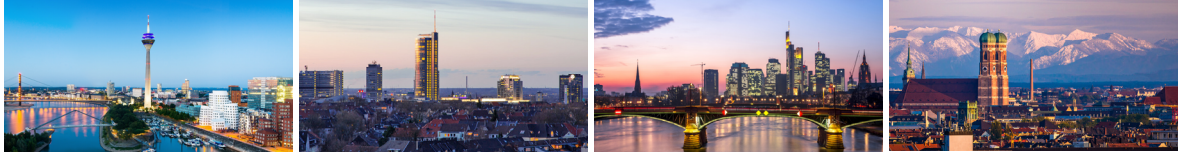

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PATENTANWÄLTE

SPC Manufacturing Waiver Enters into Force 1 July 2019

Following a heavily controversial discussion throughout legislative bodies, interest groups representing various stakeholders, and pharmaceutical industry, the EU 2019/933, [1] which is an Amendment to Regulation (EC) No. 469/2009[2] concerning supplementary protection certificates for medicinal products will enter into force on 1 July 2019, i.e. twenty days after the publication in the Official Journal on 11 June 2019. After publication of a respective proposal by the European Commission in May 2018, the final version of the Amendment had been adopted by the European Parliament on 17 April and by the Council on 14 May 2019, respectively.

A supplementary protection certificate (SPC) is an intellectual property right *sui generis* that enters into force after expiry of its basic patent and is intended to compensate for the long time period needed to obtain regulatory approval for human and veterinary medicinal products, and for plant protection products as well. Within the limits of the basic patent and extending only to the product covered by the regulatory market approval and its authorized use, the certificate confers protection for up to five additional years. With regard to many successful therapeutic products, these additional years of protection can be of enormous commercial value for the innovator. Based on the EC Regulation that is directly applicable in all member states, the application for an SPC and its grant occurs on national level.

The objective of the Amendment to said regulation, that has now entered into force and that is also referred to as "SPC manufacturing waiver", is *"to promote the competitiveness of the Union, in a manner that creates a level playing field for makers of generics and biosimilars in relation to their competitors in third-country markets in which protection does not exist or has expired"*, as defined in Recital 29 of the Amendment. Most of its provisions are relating to Art. 5 of Regulation (EC) No. 469/2009, dealing with the effects of the certificate which – within the limits mentioned above – confers the same rights as the basic patent. The Amendment limits these rights insofar as the SPC now does not confer protection any more against acts comprising

> *"(i) the making of a product, or a medicinal product containing that product, for the purpose of export to third countries; or (ii) any related act",*

wherein the term ´third countries´ relates to countries outside the EU, and the term ´any related act´ includes, e.g., acts like possessing, offering to supply, supplying, temporary storing or advertising for the exclusive purpose of export to third-country destinations, as specified in Recital 9 of the Amendment.

As a second and heavily debated modification of the SPC Regulation, the Amendment provides that the SPC does not confer protection any more either against acts comprising

> *"(iii) the making, no earlier than six months before the expiry of the certificate, of a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making, in order to place that product, or a medicinal product containing that product, on the market of a Member States after the expiry of the corresponding certificate; or (iv) any related act".*

This means that innovators will not be able to prevent stockpiling of generics or biosimilars products for day-1 market entry in the EU during the last six months before SPC expiry.

1 https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32019R0933&from=EN

2 https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:152:0001:0010:DE:PDF

In Our Own Affairs

We still have vacancies for our preparatory course for Part C and D of the European Qualifying Examination (EQE) on 12/13 December 2019. The course scheduled for 30 November /1 December 2019 is already full booked, however, so that interested persons will have to place their names on a waiting list. The course focuses on test-taking techniques and strategies that can help candidates avoid errors and maximize their chances of passing the C and D portions of the EQE. Our experience has shown that well-prepared text-taking materials can significantly raise the chances of success. Our intention is to impart the required methodology to the course participants. Inasmuch, the course should be regarded as a supplement to a thorough grounding in the legal principles of the European Patent Convention. The course participants will learn how to apply their substantive knowledge of the EPC as broadly as possible in order to help them pass Parts C and D of the EQE.

