ABUSE OF PATENTABILITY CRITERIA WHEN PATENTING INVENTIONS RELATED TO MEDICINES

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It is well known that intellectual property monopolies for medicines reduce physical and economic availability. Main purpose of the study is to conduct brief review of foreign scholarly views on evergreening patenting practice in the field of pharmaceuticals, to demonstrate implications of such abusive practice and to exemplify good practices used in several countries to address the problem. Evergreening practice poses a serious challenge for healthcare system of Ukraine, but there are promising examples in several countries (e.g. Argentina, Brazil, India) of limiting evergreening.

Keywords: evergreening, secondary patents, TRIPS flexibilities, patentability criteria, medicines, pharmaceuticals

Introduction. It is well known that intellectual property monopolies regarding medicinal products reduce physical and economic availability during the term of such monopolies [1, 8], as the number of potential manufacturers, suppliers of such products is limited in order to obtain increased profits by the company that developed the medical product to recoup alleged R&D investments. For example, new treatment for cystic fibrosis by target therapy using small molecule medicine combination of ivacaftor/elexacaftor/tezacaftor (brand name Trikafta/Kaftrio) costs in Unites States up to $ 311,000.00 per patient per year, while generic version of the same drug from Argentina (Trixacar) costs $ 60,000.00 [2], and actual cost of manufacturing is probably far lower than that given that the drug consists of just a small molecule compounds. While there are from 900 to 4000 people with cystic fibrosis living in Ukraine [2], the patent owner Vertex having been granted and paying fees to support in force at least 4 patents allegedly related to Trikafta in Ukraine (No. 10261 valid until 2029, 104876 valid until 2028, 124567 valid until 2035, 125245 valid until 2035), have not responded to several requests of MoH Ukraine to enter the Ukrainian market [3]. Non-willingness of Vertex to obtain marketing authorization is precluding circulation of the drug on the private market and blocks possibility of state funding of access to this medicine in Ukraine.

Another example is drug for treatment of ovarian and prostate cancers Olaparib which costs in Ukraine at private market $ 49,608 [4] per 2 year treatment course [5] ($ 2,067 per month), while being small molecule drug it is sold less than 3x times cheaper in India in generic version at $ 15,864 [6] per 2 year treatment course ($661 per month). While there is no compound patent granted in Ukraine and only two secondary/evergreening patents are

protecting the Aztra Zeneca monopoly on medicine — No. 94209 valid until 2024 (for method of treatment) and No. 106878 valid until 2029 (for pharmaceutical compositions).

Since Ukraine is a member of the WTO and undertook to implement the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS), which obliges countries to issue patents for medicines, the question arises as to what ways there are within the framework of international law, including the TRIPS Agreement, to ensure access to cheaper generic versions of medicines in Ukraine during the martial law period. According to the developed by scholars and international organizations strategies/interpretations aimed at ensuring access to medicines within the provisions of the TRIPS Agreement, the so-called "TRIPS flexibilities" [7, 3], states can limit intellectual property rights to ensure access to generic cheaper medicines in several ways, which include strict application of patentability criteria to prevent granting of unmerited patents [8, 15].

Literature review. In domestic science, a number of works by U. Kapitsa, O. Gurgula, O. Kashyntseva [9], O. Ponomaryova [10], O. Zhikharev [11], A. Gomenyuk, were devoted to the issues of patenting of medicinal products. Below, O. Gurgula's study regarding the obvious-to-try test, as a method of preventing the issuance of evergreening patents, will be considered in more detail [12]. In foreign science, the issue was quite extensively studied by C. Correa, A. Kapczynski, G. Chaves, M. Viera, T. Amin and many others.

The purpose of the study is to conduct brief review of foreign scholarly views on evergreening patenting practice in the field of pharmaceuticals, to demonstrate implications of such abusive practice on quantitative and temporal extension of monopolies on medicines and to exemplify good practices used in several countries to address the problem.

Results of the study. Although there is no legislative definition of the strategy of evergreening of patents, Carlos Correa defines it as 'a strategy by which pharmaceutical companies apply for patents over derivatives, formulations, dosage forms, etc. of known drugs in order to extend their exclusive rights beyond the expiry of the original patent' [13, 1].

According to Kapczynski, Chaves, Viera and other researchers, patents can be divided into primary or patents that protect an active pharmaceutical ingredient/substance, and secondary patents that protect new forms of a known substance, methods of medical use of a known substance, etc. and are aimed at extending the monopoly beyond the expiration date of the substance patent. There are several approaches to the name of patents or clauses of patent formulas that do not relate to the active pharmaceutical ingredient (substance) of the medicinal product: «evergreening» patents [14, 18], «secondary» patents [15], [16, 428], «follow-on» patents [12, 3], «later — issued patents»[17, 1].

