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Intellectual Property

SPECIAL

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Protect yourself against bootleggers

IP The emerging biosimilar market is subject to a hefty lawsuit. In March, a preliminary decision over Amgen's and Sandoz' litigation on the Swiss' biosimilar version of Neupogen is expected, with potential impact on the market access of biosimilars in general. Other challenges in the IP space affecting the biopharmaceutical sector involve the EU's new clinical trials policy, second medical use patents and EU antimonopoly and antitrust litigations.

In February, shortly after a FDA panel gave the green light for marketing a Neupogen copycat in the US, Amgen took legal action to delay its market launch. The injunction request is part of a patent suit Amgen filed last November (Case3:14-cv-04741-EDL), in which the US biotech giant accuses Sandoz of "having not followed all the statutory requirements that must be met before ... [Sandoz'] product can legally be sold." Amgen claims Sandoz deliberately withheld documents until after the deadline – such as its application for FDA approval – according to the Biologics Price Competition and Innovation Act. The Act requires biosimilar makers to share information on the application and manufacturing process to give them a chance to see if there are any patent infringements.

Delaying market access for competitors

Amgen wants the court to specify that Sandoz was unable to notify Amgen about its intent to market its Neupogen biosimilar until the copycat drug had been approved by the FDA. If the court agrees, this would delay future market launches of every biosimilar approved in the US.

Other current legal challenges affecting the biopharma branch involve protection of trade secrets. On p.68, experts from Dentons outline the impact of new clinical trails reporting duties set to be established in Europe by 2016.

How strategies intended to prolong a product's life-cycle can collide with EU competion law, is described by attorneys at Boehmert&Boehmert. Finally, experts at TaylorWessing give insight on the difficulties to enforce patents of second medical use and protect patented matter against off-label competition. ■

IP, monopoly & antitrust issues in the pharma sector

PATENTS Antitrust pitfalls – even the severability clause cannot rescue contracts containing serious antitrust issues that threaten contract and business and may ensue drastic fines.

› Ute Kilger and Julian Waiblinger, Boehmert & Boehmert, Berlin

Qualcomm agreed to pay China $975m in fines after a long antitrust investigation into the way the chip-maker licensed patents to Chinese companies in the mobile phone market, and it agreed to relaxed licensing schemes reducing royalty payments that mobile phone makers in China must pay. This issue may also be of concern for pharmaceutical companies.

Monopoly vs Competition Law?

Patents provide monopolies for short periods of time for patentable innovations securing return in investment into innovations. Competition law promotes or seeks to maintain market competition by regulating anti-competitive conduct by companies. Competition law and patent law seem to aim conflicting issues, namely to what extent is it justified to enforce patents to secure return-on-investment into innovations and when is a monopoly position abused in conflict with competition law.

The European Commission (EC) investigated that question in its competition inquiry in the pharmaceutical sector launched in 2008. The EC's objective was to examine the reasons why fewer new drugs were brought to market, and why entry of generic drugs was occasionally delayed.

Special challenges for the pharmaceutical industry

Pharmaceutical industry faces challenges when seeking return-on-investment for innovations. Pharmaceutical products have long product cycles and development is very costly. It may take ten years from inventing pharmaceutically active compounds to their marketing. Basic patents covering said compounds are often filed at least ten years before market entry. As the patent term is twenty years, basic patents may expire before return-on-investment is reached. Furthermore, validation and development of inventions directed e.g. to new medical indications or new administration routes adding substantial value to the patient, also require large investments. Pharmaceutical companies, therefore, created patent portfolios comprising "secondary patents" covering the business of said compound to secure later inventions. "Secondary patents" may relate to formulations, to new medical uses or to patents covering administration regimens. Such patent portfolios comprising secondary patents were a focus of the EC when investigating whether pharma life cycle management strategies constitute antitrust issues since secondary patents or patent clusters allegedly delay generic market entry.

