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Presentation
Intellectual Property as a Driver of Ukraine's Pharma Sector: Ongoing IPR Reforms

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Switzerland-Ukraine Pharma Roundtable

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I. Ukraine's International Obligations in the Area of IP Rights

The good news is that Ukraine has been always very active in joining international conventions. Moreover, as the EU-Ukraine Association Agreement took effect on 1 September 2017, there is much more serious work being carried out on harmonizing Ukrainian legislation with EU standards. This tendency is fully applicable to the area of Intellectual Property (IP) rights, including in the Pharma sector.

There are several important international documents applicable to the IP rights, including in the Pharma sector:

- Directive 2001/83/EC of the European Parliament and of the Council "On the Community Code Relating to Medicinal Products for Human Use" (https://ec.europa.eu/health//sites/health/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf);
- Patent Cooperation Treaty (PCT) (as modified on October 3, 2001) for International Patents http://www.wipo.int/wipolex/en/treaties/text.jsp?file_id=288637
- Agreement on Trade-Related Aspects of Intellectual Property Rights (**TRIPS**), which is the key international for the IP rights protection, and which has been implemented into Ukrainian law https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm

IP rights in general, including in the Pharma sector, may seem to be a very technical subject. In fact, the IP rights are in the center of the global debate between the rightholders and governments with regards to affordable access to medicines and relaxing conditions for generic competition, especially in countries with low income and economies in transition.

The international basis for the legal regime of IP rights is TRIPS, but how each government implements TRIPS in its own legal system makes a big difference.

There are two approaches on the opposite sides of the spectrum:

- First approach is to implement TRIPS as strictly as possible and, furthermore, to provide additional protections not directly required by TRIPS. This approach is known as "**TRIPS-plus effect**", and it favors

rightholders, with what some experts consider as an excessive level of IP protection. Ukraine, until now, has followed this approach.

- Second approach is taking full advantage of the so-called "**flexible mechanisms of TRIPS**", when governments opt for a lesser level of protection within the TRIPS framework, which results in more affordable medicines for the population. At present this second approach, to various degree, is gaining global popularity.

Although Ukraine has been adhering to the first, **TRIPS-plus approach**, the overall Pharma sector reforms and specific pending legislations aim to follow the global trend, and to shift this approach to taking advantage of the **flexible mechanisms of TRIPS.** This would allow for what the government believes to be *a fair balance* between interests of rightholders and the right of Ukrainian population to have access to affordable medicines.

I am not going to take sides in this debate; the notion of "fair balance" may be interpreted differently by the industry/rightholders on one side, and by the governments on the other. I just propose to examine the key markers of the IP rights protection regime in Ukraine, looking at the current legislation, its standing with TRIPS, and pending proposals concerning each marker.

II. Key Markers of the IP Rights Protection Regime

1. Protection terms

According to Article 6 of the Law of Ukraine "On Protection of the Rights to Inventions and Utility Models (the "**Patent Law**"), the term of patent protection in Ukraine is 20 years. This term, however, can be prolonged for up to 5 years. This creates a longer protection term than required by TRIPS or by EU legislation because:

- TRIPS does not require prolongation of the patent protection term; and

- the total patent protection term in Ukraine is longer than in the EU, calculated under the certain formulas, taking into account the prolongation.

2. Patent Protection of utility models and industrial designs

A lot of questions arise from the fact that current Ukrainian legislation allows obtaining patents not only for ***inventions***, but also for two items that do not require "inventive level" (under TRIPS - an "inventive step"): ***utility models*** and ***industrial designs.***

The legal protection regime concerning utility models at present is almost identical to inventions, with the only major difference being in the patent protection term, which is 20 years for inventions and 10 years for the utility models. The latter term, however, can be easily prolonged by the rightholders making only minor adjustments, leading to "Evergreen patents", as I explain with regards to the next marker.

Pending bills propose to separate inventions and utility models.

