Limitations to patent rights: The fair use of protected inventions

Continuing our reflections on the limits of the patent protection that started with our previous post in the "Patents Without Secrets" (compulsory licenses), we would like to present you the crucial information concerning the institution of the fair use of others' protected inventions.

The fair use of others' invention has been authorized by the Polish legislator in numerous cases listed in Article 69 of the Act of 30 June 2000 on Industrial Property Law (hereinafter: IPL). Before we proceed to its detailed analysis, it is worth to point out that they are divided into two distinct groups: situations wherein limitations to patent rights are created by operation of law and can apply to any patent, and situations where the fair use is allowed on the grounds of an administrative decision.

The scope of the exclusive rights of a patent holder under Article 63 of the IPL

First of all it must be highlighted that **the scope of the patent rights, according to Article 63 Section 1 of the IPL, encompasses the exclusive right to use an invention in commercial and professional purposes within the territory of the Republic of Poland.** This provision shall be understood to signify that the use in all the other purposes would fall beyond the scope of exclusive rights of the patent holder. **The exemptions es-**

tablished by Article 69 which regulates the fair use of others' invention, **would include only that use which is covered by the protection, i.e., commercial or professional.**

Relevant regulations of international law

As it is usually the case when it comes to that particular field of law, the shape of regulations adopted by the Polish legislator has largely been determined by the relevant norms of international law. In this context it is necessary, as professor Du Vall points out in "Patent Law", to apply the three-step test formulated in the TRIPS Agreement. Namely, the exceptions to the exclusive rights conferred by the patent are permissible as long as they remain limited, and moreover such exceptions:

1) Do not unreasonably conflict with a normal exploitation of the patent;
2) Do not unreasonably prejudice the legitimate interests of the patent owner;
3) Take account of the legitimate interests of third parties.

Inherent limitations to patent rights: the fair use by operation of law

Just like we promised, let us move on right now to a more detailed analysis of situations in which the fair use of a protected invention is permissible — beginning with the first group of those cases, labeled as **inherent limitations, which are created by operation of law and apply to any patent.** It must be added that another common feature of the cases belonging to this category, is **the lack of remuneration for the use.**

A. The transport exemption

The provision of Article 69 Section 1(1) indicates that **the patent holder's rights are not infringed by the use of the invention pertaining to the means of transports, parts thereof or devices that temporarily enter the territory of the Republic of Poland, as well as the objects in transit entering this territory.** This case is known as the transport exemption and it plays a significant role from the point of view of international trade.

In its phrasing the aforementioned provision of the IPL refers to Article 5ter of Paris Convention for the Protection of Industrial Property of 1883, according to which in any country of the Union the following shall not be considered as infringements of the rights of a patentee: 1) the use on board vessels of other countries of the Union of devices forming the subject of his patent in the body of the vessel, in the machinery, tackle, gear and other

accessories, when such vessels temporarily or accidentally enter the waters of the said country, provided that such devices are used there exclusively for the needs of the vessel; 2) the use of devices forming the subject of the patent in the construction or operation of aircraft or land vehicles of other countries of the Union, or of accessories of such aircraft or land vehicles, when those aircraft or land vehicles temporarily or accidentally enter the said country. **It shall be pointed out that the scope of the exemption in the Polish legislation has been designated as broader than its counterpart in Paris Convention:** it has been extended to included the objects which are in transit — and as professor du Vall observes, the objects in transit have not been specified by the legislator; therefore it can be "any device, product or substance belonging to the subject matter of the patent".

The exemption applies regardless of which means of transport is employed in a given case. Some doubts might arise, however, when it comes to the temporal limits of the permissible fair use of an invention. In the commentary to the IPL edited by professor Sieńczyło-Chlabicz, it is explained that the length of time when a given means of communication, its part or devices can stay within the Polish territory, would depend on "purpose and means of transport".

B. The research exemption

According to Article 69 Section 1 (3) of the IPL, **the patent is not infringed by the use of the invention for research and experimental purposes, for its evaluation, analysis or education.** In the commentary to the IPL by doctor Michalak the necessity to study an invention during the period of the protection is invoked as the reason for the implementation of such an exemption. If we were guided by the literal wording of the provision, we could assume that the exemption may apply to research that is conducted in the purpose of commercialization of the results; it is not restricted to "a pure science" aiming just to satisfy the academic curiosity.