According to Chaves, Viera in the pharmaceutical field primary patents or claims are only those that relate to the active pharmaceutical ingredient (API) or to the API synthesis process [18, 186]. Chaves, Viera classified the following claims as secondary claims that are actively used by the pharmaceutical companies in evergreening practice:

1. Compositions;
2. Markush formula claims;
3. Selection patents;
4. Dosage;
5. Polymorphs;
6. Salts, ethers and esters;
7. Combinations;
8. Enantiomers;
9. Intermediates (intermediate products);
10. Product-by-process claim (claim aimed at the product, which is described by the method of its production, for example, product X obtained using process Y);
11. Prodrugs and metabolites;
12. Method of treatment;

13. Use (second medical use);
14. Methods of administration of the medicinal product [18, 186–188].

All these secondary claims are actively used by the pharmaceutical industry: firstly, to obtain a large number of patents (creation of patents clusters or patent thickets) regarding the medicinal product for the widest possible protection of all aspects of its production and use, similar to future medicinal product compounds and their forms, 'to create an enforceable right' [16, 393] and 'to create [published] prior art' [16, 393] in order to discourage competitors to pursue development of similar products in the same area, the so-called «defensive patenting strategy»[16, 393]. For example, the drug Humira (adalimumab) for the treatment of rheumatoid arthritis of the company Abbvie is protected by 'more than 100 issued United States patents' [19, 1]; secondly, for the artificial extension of the monopoly thanks to secondary patents, which continue to operate after the expiration of the primary patent (in the understanding of Cháves, Viera and Kapczynski, this is the strategy of evergreening) [18, p. 45]; and, thirdly, to implement the strategy of transition (transfer of patients) to a new formulation of an already known medicinal product in order to continue the monopoly, the so-called 'product hopping'[20] (for example, pharmaceutical company Gilead's switched from tenofovir fumarate, an HIV drug, to tenofovir alafenamide, which is a prodrug of tenofovir).

It appears that before the 90-s of the XX century some pharmaceutical companies only patented new chemicals with a single patent, but they later changed their patenting approach to gain a monopoly on so-called product 'lifecycle initiatives'. The number of patents issued for medicinal products began to grow rapidly and, for example, according to the results of the EU pharmaceutical sector survey in 2009 [16, para 486], there were about 40,000 issued patents or pending patent applications for 219 medicinal products in the 28 EU member states, according to data from pharmaceutical companies. Of the pending patent applications, about 93% were classified as secondary, and of the issued patents, 84% were classified as secondary patents, which was a result of the evergreening strategy [16, para 427]. Similar results were reported in studies in Thailand, where 2,188 patent applications related to pharmaceuticals filed over 11 years from 2000 to 2010 were analyzed, of which 84% of patent applications in Thailand were examples of evergreening, and 74% of granted patents also fell into this category [21].

According to a study of Kapczynski, Park and Sampat in the United States of 1,304 patents for medicinal products indicated in Orange Book USA, 'effectively all chemical compound patents are filed before drug approval, and early enough that only 11% issue after the approval date' [15, 6]. While secondary patents are filed later, with nearly one in five secondary patents filed after the drug is approved by the FDA, and close to half issuing after the approval date [15, 6]. Considering the fact that the main argument for the introduction of the institute of the extension of the term of validity of patents for medicinal products was the thesis about the shortened effective term of the patent protection for a medicinal product due to the delay in the regulatory registration of the medicinal product, it seems logical that secondary patents do not deserve such an extension of the term of validity and mere existence of secondary patents undermines main purpose of the institute of patent term extensions. In Ukraine, institute of supplementary protection certificates (SPC) was introduced with similar substantiation that EU and Ukraine '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.' [22, article 220], while evergreening of patents appears to be also widespread phenomenon in Ukraine [23, 55], meaning that even when effective protection of primary patent filed before marketing authorization is shortened there will be still patent monopoly on given medicine secured by secondary patents. In addition, according to this study,

independent secondary patents on average add a significant amount of time to the statutory terms of patent protection of an invention (20 years) and there is a trend towards an increase in obtaining independent secondary patents for medicinal products with higher sales volumes. Thus, for medicines'that have chemical compound patents, secondary patents add on average between 4 and 5 years of additional nominal patent term' [15, 6]. Relative to drugs that do not have patents on the active substance, pharmaceutical companies rely much more on secondary patents to maintain a monopoly in the market. In such cases, according to Kapczynski, Park and Sampat study when there are secondary patents, they generate an average of 9 and 11 years of patent term beyond the standard data exclusivity period. [15, 6].