The courses are free of charge and will be held in Dusseldorf at our offices on Speditionstrasse 21. The course lecturers will be Dr. Torsten Exner, Dipl.-Ing. Andreas Gröschel and Dr. Aloys Hüttermann.

You may register via email at eqe@mhpatent.de. (Please include your full name, your employer, and your preferred date.)

As a balancing measure, the Amendment imposes a notification obligation on the maker, requesting the maker to provide certain information to the Patent Office in the member state in which the manufacturing is to take place, and to the SPC holder, no later than three months before the start date of manufacturing in that member state. This information includes name and address of the maker; an indication of whether the making is for the purpose of export, of storing, or both; the member state of making – but not the specific location or branch; – the number of the certificate granted in the member state of production; and the reference number of the marketing authorization in each third country of export as soon as it is publicly available. Furthermore, products made for export to third countries are required to be labelled by an "EU export" logo that has to be affixed to the outer packaging of the product and where feasible to its immediate packaging.

The SPC manufacturing waiver does not apply to SPCs that have already taken effect, but to SPCs that will be applied for on or after today's entry into force of the Amendment. SPCs that have already applied for, but will take effect on or after today's entry into force of the Amendment, will also fall under its provisions, but only starting three years from now (i.e., from July 2022).

Albeit praised by the European Commission as well-balanced compromise and allegedly *"removing a major competitive disadvantage of EU manufacturers"*, comments were much divided among stakeholders throughout the legislative process. Whereas "Medicines for Europe", an organization representing the interests of generics and biosimilars makers, thanked the EU for *"a comprehensive waiver"*, lobby groups for originator companies were afraid of a *"gamble on Europe's future in medical innovation" and were seeing "far-reaching negative impacts on EU competitiveness"*. Being aware of these mixed political perceptions, the legislator has newly introduced Art. 21a into the SPC Regulation providing that within five years from now, and every five years thereafter, evaluations will have to be carried out by the Commission to assess whether the objectives of the Amendment have been achieved.

Members of the pharmaceutical and biopharmaceutical industry will have to adapt to the impacts of the amended Regulation over time. For innovators, life cycle management might become even more important than before in view of the loss of up to several months of "factual" exclusivity that was due to the need of generics/biosimilar makers for doing stockpiling *after* SPC expiry. Combinations of active ingredients with synergistic effects, for example, could serve as new medicinal products in the sense of Art. 1 of the Regulation as basis for further, overlapping SPCs. Broad territorial patent coverage also might be getting even more relevant to reduce the number of attractive patent-free "third-country" markets and thus avoid further price pressure.

Some generics/biosimilars makers, on the other hand, might want to adjust their development timelines in view of manufacturing opportunities for export and earlier stockpiling start dates. They also might want to consider additional investment into collaborations with local distributors and sales force providers in "third-country" markets in the future. Finally, as explicitly stated in the preamble of the Amendment, it is the responsibility of the maker established in the Union to verify that indeed protection does not exist or has expired in a country of export.

In Our Own Affairs

Starting with the 23/2019 Issue (which appeared on 7 June), Wasilis Koukounis will be taking over the "Patents in Practice" column in the VDInachrichten news portal. Here, he will report on the latest developments in the legal environment pertinent to patent law and patent practice.

At the annual LESI convention in Yokohama in late May, Guido Quiram moderated a well-attended panel discussion on "How Big Data, AI and IoE Impact Consumer Products." The lecture team comprised Japanese and American guests from Panasonic and Ericsson and a Korean university professor, as well as Russian and German attorneys.

On 7 July 2019 Dr. Aloys Hüttermann will give a lecture at the GRUR Bezirksgruppe West in Düsseldorf about the ongoing developments concerning the T 1063/18 with the title:" Die Auseinandersetzung um Regel 28 EPÜ – Krieg der Welten beim Europäischen Patentamt?"
Cf. Our newsletters 6/2018, 2/2019 and 4/2019.