In addition, although Article 27.3 (a) of TRIPS provides for the "exclusion from patentability of: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;", current Ukrainian law does not contain similar provisions. Therefore, it is proposed to separate medicines, diagnostic, therapeutic and surgical methods from utility models, and deprive them of patentability.

For industrial designs, which are also protected by patents, at present there is only one criterion for patentability: *novelty*. Pending bills propose to establish additional criterion of patentability for industrial design: *distinctiveness*. In addition, a possibility will be introduced for filing an appeal with the Appeal Chamber of the State Intellectual Property Service for recognizing an industrial design as invalid.

3. Evergreen Patents

Article 6 of the Patent Law provides for patenting of products and processes, as well as for «new use of a known product or process". In fact, TRIPS does not contain such a provision for patentability of a "new use". Having this provision in the law represents a risk of "Evergreen Patenting" of medicines. Therefore, a proposal is being discussed of depriving the "new use" of patentability.

In practice, the "Evergreen Patents" mean patents, which are slightly modified compared to the original patents, but lack sufficient novelty. Thus, replacing the old medicines with the new modifications, which do not have additional therapeutic advantages, is one of the methods employed by the rightholders for preserving their exclusive rights through extension of a patent term.

Another method is registration of medicines as utility models (the result of a human intellectual activity in any technological field), whereas the requirements for a utility model are much less stringent as compared to that for an invention. Such a system allows for "Evergreen Patents" for medicines because in the absence of any "inventive level" ("inventive step") requirements for utility models, adding of any features may qualify as novelty, and consequently allows obtaining of a new patent.

4. Compulsory License (Use Without Authorization of the Right Holder)

TRIPS, and especially Protocol to it of 6 December 2005 (introducing new Article 31*bis*), tend to liberalize unauthorized use of patents.

Article 31 of TRIPS allows, under certain circumstances, for the governments the use of the subject matter of a patent without the authorization of the right holder, mostly in the form of a compulsory license. Such an unauthorized use is allowed predominantly for the supply of the *domestic market*.

The Protocol, however, provides for supplementing TRIPS with the new Article 31*bis*, which allows member-states, under certain conditions, *to export* pharmaceutical products manufactured under a compulsory license, to

member-states, which do not have their own manufacturing capacities in the pharmaceutical sector for the products in question.

Although the Protocol has not taken effect yet because it has not been ratified by all members-states, Ukraine on 3 February 2016 passed the Law "On Adoption of the Protocol on Amendments to TRIPS". This Law caused controversy with pharmaceutical companies, and especially with the rightholders of patents for original drugs, which argued that expanding unauthorized use in Ukraine would result in abuse and serious violations of the IP rights.

In general, there are several proposals pending aimed at streamlining the regulation of unauthorized use, because until now this regulation has been limited to the Cabinet of Ministers Resolution *"On Approval of the Procedure for Granting the Cabinet of Ministers' Permission for Use of Patented Invention Pertaining to a Medicine"* # 877 dated 4 December 2013, which is known for its many flaws.

5. Introduction of Bolar Exemption:

The so called "Bolar Exemption" (also known as the "research exemption") is practiced in the US, Canada and the EU. According to this exemption, notwithstanding the patent rights for the original medicines, it is allowed for third parties to perform research and tests for preparing regulatory approval (for example by the FDA in the US) for a certain period before the patent for the original medicine expires. This exemption allows generic manufacturers to be ready with the generic medicines in advance, and to start production the moment the patent for the original medicine expires.

In Ukraine there are proposals pending to allow the Bolar Exemption.

6. Exhaustion of IP Rights

WIPO explains that Exhaustion of IP rights refers to one of the limits of IP rights: once a product, protected by an IP right, has been marketed either by the rightholder or by a third party authorized by the rightholder, the IP rights of

commercial exploitation over this given product can no longer be exercised by the rightholder, as they are exhausted.

