Data exclusivity

Despite the title of our series (“Patents without secrets”), this entry is dedicated to market monopoly, which concerns a specific group of products, and its source is pharmaceutical law rather than industrial property law.

Data exclusivity is a special institution that provides additional protection to manufacturers of medicinal products. It is justified, as indicated by Prof. Du Vall in "Patent Law", on the grounds of "the need to protect an entrepreneur who has incurred huge, time-consuming and cost-intensive expenses to obtain and introduce an original drug to the market." The position of such an entrepreneur would not be optimal if, immediately after receiving authorization to place his product on the market, producers of generic drugs could present proof of the equivalence of the original drug and their product and almost automatically enter the market, avoiding a similar tedious procedure including, i.a., non-clinical and clinical research. On the other hand, offering generic manufacturers the possibility of using a simplified procedure for obtaining a market authorization satisfies the needs of the public interest. It allows ”to avoid repeated testing on humans and animals where this is

not strictly necessary and to save time and expense on repeated testing ” (commentary edited by Prof. Haberko to the Polish Act of September 6, 2001 - the Pharmaceutical Law).

Therefore, **a middle-ground solution is sought,** one that offers generic manufacturers a choice: **either they undertake their own research and apply for authorization submitting its results, or, after waiting a certain period of time, they can apply for authorization based on the results obtained by the original manufacturer.**

Data exclusivity in the TRIPS Agreement

At the outset, it is worth underscoring that at the international level the guarantees of such protection have been established in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), specifically in its Part 2 Section 7 concerning protection of undisclosed information. In the context of the TRIPS regulation, the data exclusivity will be linked especially to combatting unfair competition. Pursuant to Art. 39(3), members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

The regulations at the EU and domestic levels are more detailed and elaborate: as it is noted in the textbook by professor Du Vall, “unlike the rather weak protection based on the protection of confidential information under the provisions on combating unfair competition, the protection envisioned in the provisions of pharmaceutical law creates a much stronger position of the holder of the first authorization to market a medicinal product."

Definition of a generic medicinal product

A necessary starting point in considerations of data exclusivity must be the definition of a generic medicinal product. In the commentary edited by prof. J. Haberko to the Pharmaceutical Law, there is an explanation that "**generic drugs are medicinal products that have the same quantitative and qualitative composition of active substances as the original drug" and "moreover (...) have the same pharmaceutical form.”**

The Pharmaceutical Law uses the term **“equivalent of a reference medicinal product,”** which is defined as a medicinal product which has the same qualitative and quantitative composi-

tion in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies (Art. 15(8)). This definition matches a definition of "generic medicinal product" that can be found in Art. 10(2)(b) of Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use (changed by Directive 2004/27/EC).

The Pharmaceutical Law speciftices at the same, implementing faithfully the porivisons of the amended directive, that different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy; it is necessary to submit additional information providing proof of their safety and/or efficacy (Art. 15(9)). Subsequently, it is specified that various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form (Art. 15(10)). The following section exempt the applicant from a requirement of carrying out bioavailability studies if they can demonstrate that the generic medicinal products meet the criteria defined in the EU guidelines (Art. 15(11)).

It may also happen that a generic for which an applicant seeks a market authorization in the territory of Poland is an equivalent of a reference medicinal product that has been authorized for marketing in another EU or EFTA state but in Poland. In such a situation, the applicant must indicate in the application the country in which the original medicine is or was authorized for marketing, and the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products requests the relevant authority of that country to confirm that statement and provide information at least on the full qualitative and quantitative composition of the product and, if necessary, appropriate documentation enabling a decision to be issued regarding the marketing authorization for the equivalent (Art. 15(4)). The Pharmaceutical Law also specifies that if the roles are reversed and it is the President of the Office who is addressed by an appropriate authority of another EU or EEA country with such a request, he is bound by a deadline of 30 days within which he must confirm and provide said information (Art. 15(5)).