Once again, our law firm has been included in the Legal 500 ranking in the "Patent-Issuance" section. Among the positive points mentioned was the addition of Rainer Kasseckert to our Munich office in 2017. Also named were Stefan Michalski, Aloys Hüttermann, Guido Quiram and Dirk Schulz

Federal Court of Justice Denies Compulsory License Application for a Cholesterol-Lowering Drug

In a judgment handed down on 4 June 2019 (X ZB 2/19), the German Federal Court (BGH) of Justice confirmed a lower court's denial of an application that had been submitted to secure an interim compulsory license for Praluent, a cholesterol-lowering drug marketed by the pharmaceutical giant Sanofi. Sanofi had applied for the compulsory license in a dispute with its competitor Amgen, whose active ingredient Repatha is protected by European Patent No. 2 215 124. The patent's scope of protection is so broad as to encompass Sanofi's drug Praluent.

Even though the Patentgesetz (PatentG, German Patent Act) provides for compulsory licenses and allows corresponding interim legal relief to be sought, it is rare to find a case whose framework is relevant. Indeed, the case at hand marks only the third time that an interim compulsory license for a medication has been applied for with the German Federal Patent Court since its establishment in the year 1961.

Just like the lower court, the Federal Patent Court not only held that several formal omissions had been made (e.g. failure to make sufficient effort towards securing a license on a contractual basis), but also that the issuance of a compulsory license did not constitute an overriding public interest, since Sanofi had not credibly demonstrated that Praluent offered tangible therapeutic advantages over Repatha.

The relevant patent and its US counterparts are now the subject of a heated legal dispute. The claims category in question (functional anti-body claims) is being strenuously contested, given that it grants the patent-holder an enormously broad scope of coverage.

In the opposition proceedings, Amgen's European Patent was maintained in a restricted form that nonetheless remains relevant for Sanofi, and an appeal is pending. In the USA, two parallel patents were upheld on the district court level and a permanent injunction was issued against Sanofi. Said injunction was stayed by the Federal Appeal Court, which then remanded the case to the District Court with the stipulation that the jury be given better instructions on points pertinent to the patents' legal validity. In so doing, however, the Federal Appeal Court intimated that it did not consider the patents valid because the "written description requirement" had not been met.

Yet the District Court jury took a different view and, in an initial judgment, confirmed broad parts of its earlier decision regarding the patents' legal validity. It is safe to assume that this decision will be re-submitted for review on appeal to the Federal Appeal Court. (The case was the subject matter of a lecture presented by a US colleague of ours on 6 June at our Rhineland Biopatent Forum for this year.)

A decision from the District Court regarding the stayed injunction is still pending. Ever since the decision handed down in the eBay v. *MercExchange* case, the permissibility of a permanent injunction in the USA has been subjected to a four-point test. An interesting point in this context is that the District Court issued an injunction order despite having determined that a permanent injunction against Sanofi was not in the public interest (because this would effectively take an independently developed, useful medication off the market).

The Federal Appeal Court criticized this approach as not being in line with established legal precedent, namely in that it contravened Point 4 of the aforementioned test. At the same time, however, the Federal Appeal Court also emphasized that the question of whether an injunction order was trumped by a public interest could not be decided by merely adducing the general argument that it is in the public interest in principle for there to be multiple manufacturers of a

In Our Own Affairs

As in previous years, our law firm can be found in IAM Magazine's ranking in the area of patent issuance and nullification. Two of our partners, Guido Quiram and Dr. Aloys Hüttermann, were also listed in "IAM Patent 1000: The World's Leading Patent Professionals", whereby Guido Quiram's skills in structuring and issuing patent applications came in for particular praise.

Our law firm is currently seeking patent attorneys (male/female/other), particularly in the field of information technology, as well as candidates (male/female/other) in all other areas of specialty. If interested, please contact Ms. Judith Felsner at bewerbung@mhpatent.de

given live-saving medication. With this tenor, the Federal Appeal Court remanded the question of the injunction order back down to the lower court. A corresponding decision by the District Court can be expected by the end of June 2019. The outcome remains to be seen.