However, patents are granted only for inventions that provide considerable benefit over the prior art. Therefore, to obtain a patent in case of a medical benefit, shall be justified. In addition, the generic industry is free to use compounds as soon as basic patents expire, but may not use secondary patents directed e.g. to new formulations. In countries like India, there is such concern about secondary patents delaying generic market entry that it is quite impossible to obtain patents on

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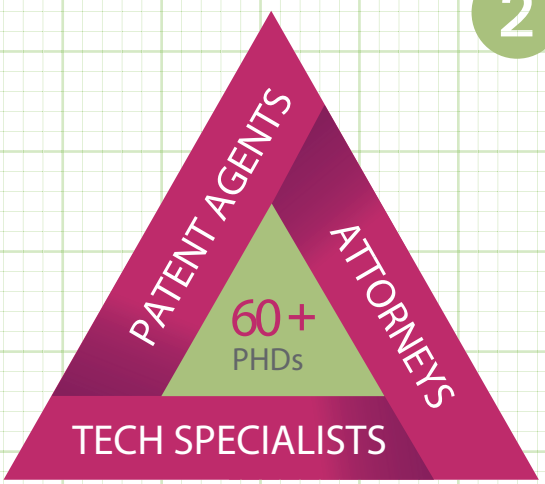

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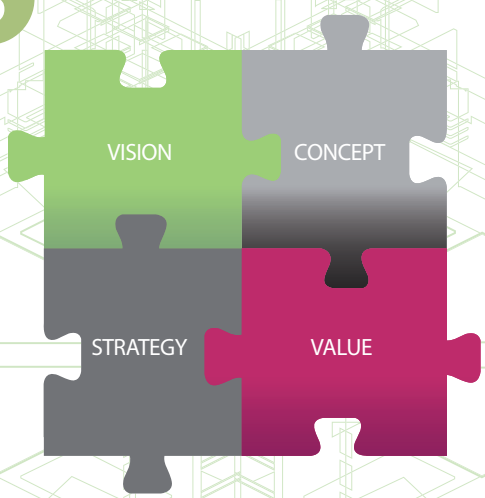

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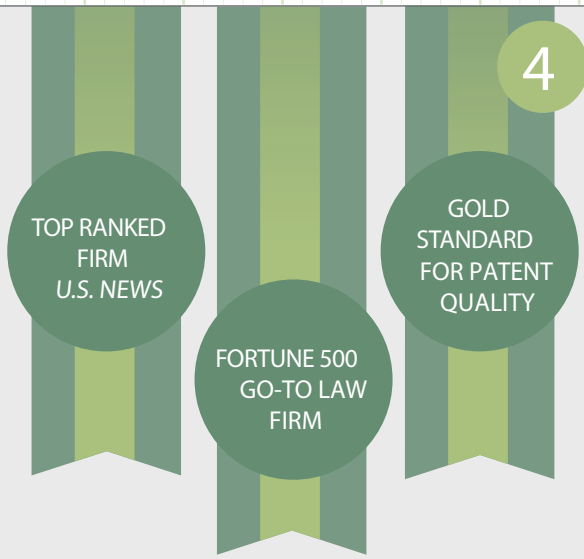

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new formulations. It is reasoned that such "inventions" are of minor value and lack substantial benefit to justify a monopoly. Such patents were tricks of the industry used to keep generics off the market. This reasoning is not plausible, because if secondary patents directed to new formulations are of no value, generic companies may choose non-patented formulations comprising the active ingredient. If, however, new formulations provide a benefit and the generic industry does not want to do without it, these formulations must be eligible for patent protection.

The European Commission's focus on Patent Settlements

Another issue concerns the EC. Following its sector inquiry of 2009, it announced it would intensify its scrutiny of the pharmaceutical sector under EU competition law, including the continued monitoring of settlements between originator and generic drug companies. According to the EC, generic delays are problematic because generic products are cheaper two years after market entry. Competition by generic products resulted in lower prices for consumers. In its sector inquiry, the EC found that originator companies use instruments, e.g. patent settlements, to extend the commercial life of their products without generic entry.

Patent Settlements vs Competition Law concerns?

Patent settlements are agreements to settle patent disputes. Under EU competition law, settlements can be regarded as a legitimate means to end private disputes or litigation. This is acknowledged by the EC in its 5th Report on the Monitoring of Patent Settlements of 5 December 2014. It states that settlements may save courts and patent offices time and effort, and could have a positive impact in the society's best interests. However, some forms of settlements in the pharmaceutical sector may be problematic from a competition law perspective. According to the EC, this holds especially true for settlements leading to delayed generic entry in return for value transfer by the originator to the generic company. Such agreements are also referred to as "Pay-for-Delay"-agreements. Other problematic settlements include agreements on restrictions beyond the territorial scope, the period of protection or the exclusionary scope of the patent. According to the EC, also agreements on a patent, which the holder knows does not meet the patentability criteria, can be problematic under EU competition law.

