Exhaustion of patent rights

Patent exhaustion determines the limits of the monopoly that the patent holder is entitled to**.** If a product that constitutes the material embodiment of the rights under the patent is placed on the market by the right-holder (or with their consent), they lose control over its further fate. **Due to the exhaustion of the right, the right-holder cannot take actions aimed at opposing the use of their product that by their consent has already been placed on the market, in particular, cannot prevent its resale.** In the first part of this article, we briefly discuss how the legislator defines the content of patent rights and invoke the relevant provision regarding exhaustion of rights in the Act of June 30, 2000 - Industrial Property Law (IPL). Next, we embed this regulation in the context of the legal system of the European Union (EU) — since we are dealing with the incorporation into the Polish system of the solution developed by the Court of Justice of the EU (CJEU). We also point out some doubts that may arise regarding specific aspects of the application of the IPL's relevant provision.

Exhaustion of patent rights as a patent limitation

As is well known, pursuant to Art. 63(1) of the IPL, by obtaining a patent, a patent holder acquires the right to exclusive use of the invention in a commercial or professional manner in the territory of the Republic of Poland. Importantly, if a given invention concerns a manufacturing method, the protection also extends to products obtained in this way (Art. 64(1)). Art. 66 defines the content of the patent, establishing "a catalog of activities amounting to an invasion of the sphere of exclusivity" (Ewa Nowińska, Urszula Promińska, Krystyna Szczepanowska-Kozłowska, *Prawa własności przemysłowej. Przedmiot, treść i naruszenie*, Wolters Kluwer, Warsaw 2021). The IPL specifies that the patent holder may prohibit a third party who does not have their consent from the following forms of commercial or professional use of the invention:

> 1) producing, using, offering, placing on the market, storing or warehousing the products being the subject of the invention, exporting or importing them for these purposes; or
> 2) using the method that is the subject of the invention, as well as using, offering, placing on the market, storing or warehousing products obtained directly by such a method, exporting or importing them for these purposes.

However, if the patent is exhausted, the patent holder loses the right to challenge such actions in relation to products constituting the material embodiment of the patent; therefore, it must be concluded that we are indeed dealing with a form of a patent limitation.

The relevant regulation on patent exhaustion can be found in Art. 70 IPL. Pursuant to Section 1, **the patent does not extend to activities relating to the product according to the invention or manufactured using the method according to the invention, that involve in particular offering it for sale or further placing it on the market, if the product was previously placed on the market in the territory of the Republic of Poland by the right-holder or with their consent.** Moreover, import into the territory of the Republic of Poland and other activities referred to in Section 1, regarding a product previously placed on the market in the European Economic Area (EEA) by the right-holder or with their consent, do not constitute an infringement.

The territorial scope of the patent exhaustion

We can talk about exhaustion on either a national or regional scale. Domestic exhaustion is not a controversial institution. As pointed out in the monograph “Prawo patentowe” (*Patent Law*) by Michał du Vall, international exhaustion poses far more challenges (ed. Elżbieta Trapie, Piotr Kostański, Justyna Ożegalska-Trybalska, Paweł Podrecki, 2nd ed., Wolters Kluwer, Warsaw 2017). The concept of international exhaustion presupposes that if the invention is protected by a patent

in several countries, marketing a product according to the invention (or manufactured using a method according to the invention) by the right-holder in only one such state would mean the loss of the exclusive right to this product also in the other states. The monograph indicates that allowing such a possibility would be contrary to the rule enshrined in Art. 4 bis of the Paris Convention for the Protection of Industrial Property of 1883, according to which "patents applied for in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or not" (the principle of territoriality). Moreover, the monograph indicates that no clear rules in this regard have been developed at the international level. The TRIPS Agreement leaves state parties discretion to regulate the exhaustion of rights.

It should be noted that **in the territory of the EU, or more broadly — the entire EEA, we are dealing with a supranational, regional form of patent exhaustion.**

A different question is whether the EU Member States could apply international exhaustion. It is worth noting that the judgment of the CJEU of July 16, 1998 in case C-355/96 *Silhouette v. Hatlauer* demonstrates that states do not have such freedom to establish an international system of exhaustion of rights with respect to trademarks. The possibility of extending the rule formulated in this case to patents remains a controversial issue. In the WIPO document of April 2022 we can read that the prohibition of international exhaustion applies to patents as well. However, the monographyby Du Vall spotlights an important difference: under the EU law, the provisions regarding trademarks have been harmonized, which cannot be said about the regulations on patents — this might support the possibility of accepting international exhaustion.

The origin of the exhaustion of patent rights in the EU

At the EU level, the principle of exhaustion of patent rights was elaborated in the case-law of the CJEU and dates back to the 1970s (so in the strict sense, it predates the EU itself as we know it today). It should be emphasized that one of the basic principles of the EU internal market is the principle of free movement of goods, expressed in Articles 28-37 of the Treaty on the Functioning of the EU. There is, therefore, a tension between that principle and the territoriality of patent rights. The institution of exhaustion should, therefore, be viewed as an attempt to reconcile them.

In the CJEU case-law, the concept of exhaustion of rights appeared for the first time with respect to copyright in the judgment of June 8, 1971 in the case of *Deutsche Grammophon Gesellschaft v. Metro-SB-Grossmärtke*, C-78/70. The Court held that although the Treaty does not affect national legislation relating to industrial and commercial property rights, the manner in which those rights are exercised may nevertheless fall within the scope of the Treaty's regulation. It further em-

phasized that although the provisions of the Treaty allow for derogations from the free movement of goods justified by the protection of industrial and commercial property, **such derogations are permissible only to the extent that they are justified for the purpose of safeguarding rights which constitute the specific matter of such property**. The Court held that where a record producer exercises his exclusive rights to distribute protected products placed on the market in one Member State in such a way as to prohibit their sale in another Member State on the sole ground that such distribution has not taken place on the national territory, there is a violation of the rules on the free movement of goods within the internal market.

