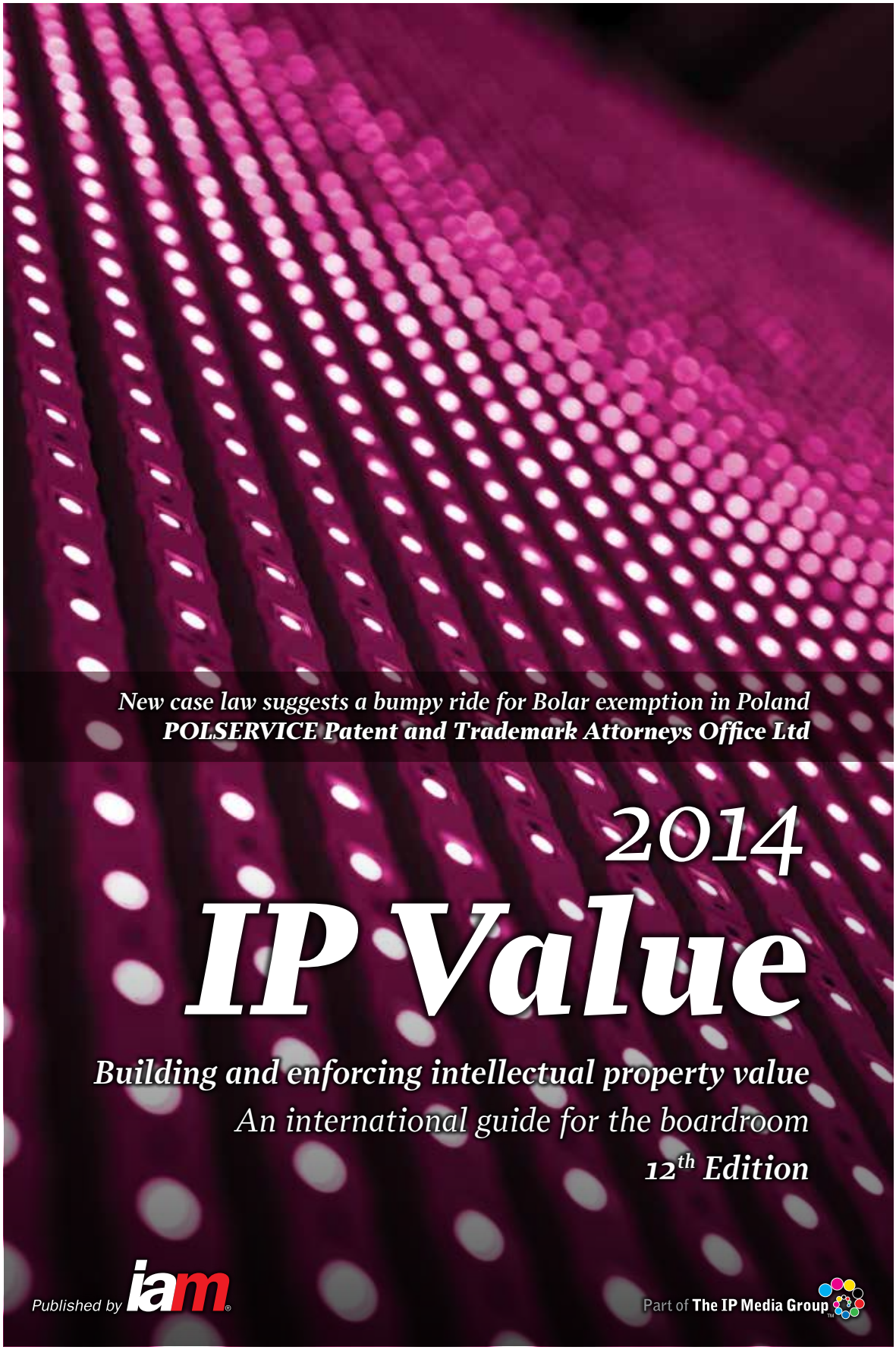

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New case law suggests a bumpy ride for Bolar exemption in Poland

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Patent law sets out specific provisions with respect to the protection of medicinal products and biotechnological inventions. These provisions are determined by two main factors: medicinal products are difficult to discover and develop, and at the same time – being chemical compounds or mixtures thereof – they are extremely susceptible to copying. That is why manufacturers of original medicines (originators) protect their products using patents. The exclusive rights granted by patents enable them to recover costs incurred in developing a new product and fund further research.