Following the Citalopram case, in which the EC fined the Danish originator company Lundbeck with €93.8m for entering into a "Pay-for-Delay"-agreement with generic drug companies, the EC has continued its approach on anti-competitive patent settlements. In 2014, the EC imposed fines totalling €427.7m on the French originator company Servier and five producers of generic medicines for concluding a series of agreements aimed at protecting Servier's bestselling drug, Perindopril, from price competition by generic companies. The EC found that, through an acquisition of technology and a series of patent settlements with generic competitors, Servier implemented a strategy excluding competitors and delaying entry of generic drugs to the detriment of the public and in breach of EU antitrust rules. The EC pointed out that it was legitimate and desirable to apply for patents, to enforce them, to transfer technologies and to settle litigation, but that Servier misused these tools by shutting out a competing technology and buying out competitors that had developed cheaper drugs, to avoid competition on their own merits. The EC held that this violated EU antitrust rules prohibiting the abuse of a dominant market position (Article 102 of the Treaty on the Functioning of the European Union - "TFEU"). The patent settlements between Servier and its generic rivals were also anti-competitive agreements prohibited under Article 101 TFEU.

Conclusion

The above decisions of the EC do not imply that all patent settlements per se violate EU competition law. On the contrary: the EC's 5th Report on the Monitoring of Patent Settlements of 5 December 2014 suggests that the number of patent settlements giving rise to antitrust concerns is low. The Commission points out that, generally, pharmaceutical companies settle patent disputes in line with EU antitrust rules. However, as assessments of patent settlements for compliance with antitrust rules must be made on a case-to-case basis, it is advisable for originators and generic companies to examine relevant antitrust implications before entering into such settlements.

The risks at stake are considerably high: agreements containing provisions that are prohibited under EU competition law can be void as a whole. More importantly, the parties to anti-competitive agreements run the risk of being fined with substantial charges by the EC or by national competition authorities. Furthermore, there is a substantial risk that companies affected by an anti-competitive agreement raise damage claims against the parties of the agreement. Hence, it is key for companies in the pharmaceutical industry to assess potential risks under EU competition law before it becomes too late or too expensive. ■

Pictures: Bertold Werkmann / fotolia 2015

Transparency vs protection of business secrets

EU CLINICAL TRIALS REGULATION Balancing confidientiality vs transparency is the goal of new EU rules.

› Peter Homberg, Partner, Dentons, Frankfurt/Main, Germany; Jean-Marc Grosperrin, Partner, Dentons, Paris, France

Clinical trials are a significant economic factor with an investment volume of around €20bn per year in the European Union (EU). They are a necessary precondition in the process of obtaining a marketing authorisation for medicinal products. Furthermore, the effects of one or more new or already approved drugs are established, compared, and tested within the scope of clinical trials with medicinal products for human use, in order to develop and enhance medicinal products and methods. This also leads to benefits for patients who can gain access to innovative treatments as a result of such clinical trials.

Regulatory Framework and objective of the Regulation

Currently, the main regulatory framework regarding clinical trials in Europe is stipulated in the Directive 2001/20/EC. On 27 May 2014, the Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC ("Regulation") was published in the Official Journal of the European Union and entered into force on 6 May 2014. However, the regulation will apply no earlier than 28 May 2016. According to recital (85) of the Regulation, its objective is "to ensure that, throughout the Union, clinical trial data are reliable and robust while ensuring respect for the rights, safety, dignity and well-being of subjects".

