Launch-at-risk of generics not that risky anymore

When the intellectual property court will refuse to grant security to the holder of a patent for an original drug

The decision of June 4, 2024 of the Intellectual Property Division of the Regional Court in Warsaw handed in the case regarding rivoraxaban (reference no. XXII GWo 225/24), should be of interest to all producers of generics considering the so-called launch-at-risk.

The launch-at-risk refers to a situation in which a generic product is introduced to the market while the proceedings to invalidate the patent for the original drug have not yet been finalized. In such a case, of course, the patent holder can be expected to bring an infringement action, in which they will certainly seek security in the form of an injunction to withdraw the generics from the market. In fact, until now, security kept in force over the lengthy litigation effectively prevented the generic manufacturers from selling their products.

Meanwhile, **based on the last year's changes the Polish civil procedure, a new judicial practice is developing.** Courts are required to take into account pending invalidation proceedings and the likelihood of their specific outcomes — which significantly changes the position of generic producers.

The rivoraxaban case

Rivoraxaban is the active substance of an anticoagulant drug classified in the group of factor Xa inhibitors. The plaintiff in the infringement proceedings holds the European patent PL/EP 1845961 for the invention "Treatment of thromboembolic disorders with rivaroxaban", commercialized as the medicinal product Xarelto. It is worth mentioning that the ongoing proceedings are merely a part of a number of similar cases recently initiated by the patent holder against generic producers in various jurisdictions. As a matter of fact, in its decision, the Regional

Court in Warsaw referred to judgments handed in France, England, and the Republic of South Africa.

The allegations formulated in the proceedings regarding the invalidation of the PL/EP patent 1845961 concern two fundamental issues:

a) There is no invention

As we read in the court's ruling, "the concept of invention implies (...) the methodical use of controllable forces of nature in order to achieve a causally perceptible result." Meanwhile, the patent claim refers to the use of tablets for the production of a drug for the treatment of a thromboembolic disorder administered no more than once a day for at least five consecutive days. In the court's view, the phrase "once a day", which does not indicate any quantity, is so broad that it "does not actually contain technical information". It is not possible to derive from the patent description any clear information about dosage. Therefore, we are dealing with a reference to a scientific discovery rather than an invention.

b) There has been no sufficient disclosure

The description itself, according to the court, is unclear. Some of the information presented in it is not based on available research. Importantly, information on dosage cannot be extracted from the patent description.

The Regional Court in Warsaw found these arguments convincing. Ultimately, **it dismissed the request for security on the grounds of the probability of patent invalidation, which it assessed as higher than 50%.**

Not only rivoraxaban

It is worth noting that the decision of the Regional Court in Warsaw of June 2024 is not its first ruling in which it refused to grant security to the patent holder based on the likelihood of patent invalidation. In the case no. XXII GWo 313/23, the same court dealt with an application for security filed by K sp. z o. o., a manufacturer of accessories and furniture for children, holding the patent PL/EP 1795424 "Transformable seat inlet for child's or doll's pram". The company requested the seizure of baby strollers produced by T. S.A. and ordering it to cease, for the duration of the legal proceedings, producing, importing, offering, and marketing under its brand in Poland strollers with the function of transforming a gondola into a seat.

The Regional Court noted that invalidation proceedings regarding patent PL/EP 1795424 were in fact ongoing (they were at an early stage of an exchange of letters between the participants). At the same time, it took note of the invalidation of the patent in Great Britain due to the lack of novelty of the claimed solution according to the patent in relation to the Chinese utility model no. CN 2739057Y, as well as due to the lack of an inventive level of the solution according to the patent. Taking into account this information (provided by the parties), the court concluded

that there was a high probability of invalidation of the patent, which was why the application should not be granted.

The legal basis

It should be emphasized that this practice is still something of a novelty. In the former state of law, when deciding to grant security, the court would not take into account the likelihood of the patent being invalidated in other proceedings. In Poland, these proceedings are conducted autonomously before distinct authorities: infringement proceedings before courts, and invalidation proceedings before the Patent Office of the Republic of Poland.

However, the recent amendments in the Polish Act of November 17, 1964 - Code of Civil Procedure (CCP) in a sense abolish this autonomy of proceedings. Namely, it is due to Art. 730^1 § 1^1, which was introduced by the Act of March 9, 2023 amending the Code of Civil Procedure and certain other acts that is effective from July 1, 2023.

In accordance with the new rule:

In the matters mentioned in Art. 479^{89} [intellectual property cases], when assessing whether the claim is substantiated, the court takes into account the likelihood of invalidation of the exclusive right in other ongoing proceedings. This circumstance is determined based on information from the parties, unless it is known to the court ex officio.

The security can be granted to the applicant if two conditions are met. First, they demonstrate a legal interest, which is defined in Art. 730^1 § 2: it exists when the lack of security prevents or seriously impedes the execution of a judgment rendered in the case or otherwise prevents or seriously impedes achieving the purpose of the proceedings in the case. What is more, the second condition for granting security is that the claim is substantiated. It is explained in the literature that, “substantiating is a substitute, or surrogate, for evidence in the strict sense, which does not provide certainty, but only the credibility (probability) of a certain fact”. (See Art. 243 KPC Zieliński 2022, ed. 11/Flaga-Gieruszyńska Code of Civil Procedure. Comment 2022, ed. 11). Substantiating is therefore exempt from strict evidentiary formalities, but the court is unlikely to rely on the parties' statements alone if they are not supported by additional materials (Ibid).

In the current state of law, the court, when assessing whether the claim has been substantiated, must therefore — based on the information provided by the parties, unless it is in possession of such information ex officio — assess the chances of invalidating the patent in other ongoing proceedings. **Therefore, the allegations formulated in the proceedings before the Polish Patent Office become a relevant point of reference for it**. In other words, a high probability of invalidation precludes the court from granting security (see A. Gołaszewska, *Changes in security proceedings in intellectual property matters - comments under the Act amending the Code of Civil Procedure of March 9, 2023*).

What this new practice means for the generics producers

It is worth paying attention to the benefits this solution offers to generic producers. One may be tempted to say that from their point of view it is **a true game-changer that will inevitably affect the way they devise their strategy for placing the generics on the market.**

The court's obligation to take into account the likelihood of a patent being invalidated in other ongoing proceedings **allows us to expect that security will be granted less frequently than has been the case up to this point.** If a prior invalidation application has been filed and is supported by solid allegations, and the generic manufacturer then raises this fact before the court in the infringement proceedings, the court will not be able to ignore it. Therefore, it becomes less risky for such a manufacturer to introduce a product to the market before the invalidation decision becomes final. They do not come immediately under fire of the holders of patents for the original drugs requiring them to withdraw the generics from the market. **The newly amended law and judicial practice, therefore, substantially reinforce the position of the generics producers.**