ingredient you can use *any of them* but *not each of them*[16]. The marketing authorisation is either a national product license issued by the Medicines and Healthcare Products Regulatory Authority, the Veterinary Medicines Directorate or a valid UK plant protection product authorisation and an authorisation issued through the European Agency for the Evaluation of Medicinal Products. It must be the first *one granted to place the active ingredient* on the UK market[16]. It is also obligatory to inform if an earlier authorisation for the active ingredient exists in another country of the European Economic Area. The date of the first valid authorisation in the European Community, determines the length of the certificate[16].

Thus, coming back to the Article 220 of the EU-Ukraine Association Agreement, we are facing with the following demands. The Parties recognise that medicinal and plant protection products protected by a patent in their respective territory may be subject to an administrative authorisation procedure before being put on their market. They recognise that the period that elapses between the filing of the application for a patent and the first authorisation to place the product on their respective market, as defined for that purpose by the relevant legislation, may shorten the period of effective protection under the patent. The Parties shall provide for a further period of protection for a medicinal or plant protection product which is protected by a patent and which has been subject to an administrative authorisation procedure, that period being equal to the period referred to in paragraph 1, reduced by a period of five years.

Article 27-1 of Draft Law established that the owner of a patent to an invention, the subject of which is an active substance of a medicinal product, a product for animal protection, a product for plant protection, which may be introduced into the civilian circulation in Ukraine upon the permission of the competent authority, has the right to extend the validity period of intellectual property rights to such invention (supplementary protection), which is certified by the supplementary protection certificate. The rights to supplementary protection are limited to the product authorized by the relevant competent authority and its use, respectively, as a medicinal product, a product for animal protection, a product for plant protection, within the rights granted by the corresponding patent at the time of applying for the issuance of a supplementary protection certificate, and are valid if such market authorization is effective. The term of additional protection equals the period between the date of filing an application to the Office and the date of receipt by the owner of the patent of the first permit of the competent authority, reduced by 5 years. The term of supplementary protection can not be more than 5 years. For an invention the subject of which is the active substance of a medicinal product and for which pediatric investigation

has been carried out and the results of which are reflected in the product information that has been authorized by the relevant competent authority, the terms of the supplementary protection specified in paragraphs 1 and 2 of this part are increased by six months. The application must reach the Office within 6 months from the date of publication of the information on the state registration of the invention or from the date of issue of the first permit of the relevant competent authority, whichever is later.

Implementation of the non-commercial use with public health purposes, also known as governmental use

The non-commercial use is very similar regime to the compulsory license use, but is not the same. Ukrainian patent legislation determines the compulsory license regime in a Health Care but does not determine the government-use regime in a manner satisfied to use such legal instrument without risks to be sued. Let us stress, that one of the progressive step of the Ukrainian national reform is the international procurements of medicines by the determined international organizations, however, it has reflected the gape of Ukrainian patent legislation in a part of government-use of inventions on medicines. Despite that year to year Ukraine has very difficult situation with access to medicines we had not political will to use this mechanism. Actually, how it was mentioned above, the Ministry of Health of Ukraine and the National Academy of Law Sciences of Ukraine have established the Common Working Group on Intellectual Property and Economic Access to Medicines. The EU of compulsory licensing in Health Care Sphere basing on the Antitrust Legislation and Protection of the Consumers' Rights demonstrate the perspectives in such field in Ukraine as well. Using the experience of the EU draft the changes and amendments to legislation of Unfair Compaction and Antitrust legislation in the pharmaceutical market for the protection of patients' rights on medicines. Determine the strategy and drafting legislation in unfair competition and antitrust legislation on the sphere of pharmacy also shall be the priority of Ukrainians reforms. We are able to promote the necessity to provide consistent State Policy in the sphere of access to medicines by the mechanisms of IP Law and Antitrust Law.

Conclusion

Summarizing mentioned above, the expecting results of the Patent Reform in Health Care and Access to Medicines under the TRIPS flexibilities and under the Ukraine-EU Association Agreement is to keep balance between the Intellectual Property rights and Society interests in the sphere of Health Care, to ensure the access to the essential medicines and to implement the highest standards of protection of innovations in medicine and pharmaceutical market. The draft of the Ukrainian Patent Reform had been presented in the Global Summit in Intellectual Property and Access to Medicines in January 15-17, 2018 in Marrakesh and Ukrainian delegations felt the support of international community.

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