Apart from providing a monopoly for the inventor, patent law is also designed to promote technical progress. Therefore, it is crucial that patents do not stifle such progress. In the well-established fair use doctrine of copyright law, some uses of protected works – such as reproduction for the purposes of scholarly teaching, criticism and reporting – are not regarded as infringements, although they are unauthorised, because they have a social benefit. Surprisingly, there is no direct parallel to this in patent law.

Probably the most important exemption to the rights conferred by patents is the so-called 'research exemption', which allows protected inventions to be used for experimental purposes. The exemption was recognised in the United States at the beginning of the 19th century based on common law, while the doctrine itself stems from the 1813 appellate decision by Justice Joseph Story in *Whittemore v Cutter* (29 Fed Cas 1120, CCD Mass 1813). According to that decision, the legislature's intention could not have been to punish someone who infringes "merely for experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects". Later decisions confirmed that the research exemption must be interpreted narrowly and should be limited to purely scientific experiments.

For many years, the exact limits of the research exemption with respect to medicinal products remained unclear and extensive discussions were held, in particular on the question of whether a protected invention could be used to perform tasks necessary to obtain authorisation to place a product on the market. This question is of particular relevance to medicinal products. On the one hand, such activities could be regarded as falling within the research exemption, because they involve research and tests, and the evaluation and analysis of the invention. However, it is clear that such use has no cognitive nature and is of a purely utilitarian character.

This is a far from trivial issue which has found different, often inconsistent, solutions in different countries. The economic dimension to the research exemption is also striking: originators spend enormous sums of money (it is estimated that the total cost of developing a new medicinal product averages $500 million) and are unwilling to assume that use of their invention, even for the above-described purposes, is allowed during the term of patent protection. In practice, such gatekeeping can extend the actual life of a patent to well beyond the maximum time limit established by law; manufacturers of generics are naturally keen to start production as soon as patent protection expires. On

the other hand, due to the need to obtain marketing authorisation, there is a significant delay between filing a patent application and patentees being able to begin production of medicinal products — this is why the actual protection time of pharmaceutical inventions is always shorter, compared to that for inventions in other areas.

Such conflicts between pharmaceutical companies are sometimes reflected in clashes of national interests, depending on whether generic industries or original medicine manufacturers dominate in a particular country. The real breakthrough in this area took place in the United States in the 1970s. *Bolar Pharmaceutical Co v Roche Products, Inc* pitched generic drug manufacturer Bolar against Roche, the manufacturer of Valium — the active ingredient of which was protected by a valid patent. Bolar wanted to obtain authorisation from the US Food and Drug Administration (FDA) for its generic version of Valium, so it used Roche's patented compound in tests in order to confirm that its generic product was equivalent. Bolar claimed before the court that its use of a patent-protected product was not an infringement, in light of the experimental use exception. However, the Court of Appeals for the Federal Circuit rejected Bolar's argument, being of the opinion that the experimental use exception did not apply because Bolar's experiments had a purely business purpose — the company intended that its generic product would compete with Roche's Valium after the patent expiration date.

According to Bolar, experimental use of the patented chemical was justified by the public policy in favour of the availability of generic drugs immediately after the relevant patents expire, because denying such use would extend Roche's monopoly beyond that date. The court also rejected that argument, claiming that such policy decisions should be made by Congress. Moreover, the court indicated that apparent policy conflicts between statutes such as the Food and Drug Act and the Patent Act should be decided by Congress, not the courts.

Soon after *Roche v Bolar*, Congress passed a law permitting the use of patented products in experiments aimed at obtaining FDA approval (informally known as the Hatch-Waxman Act). The limitation of the patent protection presented here is commonly referred to as the 'Bolar exemption', after the defendant. According to US law (35 USC Sec 271 (e)(1)), it shall not constitute infringement to use a patented invention solely for uses that are reasonably related to the development and submission of information required by the FDA. On the other hand, however (35 USC Sec 271 (e)(2)(A)), the submission of an application for marketing authorisation for a drug claimed in a patent is considered to be an infringement (regardless of whether it is an abbreviated application for a generic drug or a new drug application).

In European countries, the research exemption is governed by national regulations. However, although the wording of these provisions may be similar, their application is often different. The following six types of experiments may be indicated:

- experiments focused on verifying the patent specification in terms of fulfilling the patentability requirements by given invention;
- experiments conducted for purely scientific purposes;
- experiments conducted to adapt the invention for commercial purposes;
- experiments aimed at gathering information on the product that is necessary to meet the requirements of relevant authorities;
- experiments conducted in order to obtain a compulsory licence; and
- experiments directed towards discovering unknown aspects of the invention.

