Patent linkage in the proposed amendment to the Polish Reimbursement Act

In Poland, the work on the amendment of The Act of 12 May 2011 on the Reimbursement of Medicines, Foodstuffs Intended for Particular Nutritional Uses and Medical Devices is currently in progress. **The project developed by the Ministry of Health was published in the Public Information Bulletin of the Government Legislation Center on 30 June 2021.** On the same day, an invitation to public consultations was issued — the consultations lasted for 2 months, until 31 August. Even though the project has not been submitted to the parliament as of this moment, it proposes certain regulations that merit a closer look right now. Should the new provisions enter into force in a form that is currently envisioned, it would not be possible to grant a reimbursement decision for a generic medicine during the term of the protection of an original medicine. In consequence, **the adoption of the legislation would lead to the introduction of the controversial institution of the patent linkage into the Polish legal order.**

In this Legal Report we would like to analyze the changes in the relevant provisions that the project of the amendment includes. Next, we will examine the *ratio legis* as described in the project's justification. In the subsequent part of this article we will attempt to situate the proposed regulation in a broader context of the EU law, which to a far extent limits the legality of patent linkage in domestic systems — leaving, however, a certain room

for maneuver that, as demonstrated by inconsistent practice, tends to be exploited by the member states.

The proposed changes in the currently binding provisions

The proposed changes that are of interest to us concern mostly two particular provisions of the Reimbursement Act: **Article 11 and Article 24.**

Pursuant to Article 11, the reimbursement of a medicine, foodstuff intended for particular nutritional uses, and medical devices is granted on the basis of an administrative decision of the minister competent in the matters of health (the amendment specifies that denial of reimbursement shall also take the form of an administrative decision). From our point of view, the key addition is **new Section 1a.**

The minister competent in the matters of health denies the reimbursement of a medicine, foodstuff intended for particular nutritional uses, medical devices, if at the time when the request for reimbursement is filed, at least one original counterpart which is reimbursed for a given indication enjoys a patent or market exclusivity protection.

Some modifications have also been suggested with regard to the period for which a reimbursement decision is issued: currently, according to Section 3, it is 3 or 2 years (and for medicines fulfilling the criteria established in new Article 13a, i.e., manufactured in Poland or manufactured with the use of an active substance that is manufactured in Poland, this period should be 3 or 5 years). The term of validity of the decision cannot at the same time exceed the period of the market exclusivity. Let us remark here that this mention of the market exclusivity refers to the Act of 6 September 2001 - Pharmaceutical Law. In Article 15 Section 2 it is provided that, regardless of a granted market authorization, the counterpart of a reference medicinal product cannot be allowed to enter into the market earlier than 10 years after the first market authorization for a reference medical product was granted in the EU or EFTA member state. **Section 3a, added in the amendment, ties the maximum period of the validity of the decision with the duration of the patent or the supplementary protection certificate (SPC) protection, should it expire earlier.**

The subsequent provision in which the project of the amendment introduces some far-reaching changes is Article 24, opening the fifth chapter of the Act dealing with the procedural aspects of the reimbursement. According to new Section 1a, in case of an application for an increase of the administrative price of a medicine, a foodstuff intended for particular nutritional uses, or a medical device that is filed within the term of validity of the reimbursement decision but before the expiration of market exclusivity or patent protection,

as well as within 12 months of the term of the first reimbursement decision made after the occurrence of such circumstances, **the application has no legal effect and it shall not be processed.** Moreover, the amendment indicates that, where appropriate, one of the attachments to the application referred to in Article 24 Section 1 (i.e., apart from the aforementioned application for an increase of the administrative price, it can be, for instance, an application for the reimbursement or for the determination of the administrative place), shall be a patent document or a decision granting an SPC (Section 2(6)).

The project's justification

The project of the amendment is of a comprehensive nature — it constitutes an overview of the currently binding regulations and it proposes corrections to the flawed solutions, clarifications to those that raise interpretative difficulties, as well as the introduction of some novel institutions that are supposed to contribute to the increase of the production of medicines or active ingredients on the Polish territory. The preamble to the justification identifies some specific goals that the amendment is supposed to achieve: the changes we are considering here are falling mainly within the scope of the 6th goal pinpointed by the Ministry of Health, i.e., improving the transparency of the reimbursement decisions and increasing the level of confidence in the dialogue between the participants of the system.