This case once again serves to highlight clearly the differences between the respective benchmarks appealed by US and German courts when it comes to compulsory licenses and/or permanent injunctions in the pharmaceutical sector.

Federal Court of Justice Clarifies Jurisdiction for Divisional Applications and Allows Division in Appeal Proceedings

In Decision No. X ZB 9/18 recently issued in the ***Abstandsberechnungsverfahren*** case ("Procedure and System for Distance Calculation"),[3] the German Federal Court of Justice (BGH) provided conclusive clarification on several key aspects of dividing a patent application in the context of German proceedings.

The background for the decision was an application that had been denied in an objection proceeding. The applicant had thereupon filed a declaration of division with the German Patent and Trademark Office (DPMA), which had in turn forwarded the declaration to the German Federal Patent Court (BPatG) under the assumption that this was the competent court of jurisdiction, but the declaration had not been received until after the one-month deadline for an appeal on points of law pursuant to Section 102 of the ***Patentgesetz*** (PatG, German Patent Act).

In its decision, the Federal Patent Court ruled that a declaration of division was in principle still possible within the appeals deadline,[4] thereby following by analogy the decision taken in the *Graustufenbild* ("Grayscale Picture") case,[5] which had held that a division could permissibly be made within the objection deadline even if no objection was ultimately filed. In this case, however, the Court held the division to be invalid. The reasoning given was that the declaration of division should have been submitted to the competent authority, in this case the Federal Patent Court. And while the Federal Patent Court had indeed received the declaration of division, this had not occurred in a timely manner.

The applicant thereupon proceeded to re-declare the division of the patent application while also applying for a re-establishment of rights. While this was held inadmissible by the Federal Patent Court, the corresponding appeal on points of law was nonetheless admitted.

The Federal Court of Justice thereupon vacated the decision of the Federal Patent Court, granted the division, and remanded the matter to the German Patent and Trademark Office (DPMA). In its reasoning, the Federal Court of Justice made clear that a division was

3 http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&Datum=Aktuell&Sort=12288&nr=96499&pos=17&anz=519

4 BPatG, Decision of 18 November 2004 in the Entwicklungsvorrichtung Case - 20 W (pat) 46/04.

5 BGH, Decision of 28 March 2000 in the Graustufenbild Case - XZB36/98, Journal of the German Association for the Protection of Intellectual Property (GRUR), 2000 Edition, 688 Marginal Note 10.

possible even during a pending legal appeal. Although this option had been denied in a prior decision from the year 1979, the ruling handed down in the subsequent *Graustufenbild* case had made clear that the approach taken in the earlier case would no longer be followed.

More important in practical terms, however, was the Federal Court of Justice's conclusion regarding institutional competence, which held as follows: Once an objection contesting an application is pending before the Federal Patent Court, it is the Federal Patent Court which shall thenceforward have jurisdiction over the division, both in terms of receiving the division and evaluating it on the merits. The only possible exceptions would be those expressly provided for by statute (cf. the BGH decision in the *Mehrfachsteuersystem* ("Multiple Control") case).[6]

But if the Federal Patent Court has already adjudicated the appeal – as in this particular case – then, according to the BGH, jurisdiction for receiving and reviewing the declaration of division necessarily shifts back to the Patent Office. The reason given is that the Federal Court of Justice functions merely as a court of judicial review and is thus neither able nor permitted to review a declaration of division.

It therefore followed, according to the BGH, that the applicant had in the first instance declared the division vis-à-vis the correct competent authority, i.e. the DPMA, within the one-month appeals deadline stipulated by Section 102 of the German Patent Act (PatG), thereby making the declaration valid. Thus, the matter was remanded to the DPMA so that the division issue could be dealt with.

By virtue of this decision, the Federal Court of Justice has put an end to a longstanding controversy concerning proper jurisdiction over divisional patent applications. Thus, it is now clear which authority (i.e. the DPMA or the Federal Patent Court) is competent to receive a declaration of division at any given stage of a proceeding.

6 BGH, Decision of 15 December 1998 in the Mehrfachsteuersystem Case - X ZB 2 / 98 (BPatG).

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