It should be emphasized in the light of those considerations that it **is absolutely crucial whether we are dealing with a generic.** In the event of the lack of equivalence of medicinal products (if the generic does not meet the requirements or if it has different indications, a different method of administration, a different strength or pharmaceutical form compared to the original drug, differs with respect to the active ingredient, or if bioequivalence cannot be demonstrated by bioavailability tests), **the applicant will not be exempt from the obligation to present the results of non-clinical or clinical trials and, therefore, will not be able to use the simplified procedure for obtaining marketing authorization.**

Data exclusivity under the Pharmaceutical Law

The provision of Art. 15 of the Pharmaceutical Law Act provides that, regardless of the protection resulting from the provisions of the Act of June 30, 2000 - Industrial Property Law (PWP), **the responsible entity is not obliged to present the results of non-clinical or clinical trials, provided that certain specific circumstances occur.** The term "responsible entity" means an entrepreneur or an entity conducting business activity in an EU Member State or a Member State of the EFTA - a party to the Agreement on the EEA, which applies for or has obtained a marketing authorization for a medicinal product (Article 2 point 24). What will be the circumstances exempting the applicant from the obligation to present the research results? Firstly, that provision will apply if we are dealing with generic drugs: there must be equivalence between the drug for which the entity wants to obtain authorization and the drug already authorized for marketing (original drug). **Two scenarios** are possible in this case:

A) **The entity that has a marketing authorization** for the reference medicinal product (original drug) **has agreed** to use the results of non-clinical and clinical tests contained in the documentation of the original drug for the purposes of the evaluation of the the application for marketing authorization of the equivalent;

B) **A period of at least 8 years has passed from the date of issuance of the first marketing authorization** for the reference medicinal product in any of the EU or EEA countries **to the date of submission of the application for marketing authorization for the equivalent of the reference medicinal product in the territory of the Republic of Poland.** Likewise, the EU directive stipulates that the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if they can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised for not less than 8 years in a Member State (Art. 10(1) para. 1 of directive 2001/83/EC.

Market exclusivity

The related institution of market exclusivity should be distinguished from data exclusivity. Pursuant to the provisions of the Pharmaceutical Law, **a generic drug cannot be placed on the market by the responsible entity before the expiry of 10 years from the date of issuance of the first marketing authorization** for the original drug in an EU or EEA Member State — regardless of the marketing authorization granted. (Art. 15(2)). **This period may be extended by a maximum of 12 months** if, during the data exclusivity period, a decision is made to add a new

indication or indications which, in the opinion of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, bring significant clinical benefits (Art. 15(1)(3)).

Market exclusivity is also derived from the EU directive - under Art. 10(1) para. 2, a generic medicinal product authorised pursuant to that provision shall not be placed on the market until 10 years have elapsed from the initial authorisation of the reference product. Likewise, the 10-year period can be extended up to 11 years if, during the first 8 years of those 10 years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies (Art. 10(1) para. 4)

Data exclusivity and patent protection

We must be acutely aware that — as we can read in “Patent Law” by Professor Du Vall — **“data exclusivity laws have nothing to do with patent protection”**. This results directly from Art. 15 of the Pharmaceutical Law and Art. 10 of directive 2001/83/EC (Art. 15(1) of the Pharmaceutical Law: "**Notwithstanding** the protection resulting from the provisions of the Act of 30 June 2000 - Industrial Property Law (…)”; Article 10(1) para. 1 of the Directive: “**without prejudice to** the law relating to the protection of industrial and commercial property”). Data exclusivity and market exclusivity will apply regardless of whether the reference medicinal product meets the patentability criteria; the manufacturer of the original drug benefits from the protection resulting from them without the need to submit an application or initiate any special procedure.

The system for authorizing the marketing of medicinal products and the system for protecting industrial property are separate. Therefore, it is possible that a given entity will simultaneously benefit from the protection resulting from both, and as noted by Prof. Du Vall, if the patent validity period is longer than the data exclusivity period, then exclusivity “will have no practical significance”, given that the patent will itself guarantee strong market exclusivity.