So what would be the ways of combating abuse of patentability criteria in the field of pharmaceuticals? Some researchers believe that if the checks and balances already in place in the current patent system are applied properly and consistently and operate within a sufficiently funded and well-developed procedural framework, an overly strict approach to further pharmaceutical innovation or even outright exclusion of such inventions are unnecessary and will most likely do more harm than good [24]. However, as noted the number of secondary patents increases, which leads to an unreasonable restriction of competition, blocking the development of science (due to the Markush formula or insufficient disclosure of inventions), which ultimately leads to unreasonably high prices and restrictions on the availability of medicines. In particular, the prices of patented drugs are often not related to the cost of manufacturing the drug, even after the patentee has fully recouped the investment in the development of the drug, as in the case of the hepatitis C drug sofosbuvir [25].

Today, there are few examples of successfully combating the abuse of patentability criteria, but they illustrate practices that can be adapted and used by other countries.

First of all, patent offices may stick in their examinations of patent applications related to pharmaceutical field to strict application of novelty and inventive step criteria. And in fact, prominent legal battles in various jurisdictions over blockbuster hepatitis C cure drug sofosbuvir showed that some patent offices, including in Argentina, Brazil [26] and Ukraine [27], can apply strictly patentability criteria when there is public attention (in the form of patients-led civil society organizations advocacy, media coverage, patent oppositions, etc.) to relevant patent applications.

Arguably, the most effective mechanism for limiting secondary patents for medicinal products is the implementation of the Guidelines for the Examination of Patent Applications of Chemical and Pharmaceutical Inventions in Argentina [28]. The essence of the instructions is a detailed regulation of correct application of patentability criteria, rules regarding what is an invention and what is not included in patentable subject matter according to legislation, etc. [29, 30] Following the introduction of the guidelines in 2012, the number of patents granted in Argentina in one year dropped to 54, while in Mexico, a similar market size to Argentina, the number of patents issued in 2012 for pharmaceutical products was 2,500 [29, 19]. A study of the Argentine patient organization Fundacion GEP, reports that after the adoption of the guidelines, the Argentine Patent Office rejected 95% of patent applications for antiretroviral drugs for the treatment of HIV [30].

In Brazil, a review mechanism was implemented by the National Agency for Sanitary Regulation (ANVISA), which under patent law was required to give its "prior consent" to the granting of any pharmaceutical patent by the National Patent Office (INPI) in order to protect the needs of public health and ensure strict examination of patentability. From 2001 to 2012, ANVISA rejected more than 400 patent applications that would otherwise have been issued by the patent office, and improved disclosure or narrowed the scope of protection for 40% of the applications [30].

In India, amendments have been made to the patent law such as Section 3(d), which was introduced as an amendment to the Indian Patents Act, 1970 in 2005. It consists of

three parts: (1) discovery of a new form of a known substance; (2) discovery of a new property or new application of a known substance; and (3) using a known process [31]. The first and third parts include «conditional exceptions» to patentability that can still be overcome by demonstrating: (i) an improvement in the effectiveness of the substance and (ii) that a new product is produced or involves «one new reagent». However, the second part is a categorical ban on patenting «the mere discovery of any new property or new use of a known substance» without any exception [32]. Although this rule is an extremely important precedent in the systemic regulation of the problem of evergreening, a recent study by Ali [32] of more than 2,200 pharmaceutical patents granted in India showed that 1,645 (72%) of these patents are secondary and should not have been issued under Section 3(d), which indicates the shortcomings of practical application and the need to remove the test of «enhancement of the known efficacy of known substance».

In Ukraine, until 2020, there were quite relaxed rules on patentability of medicines, e.g. methods of treatment [10, 37] or new uses of known substances were permitted for patenting. After years of advocacy by patients-led civil society organizations (e.g. 100% Life [33]) first important step was done by restatement of Law of Ukraine «On protection of rights on inventions and utility models» on 21 July 2020 when Ukrainian parliament approved governmental bill that has laid the foundations of 'policy of pharmaceutical nationalism'[9, 142] or in author's view another term would be 'policy of pharmaceutical sovereignty', by introducing the following changes aimed at better implementation of TRIPS Flexibilities in Ukraine:

