The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 1/2014

Duesseldorf/Munich, **05 June 2014** The times they are a'changing – particularly in the Biopatent discipline. Biopatent professionals live in a quickly developing world, which is sometimes hard to keep pace with. Michalski · Huettermann & Partner Patent Attorneys have decided to produce relief to this situation, and are proud to present a new information service related to Patent issues in Biotechnology. This newsletter issues on an irregular basis in order to provide information with respect to actual events, as well as in-depth-analyses of long-term developments. Patent Attorneys from our firm explain the meaning of recent developments and decisions affecting the Biopatent community, and provide expert insight into what's going on behind the scenes. In this issue, we discuss the surprising starvation of Congress's attempts to implement a further patent law reform, and explain the recent revocation of two trastuzumab patents by the UK High Court.

Innovation ("anti-troll") Act back into the freezer

Supreme Court creates fait accompli, loosens standards for loser pays it all

In Issue 5/2013 of the Rhineland Biopatent Gazette we have reported about a further patent reform that had passed the U.S. House of Representatives on December 05, 2013 ("Innovation Act", H.R. 3309), while a rivaling bill was circulating in the U.S. Senate (Patent Transparency and Improvement Act of 2013).

Both bills were meant to change the rules and regulations affecting patent infringement lawsuits, mainly to reduce lawsuits brought by non-producing entities (a.k.a. "patent trolls"), but raised concerns, among others, by BIO, which is the organization representing the American Biotech industry. In a statement, BIO said that, although they "support increased transparency and oppose abusive litigation tactics, provisions in the Act remain overly broad in important respects, and would result in too many unintended and unknowable consequences for innovators". A coalition of American Universities has expressed similar concerns, thus demonstrating that it can sometimes be difficult to distinguish Universities from Trolls. Both are non-producing entities who strive to generate income from licensing out patents.

Our colleague Hans Sauer, who is Associate General Counsel for Intellectual Property for the Biotechnology Industry Organization (BIO), intended to give a presentation about the impact of the pending new legislation at the 7th Rhineland Biopatent forum, which took place on May 22, 2014 in our office in Dusseldorf.

However, he – and all of the attendees of the Biopatent Forum with him – was surprised by the development that, one day before his presentation, the whole lawmaking process came to an arrest. Hans's spontaneously improvised contribution was nonetheless impressive, but - what has happened in Congress ?

While the Houses's draft (mainly proposed by Rep. Goodlatte) had already perished in the Senate, Sen. Leahy, who was behind the Senate's

UK Court revokes two trastuzumab patents

Floodgates open for next Biosimilar mAb in Europe ?

On April 10, 2014, the UK High Court has revoked the UK part of two 2nd generation patents assigned to Genentech in the decision [2014] EWHC 1094 (Pat) (Hospira vs Genentech).

EP1210115 relates to a particular dosage regimen of trastuzumab (Herceptin®) in the treatment of breast cancer (8mg/kg initial dose plus follow up doses of 6 mg/kg triweekly), while EP1308455, relates to a given purity level of trastuzumab (share of acidic variants below 25 %).

The claims of the '115 patent, although seemingly narrow in scope, are backed by the product label issued by the European Medicines Agency. The latter recommends two different dosage regimens, one of which is covered by the '115 patent, thus making the patent stronger than the mere claim language suggests.

The Court found the '155 patent obvious over the FDA's previous approval of trastuzumab. Although the court agreed that the FDA label did not disclose the exact dosage regimen claimed in the '155 patent, it concluded that, when reading the FDA label together with disclosures on the half-life of trastuzumab, the skilled person (viz., a team of a clinician and a pharmacokinetics expert) would have concluded that it is possible to use a less frequent dosage regimen combined with higher individual doses, taken into account the known safety profile at higher trastuzumab doses.

Because, furthermore, the patent lacked any disclosure as to results and efficiacy of the three-weekly dosage regimen, the court also concluded that, even in case the FDA label would not render he claimed subject matter obvious, the patent would fail to support any effect of the claimed regimen, and would thus be invalid for insufficiency

+ from our firm +

7th Rhineland Biopatent Forum has been a great success

33 attendees joined the 7th Rhineland Biopatent forum, which took place on May 22, 2014 in our office in Dusseldorf.