In the project's justification, the proposed changes with regard to Article 11 are described as serving to clarify the currently binding regulations. **The addition of Section 1a is motivated, according to the authors, by the necessity to ensure the transparency of the reimbursement announcements and the stability of the reimbursement list.** The resort invokes the past negative experiences in that regard and claims that **a situation where there are doubts whether it is legal for a reimbursed drug to be present on the Polish market cannot be accepted.** Apparently, such situations have occurred quite frequently: a generic secured a positive reimbursement decision and it was inserted in the list, while the producent of an original medicine enjoying the patent protection or the market exclusivity initiated judicial proceedings, requesting an injunction prohibiting the sale of the counterpart on the market. The authors of the project consider such a scenario unfavorable for patients who get to find out that they cannot purchase a medicine featured on the reimbursement list because the court has prohibited its sale.

Should the provisions be adopted in the currently proposed shape, **it will not be possible to grant a reimbursement decision for a generic medicine whose comparator is an original medicine benefitting from the patent or market exclusivity protection.**

The proposition of adding Section 3a to Article 11 is also addressed in the justification: the new rule is supposed to guarantee more level playing field when it comes to the obligations of pharmaceutical companies. Once the reimbursement decision expires, it is necessary to lower the price — right now the relevant provisions impose such an obligation only on those entities who have benefited from the market exclusivity, but are silent on the situation of those who have benefited from the patent protection, even though — as the authors of the project notice — the character of the protection on the grounds of the market exclusivity very closely resembles the one derived from the patent.

Furthermore, the Ministry of Health explicitly indicated that the purpose of changes in Article 24 is to "curtail the possibility of circumvention of the currently binding legal provisions".

The patent linkage and the Bolar exemption

As we have mentioned in the introduction to this article, the solution proposed by the Ministry of Health, would mean the introduction into the Polish law of the institution of the patent linkage. **It involves linking the market authorization decision — but also more broadly: the decision regarding the price determination, as well as, as is the case here, the reimbursement decision — to the status of the comparator's patent.**

Medicines for Europe, an organization representing the manufacturers of generics and identifying the increase of the availability of drugs to patients as its primary objective, is a very vocal critic of the patent linkage. It considers reinforcing the patent protection as unnecessary, taking into account that is sufficiently strong on the basis of currently binding regulations. The organization tries to raise awareness of the anticompetitive impact of the patent linkage: this institution is employed to effectively limit the generics' and biosimilar products' chances of entering the market.

One of the crucial arguments raised against the patent linkage is a threat it poses for the Bolar exemption (also referred to as the registration privilege). The purpose of the Bolar exemption is to permit the manufacturers of generics to start working on the development of the generics while the original medicine still enjoys the patent protection, so that it is possible to put their product on the market immediately after the patent protection expires. Considering how time-consuming the research and development process is, the monopoly of a patent owner, in the lack of this exemption, would last *de facto* long after their exclusive rights formally cease being effective. It is, thus, an absolutely essential solution from the perspective of increasing the availability of cheaper counterparts

of original medicines, and one whose main beneficiaries are supposed to be patients. The patent linkage, as it has been pointed out in the 2020 report by Medicines for Europe, would lead to undermining the Bolar exemption, going directly against its underlying goal (the report in question is available here: ***White Paper. Anatomy of a Failure to Launch: a review of barriers to generic and biosimilar market entry and the use of competition law as a remedy***).

The patent linkage in the EU

The position of the European Commission towards the patent linkage is not at any rate ambiguous: the EC consistently and strongly opposes the legality of such an institution in the system of the EU law.

From the wording of Article 126 of **Directive 2001/83/WE** of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, it is clear that **an authorization to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in that Directive.**

Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC added to it Article 10 Section 6 which reflects the Bolar exemption. According to the rule in question, **conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4** (demonstrating that a medicinal product is a generic medical product with respect to the reference medicinal product) **and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.**

As a side note, it is worth mentioning that the regulation in the Polish Act of 30 June 2000 - Industrial Property Law (chronologically earlier, though amended in the meantime) remains consistent with the EU directive. The Bolar exemption finds its expression in Article 69 Section 4: no patent 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 (we have written about in our article in *Patents*

Without Secrets series: ***Limitations to patent rights: The fair use of protected inventions (No. 1/2021)***.

