The European Take on the Bolar Provision

the conclusions from Astellas vs. Polpharma

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Introduction

The European equivalent of the American Hatch-Waxman Act is the novelization made on March 31, 2004 to Art. 10 Point 6 of Directive 2001/83/EC, which introduces regulations into European law in the light of which "*conducting the necessary studies and trials (...) and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products*" if they are performed so as to meet the requirements defined in pharmaceutical law in connection with procedures to obtain a marketing approval for a medicinal product, in particular a generic product.

Due to the lack of a unified European patent law, the aforementioned rule was embodied through the introduction of appropriate changes to the national patent laws of EU member states, including the German "Patentgesetz" (§ 11 Nr. 2b PatG) and the Polish "Prawo własności przemysłowej" (art 69 ust. 1 pkt 4 IPL).

For example, in Poland, according to the cited regulation, the following shall not be considered acts of infringement of a patent: „*the exploitation of an invention to a necessary extent, for the purpose of performing the acts as required under the provisions of law for obtaining registration or authorisation, being, due to the intended use thereof, requisite for certain products to be allowed for putting*

them on the market, in particular those being pharmaceutical products".

The need to institute a further restriction of a patentee's rights, in addition to the existing research privilege, was justified by the fact that research performed in order to prepare documentation essential to market approval is performed not for scientific, but for commercial reasons and as such do not fall under the research privilege. The substantive goal of the legislator was to balance the effect of the prolongation of legal protection as a result of the additional protection legislation (SPC) introduced at the same time. The Bolar provision should ensure that producers can introduce generic drugs immediately following the termination of patent protection.

In practice, it is particularly important to determine the scope of allowable activities and set out the parties permitted to use the patent-protected solution, based on the above cited regulations. The Polish provision, Art. 69 ust. 1 pkt 4 IPL, was formulated relatively broadly, and encompasses all activities required to obtain approval. In particular, it should therefore encompass the production of samples of the active ingredient and a generic product, whose positive stability and bioequivalence tests are required for approval under pharmaceutical law. The cited regulation does not state that to obtain MA, a producer should himself produce the API samples of the registered generic product. This is all the more true, since a company applying for marketing approval usually is not an API producer. API importing or purchasing for the purposes of research necessary to obtain an MA by the future marketing approval holder (MAH) should not constitute an infringement of a given patent.

However, to obtain such API samples for this research, the future MAH (recently more often than not, a company mainly involved in distribution) will need to find an appropriate API manufacturer. In light of the decisions discussed in this article, the legal status of the API manufacturer who does not apply for their own MA, but merely purveys the API to future MAHs, is very uncertain

and their role in generic product manufacturing may be seen as a patent infringement.

Astellas vs. Polpharma

The subject of the case before the Appellate Court in Gdańsk (signature I ACa 320/12) was the suit pressed by Astellas Pharma INC (plaintiff), which was filed against Zakłady Farmaceutyczne „Polpharma" S.A (defendant) with a demand to cease the infringement of the plaintiff's rights vested by patent PL182344. The plaintiff set out in detail the conditions of this demand, as well as the wording and form of declarations to be published by the defendant, that were meant to nullify the effects of the infringement. The plaintiff claimed that the defendant is infringing their patent rights, because without the plaintiff's permission they are purveying a product which is the subject of a patent, i.e. solifenacin succinate. The plaintiff claimed that the defendant is infringing their patent due to an advertisement placed in the periodical SCRIP which indicated that they offer a broad range of APIs available on the market, including solifenacin succinate. Furthermore, on their web page, www.api.polpharma.pl, the defendant presented a list of offered APIs, including solifenacin succinate.

The defendant placed a disclaimer on the same web page, which stated that "Products subject to patent protection are not offered for commercial purposes in countries, where this constitutes an infringement of patent rights. In Poland, patent-protected products are offered solely for experimental purposes or within the confines of the Bolar provision, in strict accordance with Polish regulations relating to intellectual property (i.e. solifenacin succinate)".

Defending against the infringement charges, the defendant asserted that all of their activities fell within the confines of the so-called Bolar provision, formalized under Polish law in art. 69 ust. 1 pkt. 4 IPL. The defendant admitted, that as such activities they understand the sales of a patent-protected substance to other parties in order for them to carry out activities required for registration

or market approval.

The Gdańsk court (both instances) decided that such sales go beyond the provision allowable under law. According to the court it was not relevant to ascertain whether the purchasers of solifenacin succinate actually intended to use the substance in experimental research, or for other purposes. The goal was irrelevant, according to the court, for which the purchaser obtained the substance. The only relevant criterion was the irrefutable fact that the defendant produced the substance and sold it to another entity (Hexal AG).

A similar conclusion was reached by the court in Düsseldorf, in stating that the defendant's activities constitute an infringement of the plaintiff's patent and do not fall within the scope of activities allowable under § 11 Nr. 2b PatG.

Conclusions

The aforementioned court decisions only seem to be the consequence of the cited regulations. In reality, it is very doubtful whether they are in keeping with the intent of the law as set down in therein. Since the intent of the legislator was to ensure the possibility of obtaining an MA while the patent was still in force, so as to be able to initiate the sales of a generic product without undue delay after the protection ceases, then any activities by the patentee meant to hinder the acquisition of an MA for a generic drug should be at odds with the public interest expressed in these regulations. As a consequence, participation in activities whose sole aim is to obtain an MA should be unlimited. In particular, infringement should not include the purveying, production and sales of API samples destined solely for tests essential for obtaining an MA. It is difficult to imagine that the intent of the legislator was to favour generics producers connected with a patentee, or those few drug producers who manufacture their own APIs for all their products.

Bibliography

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