1. Exclusion of medicines from patenting by utility models;
2. Exclusion of methods of treatment, new uses of known substances from patentable subject matter;
3. Introduction of additional clarification to inventive step criterion for medicines by recognizing possibility of new modifications of known medicines not to meeting inventive step criterion unless those demonstrate significant difference in efficacy (according to Zhikharev this amendment along with exclusion of methods of treatment are measures to fight evergreening patents [11, 49]);
4. Introduction of supplementary protection certificates (SPCs) instead of blank 5 years patent term extension for medicines; introduction SPC manufacturing waiver (mirrored from EU mechanism to support local generic manufacturers);
5. Introduction of pre-grant and post-grant patent oppositions mechanisms;
6. Deleting within compulsory licensing mechanism 'ungrounded refusal' prerequisite condition (which was a clear TRIPS-plus provision, making CL mechanism unrealistic to apply in practice).[34]

While such changes are groundbreaking in comparison to previous state of patent legislation in Ukraine regarding patenting of pharmaceuticals, it is still remains to be assessed whether these changes had any influence on Ukrpatent practice in granting pharmaceutical patents. On the contrary, adoption of automatic extension of IP rights during martial law, including extending of duration of patents, is showing worrisome trend into the opposite direction [35].

Conclusion. Evergreening practice poses a serious challenge for healthcare systems of developing countries, including for healthcare system of Ukraine, in terms of meeting the needs of population while protecting the low-quality patents being granted as a result of such practices widely used by the pharmaceutical companies. While there are promising examples in several countries (e.g. Argentina, Brazil, India) supporting local manufacturing of low-cost generic medicines by limiting evergreening practice in the pharmaceutical field, Ukraine still needs to go a long way to properly address the secondary/follow-on patent applications related to medicines. The first foundational step in that direction was done by restatement of Law of Ukraine «On protection of rights on inventions and utility

models» in July 2020 by excluding methods of treatment, recognizing that new forms of known substances could be non-patentable, introducing possibility of challenging patent applications and patents by pre-grant and post-grant patent oppositions, etc., all of which will potentially help to reduce the number of secondary patent and patent claims, and now is the good time to implement those changes into life. Potential most influential next step in addressing the evergreening problem is to develop and introduced more detailed patentability guidelines in relation to pharmaceuticals to guide the patent examination of patent applications related to medicines, just like it was done in Argentina.

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Зловживанням критеріями патентоздатності під час патентування лікарських засобів

Основна мета дослідження полягає в тому, щоб провести короткий огляд поглядів зарубіжних та вітчизняних науковців на практику вічного озеленення в патентуванні у сфері фармацевтики.

В результаті аналізу було виявлено, що практика вічного озеленення патентів у сфері фармацевтики, як прояв зловживання критеріями патентоздатності, виникла відносно нещодавно в Європі, на початку 90-х років XX століття, до цього деякі фармацевтичні компанії захищали нову речовину одним патентом. І вже у 2009 році згідно з даними фармацевтичних компаній, у 28 країнах-членах ЄС було близько 40 000 виданих патентів або заявок на патенти, що очікують розгляду, на 219 лікарських засобів. Серед поданих патентних заявок близько 93% були класифіковані як вторинні/вічнозелені, а з виданих патентів 84% були класифіковані, як вторинні патенти, що було результатом стратегії вічного озеленення. Подібним чином, в США серед 1304 патентів на лікарські засоби, майже кожен п'ятий вторинний патент подається після того, як ліки схвалено FDA (тобто суттєво пізніше моменту, коли нова речовина стала відомою), і майже половина видається після дати затвердження, Крім того, вторинні патенти в середньому додають значний проміжок часу (від 4 до 11 років) до встановлених законом термінів патентного захисту винаходу (20 років), і існує тенденція до збільшення отримання незалежних вторинних патентів на лікарські засоби з більшим обсягом продажів.

Практика вічнозелених патентів створює серйозний виклик для систем охорони здоров'я країн, що розвиваються, в тому числі й для системи охорони здоров'я України, щодо задоволення потреб населення при одночасному захисті неякісних патентів, які видаються внаслідок такої практики, яка широко використовується фармацевтичними компаніями. Хоча в кількох країнах (наприклад, в Аргентині, Бразилії, Індії) є багатообіцяючі приклади підтримки місцевого виробництва недорогих генеричних ліків шляхом обмеження практики вічного озеленення патентів у фармацевтичній галузі, Україні ще потрібно пройти довгий шлях, щоб належним чином вирішити проблему з вторинними/вічнозеленими патентними заявками на лікарські засоби.

Ключові слова: вічнозелені патенти, лікарські засоби, ТРІПС, гнучкі положення, умови патентоздатності

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