While the EU provisions discussed do not leave room for any doubts regarding the illegality of tying the generic market authorization to the status of the patent for the original medicine, the situation might be more controversial if we consider issues such as determining the price of the medicine or the reimbursement. **The practice of the EU member states is not coherent in that respect.**

The practice of the EU members

One state that goes especially far is Italy — it provides for the patent linkage in its legislation. In Italian Law Decree no. 158/2012, converted by Italian Law no. 189/2012, there is Article 11(1-bis) known as the so-called **Balduzzi provision.** On its basis, equivalent medicinal products shall not be classified as drugs reimbursed by National Health System with effect prior to the date of expiry of the patent or the SPC. It must be noted that this provision does not entirely rule out the reimbursement of a generic, nor the right of its producer to file an appropriate application, however the potential reimbursement decision becomes effective no earlier than on the next day after the original medicine's patent or the SPCs expires. It is, therefore, a conditional decision.

Let us add that in February 2021 the Italian Medicines Agency (AIFA) passed a resolution clarifying certain doubts regarding the application of the Balduzzi provision, explaining that it should be applied only to patents/SPCs on the active ingredients per se (further categories of patents such as patents for specific processes for manufacturing of medicines remain, thus, outside of the scope of its application). The Balduzzi provision has been criticized by the Italian Competition Authority (AGCM); the EC has also voiced its reservations.

Nevertheless, Italy is not the only European state where we can observe the adoption of specific regulations that can be characterized as the patent linkage. For instance, **in Germany**, reimbursement from public health insurance funds is only available if a given medicine has been included to the price list managed by the private entity IFA GmbH (it is also an institution that has an exclusive competence in Germany to grant to medicines a PPN number without which their sale in pharmacies would not be possible). IFA does not put a generic on the list if a patent holder files an objection. A similar practice can be observed in **the Netherlands** with regards to G-Standaard, the Dutch medicines database. **In Portugal**, the application for market authorization filed by the generic's producer automatically allows the patent holder to start litigation against the applicant. Until recently, in that

state there was a system of the obligatory arbitration between patent holders and producers of generics, however, as a consequence of the changes implemented by the amendment of 2018, the arbitration requires consent of both parties and the disputes are in principle adjudicated by the Portuguese Intellectual Property Court. A detailed overview of the practice of the European states can be found in the 2019 Medicines for Europe report (***Position Paper. The Anti-Competitive Effects of Patent Linkage***).

Remarkably, the 2019 report contained already some critical remarks directed towards the currently binding regulations in the Polish Reimbursement Act. Specifically, Article 25(3) was found to raise some concerns: it provides that an application that Article 24 Section 1 refers to (i.a., an application for reimbursement of a medicine) shall include a proof of that medicine's (alternatively, of foodstuff's intended for particular nutritional uses or medical devices') availability on the market at the moment the application is filed. There is an objection that in fact this rule makes it impossible to place a counterpart of an original medicine on the market the next day after the expiry of the patent/SPC protection. **It is clear that the proposed regulation is a much bolder step in that direction and it should be expected that it is going to provoke much stronger criticism from the Medicines for Europe and, most probably, also from the EC.**

Summary

Let us remind you that the Ministry of Health in the justification of the project of the amendment, when addressing the proposal to add Article 11a, has invoked the necessity of ensuring the stability of the reimbursement lists and the transparency of the reimbursement announcements. The regulation currently in force has been assessed negatively as generating some undesirable situations from the point of view of patients who might find out that one or the other medicine featured on the list has been prohibited from the market because the patent holder has initiated judicial proceedings. **Nonetheless, it seems that this calculation is incomplete: what is missing is the consideration of some of the broader repercussions of such a solution.**

We have demonstrated that **the patent linkage can take different forms**. The most "traditional" variant, where the market authorization is dependent on the status of the patent for the original medicine, is not the only one. We will be dealing with the patent linkage also where such a link is established between the reimbursement decision and the patent. Undoubtedly, the regulation proposed in the amendment displays such a character.

The proposed patent linkage will cause the delays in the generics' entrance on the market and will lead to disruptions in competition. It is, therefore, doubtful whe-

ther patients will actually benefit from the amendment. It clearly contradicts the purpose that the Bolar exemption, embedded in the Polish and the EU law, is supposed to serve. Such a regulation can raise numerous legal doubts; however, an unequivocal assessment of the legality of the patent linkages other than the aforementioned traditional variant is not an easy task and there is a certain gap identifiable that the proposed regulation could possibly fit into.