Basically it means that introducing a product into commercial circulation by its first sale, the rightholder no longer can control or oppose subsequent acts of resale, rental, lending or other forms of commercial use by third parties. (http://www.wipo.int/sme/en/ip_business/export/international_exhaustion.htm)

The Exhaustion of IP rights principle has different implications depending on whether the country of importation applies the concept of national, regional or international exhaustion.

Under ***national exhaustion*** the rightholder loses the right to control the commercial circulation of its product on the domestic market, after the product is first introduced into domestic market commercial circulation by such rightholder (or an authorized third party). At the same time, ***national exhaustion*** does not prevent the rightholder to claim and protect its IP rights for the same product when it is imported into another country, which adheres to the principle of ***national exhaustion***. For example, a rightholder in Poland exhausts its IP rights when it makes the first sale of its product in Poland. At the same time, when this product is imported into Ukraine (which adheres to the ***national exhaustion*** principle), the rightholder still can claim and protect its IP rights, for example against parallel (gray) importers.

On the contrary, under ***international exhaustion***, the IP rights are exhausted once the product has been sold by the rightholder (or an authorized third party) in any part of the world. In this case, if Ukraine adheres to the ***international exhaustion*** principle, if a rightholder had introduced the product into commercial circulation anywhere in the world, it will not be able to claim and protect its IP rights when the product is imported into Ukraine. This means legalizing parallel import in Ukraine because it no longer could be opposed by the rightholder.

Because at present Ukraine adheres to the ***national exhaustion*** principle, rightholders can legally oppose parallel (gray) imports. However, TRIPS do not prevent Ukraine from switching to the ***international exhaustion*** principle, thus legalizing parallel import.

III. Bad Faith Actors in the IP Area affecting the Pharma Sector

Key problems with bad faith actors in Ukraine are the same as in many other countries:

➢ Counterfeit and falsified medicines

Although Ukraine introduced in 2011 criminal liability for falsification of medicines and circulation of falsified medicines[1], the volume of sales of falsified medications remains quite high. In accordance with the Report of the International Chamber of Commerce for 2014 "Development and Protection of Intellectual Property in Ukraine"[2], some experts believe that a share of falsified medicines on the Ukrainian pharmaceutical market may account for 40 % of the total market and 80 % - in respect of certain medicines.

In order to decrease the turnover of falsified medicines, it is necessary to undertake a number of on-going measures, including to strengthen control over imports and distribution of medicines, organize a more efficient system of bringing the infringers to justice, and decrease corruption at various government agencies (including Customs) and courts.

➢ Patent and Trademark Trolling

Ukrainian Customs maintain the Customs Registry of IP rights, in which rightholders register their rights, and in case of unauthorized (gray or counterfeit) import, the rightholders have a possibility to oppose it.

This Customs Registry of IP rights is the main object of the so-called patent and trademark “trolls” (apparently, trolls inhabit not only Facebook and Twitter).

Patent and trademark “trolls” take advantage of the rightholders failure to register their trademarks and patents in Ukraine by filing registration applications themselves. After the trademark or patent have been registered in the name of the troll, the troll registers the IP rights with the Customs Registry and in case the legitimate rightholder wants to import its products into Ukraine,

[1] Article 321-1 of the Criminal Code of Ukraine № 2341-III dated April 5, 2001

[2] http://iccua.org/wp-content/uploads/2014/07/--Rozvitok-i-zahist-intelektualnoyi-vlasnosti-v-Ukrayini---zvit-za-2014-rik.pdf

the troll demands a compensation. Trolls also may demand compensation for granting the right to use a trademark or a patent on the territory of Ukraine.

The example of a patent troll blocking the import by the legitimate rightholder is reflected in the Ruling of the High Specialized Court for Civil and Criminal cases in case № 760/20577/14-ц of 22 June 2016[3] . In this case, the plaintiff (legitimate rightholder) challenged registration by the defendant (troll) of the patent and registration with the Customs Registry of IP rights of two industrial designs "Rubber cork for bottles" of 25 January 2012 (designed to cap medicines). The court sided with the plaintiff (legitimate rightholder) and has satisfied the claim in full, relying on the expert examination, which showed that the industrial design in question did not match the novelty criterion.