It is commonly accepted that experiments that serve commercial purposes do not fall within the scope of the research exemption.

In Poland, the research exemption is regulated by Article 69 (1)(iii) of the Industrial Property Law of June 30 2000: "The following shall not be considered acts of infringement of a patent: ... employing an invention for search and experimental purposes, for the evaluation thereof, analysis or teaching."

European practice has also revealed an urgent need for the introduction of regulations similar to the US Hatch-Waxman Act. Due to the lack of EU patent law in Europe, this issue is currently regulated by pharmaceutical

law. Specifically, similar provisions were included in EU Directive 2004/27/EC, which amended the EU Medicinal Products for Human Use Directive (2001/83/EC), and EU Directive 2004/28/EC, which amended EU Directive 2001/82/EC on the Community Code relating to Veterinary Medicinal Products: "Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 [of Article 10] and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products."

However, introducing this exemption in Poland has caused controversy in relation to the interpretation of the term 'practical requirements' used in Directive 2004/27/EC. When the Industrial Property Law was introduced, the legislature found it necessary to take the interests of manufacturers of generic medicines into account. According to Article 69(1)(iv) of the law, "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 authorization, 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" shall not be considered to infringe a patent. Neither does the Polish law provide any basis for arguing that the act of submitting an application for a marketing authorisation can be deemed to be a patent infringement. Article 69(5) of the law also clearly indicates that: "Grant of the registration or the authorization referred to in paragraph (1)(iv) shall be without prejudice to civil liability for putting on the market of a product without the patent holder's consent, where such consent is required."

In practice, it is especially important to establish the range of permitted activities and decide which parties are allowed to use patent-protected solutions on the basis of the above-mentioned regulation. The Industrial Property Law regulations, as currently worded, allow for a relatively broad interpretation and thus are not completely clear. Recently, they were interpreted by the Gdansk Court of Appeal in *Astellas Pharma INC v Polpharma* (SA I ACa 320/12).

In this case, defendant Polpharma SA — one of the leading companies on the Polish pharmaceutical market and the biggest Polish manufacturer of generic medicines and active pharmaceutical ingredients (APIs) — was accused of patent infringement after it placed an advertisement offering a broad range of active pharmaceutical ingredients, including solifenacin succinate, which was protected by Astellas' substance patent PL182344. The advertisement was published in *SCRIP* magazine, which has over 100,000 readers worldwide. A list of APIs offered by Polpharma — including solifenacin succinate — was also published on the company's website, which contained the following disclaimer: "Products subject to patent protection are not offered or supplied 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 (in this case, solifenacin succinate)."

During the defence, Polpharma claimed that all of its activities that provided grounds on which the accusations were based fell within the Bolar provision, as introduced by Article 69 of the Industrial Property Law, because its customers were going to use the APIs only for testing purposes required for registration or marketing approval. Polpharma further argued that numerous generic companies need to get supplies of APIs to perform acts that are legally necessary to obtain registration or authorisation from third-party manufacturers, as they cannot manufacture them themselves. Additionally, Polpharma asked the national judge to submit the following preliminary questions to the European Court of Justice (ECJ): "Is manufacturing of patented substances permissible under Article 10(6) of the Directive 2004/27/EC where the privileged purpose will be conducted by a third party? And if the first question is answered affirmatively, which conditions must be fulfilled by third party so that the supply falls within the requirements of the Directive?"

The Gdansk Appeal Court concluded that the preliminary question was unnecessary,

as there is no conflict between a narrow interpretation of the Bolar provision and the Treaty on the Functioning of the European Union. The court held that only the party performing the test itself can take advantage of the Bolar exemption, and therefore Polpharma's arguments went too far. For the court's decision, it was important that Polpharma's only purpose in offering solifenacin succinate was to obtain financial benefits. It was not relevant whether the buyer of the protected substance intended to use it in experiments or for other purposes.

At first glance, the decision seems to be consistent with the spirit of the law. However, the legislature's intention was to provide an opportunity to obtain marketing authorisation for generic products while the relevant patents are still in force, to enable their sale immediately after the patent expires. Therefore, all activities aimed solely at obtaining registration or marketing authorisation should be permitted. It seems unjustified to favour generic manufacturers that are related to the patentee over those which manufacture APIs on their own.

For the time being, it remains difficult to predict how Article 10(6) of Directive 2004/27/EC will be interpreted in ECJ case law and national regulations that have transposed it. ***iam***

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