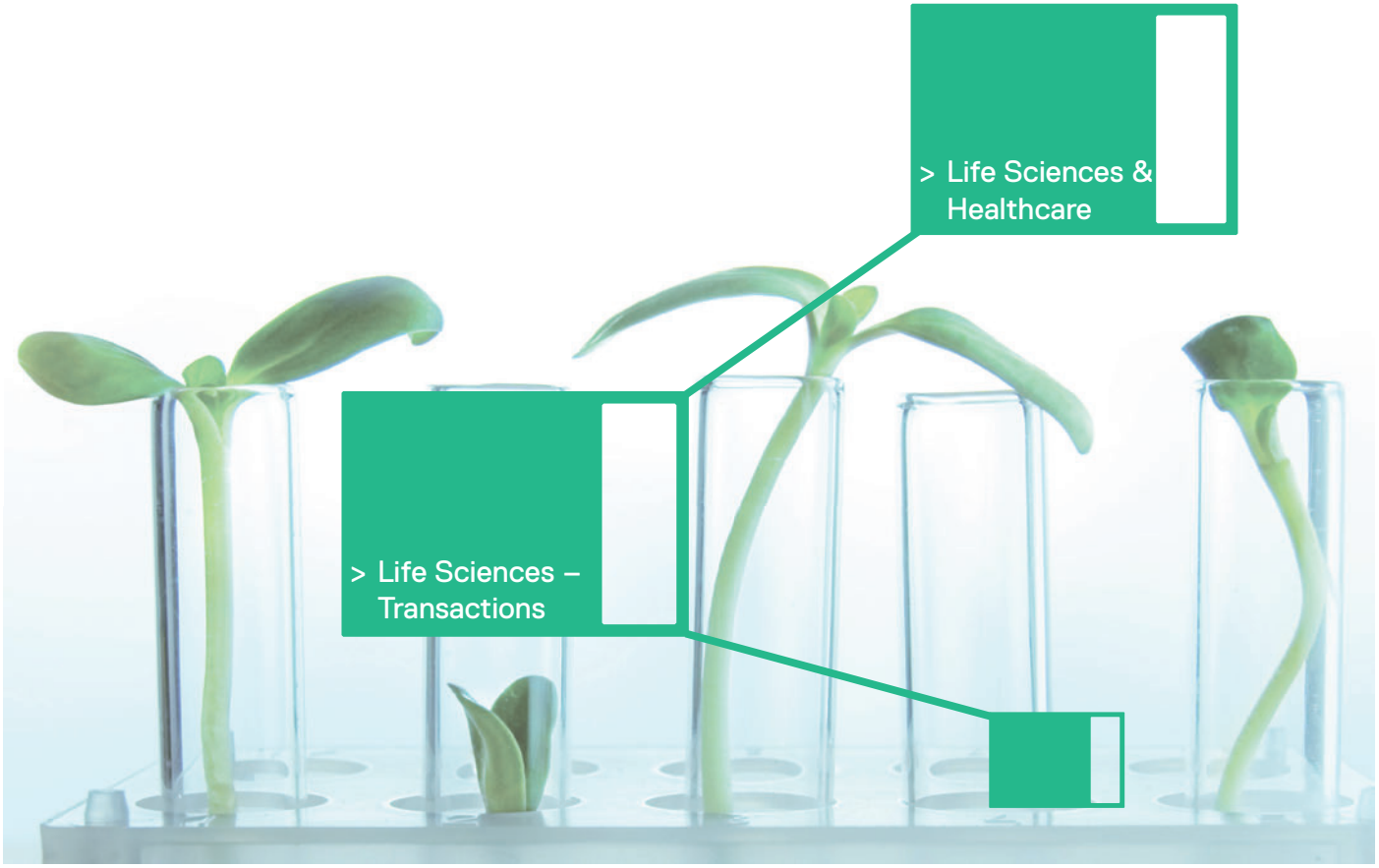
Transparency and Confidentiality

The Regulation contains, *inter alia*, stipulations regarding a new EU portal and EU database in which the clinical trial results must be made available to the public. This obligation applies to all clinical trial results, regardless of whether the outcome of the trial was positive or negative or even if the clinical trial had been withdrawn. Therefore, a summary of the clinical trial results must be made available to an EU database one year from the date of their completion. This summary shall be accompanied by a summary written in a manner that is understandable to laypersons. Model contents are set out in the attachment of the Regulation for both types of summaries. In cases where the clinical trial is intended to be used for obtaining a market authorisation for the investigational medicinal product, the applicant is also required to submit the clinical trial report within thirty days after the market authorisation has been granted, the procedure for granting the marketing authorisation has been completed, or the applicant for marketing authorisation has withdrawn the application.