The above ruling is an excellent precedent demonstrating that legitimate rightholders may indeed succeed in defending their rights in Ukrainian courts.

Besides, a legitimate rightholder may defend its IP rights in administrative, civil and criminal court, as well as by resorting to administrative proceedings at the customs border.

Nevertheless, the best and least time-and cost-consuming defense against patent and trademark “trolls” is for the legitimate rightholders to timely and properly register their trademarks and patent in Ukraine, and then register with the Customs Registry of IP rights.

- **Parallel (Gray) Imports**

At present, because Ukraine adheres to the ***national exhaustion of IP rights*** principle, the best defense for the rightholders against parallel imports is to register their rights with the Customs Registry of IP rights, and use the opposition methods stipulated by the law.

[3] http://www.reyestr.court.gov.ua/Review/58559947

IV. Pending Proposals

- On 17 November 2016 the Ministry of Healthcare ("**MH**") published on its website a draft Resolution of the Cabinet of Ministers of Ukraine "*On Approval of the National Policy for Provision of Medicines for 2025*" (http://www.moz.gov.ua/ua/portal/Pro_20161117_2.html)

Appendix №2 to the National Policy lists the proposed measures for ensuring availability of affordable medicines:

Drafting amendments to the Law of Ukraine "On Medicines" regarding introduction of the "unlicensed" regime in exceptional cases	Ministry of Health	Middle-term
Drafting amendments to the Law of Ukraine "On Protection of Rights to Inventions and Utility Models" and Resolution of the Cabinet of Ministers of Ukraine N 877 of 4 December 2013 for optimization of the procedure for compulsory licensing; drafting proposals to the Law of Ukraine "On Medicines" regarding limiting, in the public interest, of the ***data exclusivity*** (protection of clinical trial data required to be submitted to a regulatory agency to prove safety and efficacy of a new medicine) and introduction of ***Bolar exemption***, as well as and abolishment of patent link; drafting proposals to the Law of Ukraine "On Protection of Rights to Inventions and Utility Models" and to various regulations regarding introduction of the ***international exhaustion of IP rights*** principle for medicines	Ministry of Health Ministry of Economic Development	Short-term
Drafting proposals regarding amendments to the Rules of Consideration of Applications for	Ministry of Heath Ministry of Economic	Middle-term

Invention and the Applications for Utility Model for a detailed regulation of criteria of patentability in respect of inventions in the area of medicines	Development	

- On 3 February 2017 the MH published on its website a draft Resolution of the Cabinet of Ministers of Ukraine *"On Approval of the State Strategy for Implementation of the Government Policy of Provision of Medicines to the Population for 2017–2025"* (http://moz.gov.ua/ua/portal/Pro_20170203_01.html), proposing the following measures for ensuring the affordability of original (innovative) medicines for the population:

  - setting additional requirements for patentability of inventions pertaining to medicines in order to prevent issuance of "Evergreen Patents", i.e. new patents for inventions which are not innovative and provide only for insignificant modifications with insignificant improvement of the efficiency compared to the existing patents

  - taking measures, in each particular case, for ensuring affordability of innovative expensive medicines by applying, if needed, flexible mechanisms of TRIPS;

  - optimization of the procedure for compulsory licensing of the inventions pertaining to medicines;

  - incorporation into the Ukrainian law of the Bolar Exemption, under which third parties (meaning generic manufacturers) shall have the right to file an application for the state registration of generic medication prior to expiration of the term of the patent for the original medication. This would allow the generic manufacturer to start production immediately upon expiration of the term of the patent;

- cancelling the patent check requirement at the time of state registration of medicines;

- allowing parallel import of medicines through introduction of the ***international exhaustion of IP rights*** principle for medicines;

- allowing limiting, in the public interest, of the ***data exclusivity*** for medicines.

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