Whenever the research exemption is being discussed, **the most controversies arise with regard to two distinct types of the use of a given invention in the research: whether it is an object of the research** (the research of the invention), **or it serves as a mechanism or a tool applied in the research** (the research with the use of the invention). A careful study of Article 69 Section 1(3) allows us to conclude that the invention can play both parts in every case that this provision refers to, except for the use for analysis and evaluation — in those instances it can be used only as an object of the research. The scholars warn that an overly strong attachment to the linguistic interpretation of Article 69 Section 1(3) might generate some risks: if we accept that a given invention can be freely used as a tool in research, the patent holders would be de facto deprived of their protection. **Therefore, there are calls in the doctrine to consider the commercial and pro-**

fessional use of the invention for the purposes that it has been designed for as belonging to the sphere of exclusive rights of the patent holder.

C. The registration exemption

No infringement occurs when it comes to the use of an invention involving producing, using, storing, offering, placing on the market, exporting or importing, **for the purpose of carrying out activities that are required by law to obtain, also by a third party, registration or authorization as a condition for market authorization of certain products due to their intended use, in particular medicinal products** on the territory of the European Economic Area or another country (Article 69 Section (4)). This exemption is referred to as the **Bolar provision and it has been intended to strike a balance between interests of manufacturers of innovative medicines and interests of generics.**

What must be strongly emphasized is that **the Bolar exemption cannot be interpreted extensively:** it applies to **the use of an invention for a purpose that has been precisely defined as carrying out activities that are required by law to obtain registration or authorization.** Thus, it would not apply to placing products on the market: if such an action requires a consent of an entitled person and such a consent is not granted, placing product on the market would be equivalent to the patent infringement. According to Article 69 Section 5, the eventual grant of registration or authorization does not affect a potential civil liability for placing products on the market without such a consent. Due to the revision of 2019, the scope of the exemption has been broadened: the aforementioned activities can be performed as well by a party that does not seek registration or authorization for themselves, but is acting on behalf of someone else.

In the case of the Bolar exemption, the territorial scope of its application gains major significance. It is worth to cite a position of the Appellate Court in Gdańsk: in its judgment of 26 June 2012 the court stated that "the national legislator is entitled to regulate only those situations that fall under its jurisdiction", therefore "it can authorize the use of an invention without the consent of the patent holder under the Bolar exemption solely with regard to the activities related to the registration or authorization that would be issued within the territory over which it has jurisdiction".

D. The pharmaceutical exemption

It is worth adding that an infringement of a patent would not occur in case of production of a medicine on the basis of an individual medicinal prescription (Article 69 Section 1 (5)). Once again we are faced with a conflict of two distinct values: the protection of health of individuals and the protection of rights of a patent holder; the legislator

solved it in favor of the former. The production of a medicine takes place in a pharmacy; it is prepared for an individual patient who submits a medical prescription. It is not allowed to produce a medicine in a quantity that would exceed that which is indicated in the prescription. It is remarked in the commentary by professor Sieńczyło-Chlabicz that the exemption applies regardless whether the prescribed medicine is a magistral medicine, or a medicine freely available without a prescription; it is similarly irrelevant whether there are any alternative medicines on the market.

E. The breeder's exemption

The last of the exemptions belonging to the category of the inherent limitations to patent rights, was added to the IPL on the basis of the Act of 16 October 2019 amending the IPL and the Act on Court Costs. The amendment entered into force on 27 February 2020. Article 69 Section 1(6) provides that **a patent infringement does not occur in case of the use of biological material for the purposes of breeding or discovering or producing new plant varieties.** The so-called breeder's exemptions has already been introduced into the Polish legal system through Article 15(c) of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights; it has been indicated in the justification accompanying the project that such a revision is an attempt to achieve a greater coherence between the protection at the EU level and the protection at the domestic level.

The use of an invention for the state purposes

A specific case of the fair use of others' invention, governed by its distinct rules, is established by Article 69 Section 1(2) of the IPL, under which **the patent is not infringed by the use for state purposes in a necessary scope, without exclusivity rights, if it is imperative to prevent or eliminate a threat to the major interests of the state, in particular in the area of security and public order.** Such a use is not permitted by operation of law, but **it needs to have a basis in a decision of a proper minister or a provincial governor** (a patent holder shall be immediately informed about such a decision; the decision must indicate the scope and the period of the use of the invention), as provided by Article 69 Section 2. An appeal against the decision might be submitted to an administrative court (Article 69 Section 4). Another difference is noticeable in the aspect of a remuneration — as it has already been signaled before**, a person whose invention is used for the state purposes is entitled to a remuneration from the budget of the state in an amount equal to a market value of a license** (Article 69 Section 4).

In fact the conditions in which this kind of the fair use is allowed bear a strong resemblance to the premisses for the grant of the compulsory licenses, nevertheless, we must remember that we are dealing with two independent paths of obtaining authorization

for the use of a protection invention **— the main difference is related to the question of who grants a permission in a given mode**. In case of compulsory licenses it is the Polish Patent Office; when it comes to the fair use: a minister or a provincial governor.