According to the Regulation, the EU database shall be publicly accessible unless, for all or part of the data and information contained therein, confidentiality is justified due to (i) protecting personal data in accordance with Regulation (EC) No 45/2001, (ii) protecting commercially confidential information, in particular through taking into account the status of the marketing authorisation for the medicinal product, unless there is an overriding public interest in disclosure, (iii) protecting confidential communication between Member States in relation to the preparation of the assessment report or (iv) ensuring effective supervision of the conduct of a clinical trial by Member States. No personal data of subjects shall be publicly accessible.

Summary and Outlook

Despite the fact that clinical trials are a strong economic factor in the EU, it seems that the European Parliament and the Council have decided to give absolute priority to the protection of public health and thus enhancing transparency to the disadvantage of the protection of the business secrets of sponsors. Therefore, sponsors should consider that their business secrets will not be sufficiently protected under the Regulation. This in turn carries the risk that Europe will become less attractive for clinical trials. ■



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Infringement of second medical use patents

IP Enforcement of second medical use patents is difficult, particularly in the European lead market Germany. Due diligent fact finding and presentation of evidence are crucial for success.

› Dr. Anja Lunze, LL.M. Attorney at Law, Partner, TaylorWessing, Munich

Finding a new therapeutic indication for a known chemical compound and adjusting known compounds in new dosage regimes or to a specific group of patients, is an important area of innovation in pharmaceutical research. While it is well established that patent protection can be granted for such second medical use, the practical enforcement of second medical use patents, in particular with regard to adducing evidence, and in cases of cross label and off-label use[1], is rather difficult in practice.

Second medical use patents are only infringed if the drug as marketed is manifestly arranged (or obviously prepared) for the use claimed in the patent[2]. Such manifest arrangement is given if the instructions on the label or package leaflet refer to the patented use or if ready-to-use preparations of the drug are provided.

Challenge skinny labelling...

More complicated in practice are cases of cross-label or off-label use where the drug is marketed without the indication to the patented use ("skinny labelling"), but where the drug is prescribed or used for a patented purpose. Two recent German cases found that information about the drug in marketing materials and flyers, as well as explanations made by sales people, are not sufficiently attributable to the product[3]. Even though the sales people explaining that the product could also be used

for the patented purpose were employees of the drug manufacturer, the courts denied direct infringement of the drug manufacturer. The courts argued that the drug had been marketed as such – in a way not covered by the second medical use patent. As the flyers, marketing materials and explanations were not directly linked to the product, it is not certain that the customer would have taken them into consideration at all. So it is not clear that the patented purpose of the second medical use patent would have been fulfilled.

... and cross-label use

In cases of cross-label use, it may be asked whether the manufacturer could have known, or it won't have been obvious from the circumstances, that the drug was suitable and intended to be used for the use of the invention. There is no case law on this specific question in Germany yet, on whether and to what extent only indications for a potential cross-label use such as a higher number of sales can create the necessary subjective link, bearing in mind that the manufacture of the medicament as such is in the public domain and allowed.

In a similar way as the UK, Arnold J very recently found that if there is no evidence that the generic manufacturer intended the drug to be used for the patented use, there is no infringement[4].

In summary, it is difficult, but not impossible to enforce second medical use patents. The chances strongly depend from diligent fact finding and presentation of evidence for proving the subjective link between the marketing of the product on the one side, and the intention for its patented use on the other. ■

Footnotes

[1] "Off-label" use usually means the use of a drug for an unapproved indication, age group, dosage or way of administration while "cross-label" use means the use of a drug for an approved and patented indication, age group, dosage or way of administration that is not mentioned on the label instructions. In this regard, the often used term "skinny labelling" refers to label instructions that do not mention the patented use, but only the uses that are already off-patent.

[2] Düsseldorf District Court, docket number 4a O 12/03, 24 February 2004, GRUR-RR 2004, 193 – Ribavirin; Düsseldorf Court of Appeal, docket number 2 U 54/11, 31 January 2013 – Cistus Incanus; Düsseldorf District Court, docket number 4a O 145/12, 14 March 2013 – Chronic Hepatitis C.

[3] Düsseldorf Court of Appeal, Cistus Incanus, ibid; Düsseldorf District Court, Chronic Hepatitis C, ibid.

[4] Warner-Lambert Company LLC v Actavis Group PTC EHF & Ors, [2015] EWHC 72 (Pat).

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