That approach was elaborated on in subsequent rulings. For example, in the judgment of October 31, 1974 in case C-15/74 *Centrofarm BV v. Sterling Drug Inc,* the CJEU clarified **what is meant by the specific matter of protection — namely, it is the guarantee that the patentee will receive reward for the inventor's creative effort.** In this case, the Court pointed out that if the patent holder could prevent the import of products placed on the market by them or with their consent into the territory of other Member States, they could partition national markets and thus restrict trade between Member States. If they placed the product on the market themselves or someone did so with their consent, it should be considered that the right-holder already received such a reward, and therefore import restrictions cannot be justified by referring to the specific subject of protection.

Taking into account the origins of patent exhaustion within the EU, it should be emphasized, following Nowińska et al., **that patent exhaustion in Polish law "reflects the concept developed in the case law of the Court of Justice."**

When the exhaustion of rights occurs

Placing the institution of the exhaustion of rights in the context of the case-law of the CJEU (also the case-law concerning other industrial property rights, especially trademarks) is helpful in interpreting the particular grounds of the exhaustion which find expression in Art. 70(1) of the IPL.

The first situation in which the exhaustion occurs, i.e. "placing on the market in one of the EU Member States", as indicated by Nowicka et al., should be interpreted in the light of the CJEU judgment of November 30, 2004 in case C-16/03 *Peak Holding AB v. Axolin-Elinor AB* as meaning that placing on the market takes place only at the moment of sale (i.e., transfer of ownership); merely importing the products or sale within the EEA, or even offering the products for sale, is insufficient in this respect. It is worth pointing out that in the monograph by Du Vall it is the moment of "transfer of physical control over a product to a third party, regardless of the legal title" that is indicated as the decisive moment for determining whether a product has been placed on the

market. It is worth mentioning that, apart from sale, another title for transferring ownership may be, for example, an exchange or donation agreement.

As for the second situation of the exhaustion, it is again worth referring to the case-law of the CJEU when determining whether the requirement of consent of the right-holder has been satisfied. Nowicka et al. indicate in this respect that "introducing goods with the consent of the right-holder means placing them on the market by an entity that is related to the right-holder either by legal or economic ties; in the absence of such a connection, consent "should be express and affirmatively expressed." In some cases, there may be implied consent, but the entity relying on it bears the burden of providing proof of its existence; certainly the mere silence of the right-holder or the lack of notification of their objection cannot be construed as consent (the judgment of November 20, 2001 in combined cases C-414/99 to C-416/99 *Zino Davidoff SA v. A & G Imports Ltd and Levi Strauss & Co. and others v Tesco Stores Ltd and others. Reference for a preliminary ruling: High Court of Justice (England & Wales), Chancery Division (Patent Court) - United Kingdom*). Furthermore, based on the case-law of the CJEU, it can be indicated that exhaustion will not occur if the product is placed on the market by an entity holding a compulsory license (see the judgment of July 9, 1985 in case C 19/84 *Pharmon BV v. Hoescht AG*). However, if the right-holder has originally placed a product on the market in the territory of an EEA country where there is no patent protection, it is assumed that the placing on the market took place with the consent of the right-holder (see the judgment of July 14, 1981 in the case C 187/80 *Merck v. Stephar*).

The scope of the exhaustion

It should be emphasized that **the exhaustion applies to an individualized product.** The patent itself remains in force. It follows, as it is pointed out in the monograph by Du Vall, that "when assessing actions taken by third parties, the criterion of integrity and identity of the object should be applied". In other words, if the rights are exhausted, the right-holder cannot interfere with the actions of other entities in relation to this specific item. However, the situation will be different when the actions of third parties result in a violation of the integrity and identity of the item. If, for example, we are dealing with reproduction or reconstruction of that item, it will not be possible to talk about exhaustion. **All rights preceding the placing of the product on the market will continue to enjoy protection,** and the buyer does not gain the right to manufacture a given product (see Tobiasz Serafin, *Wyczerpanie praw własności intelektualnej*, Zeszyty naukowe Uniwersytetu Rzeszowskiego, zeszyt 87/2015, Prawo 16, p. 144-153).

An interesting issue that has so far been largely ignored in the literature and case-law is the question whether only the inventions indicated in Art. 70 PWP may be subject to exhaustion of rights. The provision of Art. 70 **refers only to a product according to the invention or manufactured by a method according to the invention.** The question arises whether it is possible to

exhaust rights relating to a method that is not used to manufacture a product, e.g., a patentable diagnostic method. It seems that such a conclusion cannot be reached based on the provisions of the IPL. The linguistic interpretation is quite clear: for exhaustion to be occur, a product must have been manufactured — either a product according to the invention or a product manufactured using a method according to the invention. **If the method does not lead to the manufacturing of a product that will be placed on the market, the right cannot be exhausted.** Similarly, Michał Bohaczewski, in a commentary on the IPL Act edited by Łukasz Żelechowski, points out that **placing on the market a device for the application of a patented method does not result in the exhaustion of the patent for that method** — unless, such a marketing is interpreted as the consent of the person entitled to use that device to manufacturing of products covered by the patent. Importantly, in this case we are not dealing with the application of EU provisions on the free movement of goods, thus, the justification for the institution of exhaustion of rights in the EU system will not be adequate here.

Finally, it is worth mentioning **the special case of biotechnological inventions.** Pursuant to Art. 93^5(1) of the IPL, the patent does not extend to biological material obtained by a single reproduction of biological material placed on the market by the patent holder or with their consent, **if the reproduction is a necessary result of the use** of biological material.