We were able to assemble a high-profile panel of speakers, including Hans Sauer, PhD, JD, Deputy General Counsel for Intellectual Property, Biotechnology Industry Organization, Dr. Henning Mennenöh, LL.M, Weitnauer RAe, Professor Paul Declerck, PharmD, Lab Therapeutic and Diagnostic Antibodies, KU Leuven, Belgium, and John L. Marquardt, Jr., JD, MBA, PhD, MarquardtLaw, as well as partners from our firm.

Attendees came from, among others, PharmedArtis GmbH, Wilex AG, DSM, Biontech AG, Bayer, Boehringer Ingelheim, Sartorius, BASF, SPC GmbH, Ratiopharm, Delenex, Taylor Wessing, Apceth, Weitnauer RAe, Rospatt Osten Pross RAe, UCB, Merz, IPLodge, KWS, CBH RAe, Philips, Novo Nordisk, Molecular Partners, Straeter RAe, and Tigenix.

draft, withdrew his proposed bill on May 21, 2014, stating that he found it impossible to find an „agreement on how to combat the scourge of patent trolls without burdening the companies and universities who rely on the patent system every day to protect their inventions."

It has been rumored that Senate's majority leader, Sen. Harry Reid, catalyzed Leahy's change of mind, warning him that the bill would not get to the floor even if it passed through Leahy's panel, assumedly because of opposition from trial attorneys, the biotech industry, pharmaceutical companies, and other parties.

The entire lawmaking process has thus been put on hold, making it very unlikely that it will come back into action in the pending election period.

Meanwhile, in a seemingly kind of anticipatory obedience, the US Supreme Court issued a decision on April 29, 2014, which, at least in patent trials, readjusts the established "American Rule," which generally requires parties in a litigation to bear their own costs

In the decision Octane Fitness v. ICON, the Supreme Court overturned previous decisions by the CAFC, in which the latter had imposed standards that they thought reflect the gist of 35 U.S.C. § 285. According to said section, in patent litigation, a court may award reasonable attorney fees to the prevailing party, exceptional cases provided.

The standard applied by the CAFC was that such „exceptional" condition would only be met in case a loser had brought (i) an objectively baseless claim in (ii) bad faith – a standard that the Supreme Court found to go far beyond what Congress had initially intended with § 285.

Hence, the Court overturned this policy and remanded the case back for further proceedings consistent with their opinion.

Undoubtedly, the ruling will increase the finanical risk for non-practicing entities aiming to sue others for infringement of their patent estates. Likewise, the intimidation potential owners of patent estates have against producing entities will decrease.

It remains however to be seen at which level the bar for meeting the „exceptional cases"-standard will eventually be fixed. In any case, it appears that the financial risk involved with filing a patent infringement suit will be increased.

As regards the '455 patent, the Court found that the patent lacks novelty (a prior Genentech patent disclosed compositions with 82 % native trastuzumab, hence less than 25 % acidic variants) and inventive step (a Genentech employee had presented slides at a conference on which analytical methods for separating native and acidic variants of trastuzumab were shown, plus comments were made that the acidic variants were less desirable).

The decisions are open to appeal, but it remains to be seen whether Genentech draws that option (not unlikely if you ask us).

Both European parent patents have already been revoked in opposition proceedings initiated by Biogenerix, Stada, Teva, Celltrion, Sandoz and Synthon in the EP1210115 case, and by Synthon in the EP1308455 case. Both cases are currently in appeal.

So - are the European floodgates now open for biosimilar versions of trastuzumab ?

Claimant Hospira has already a biosimlar version of infliximab on the EU market, which received approval in September 2013. Trastuzumab is a target about as attractive as infliximab, with more than 6 bn USD global sales in 2013.

In fact, Hospira's cooperation partner, Celltrion, has already received regulatory approval in Korea for a trastuzumab biosimilar called Herzuma (CT-P6). The EU clinical trials register reports three ongoing trials of trastuzumab sponsored by Celltrion.

Genentech's 1st generation patent EP0590058 has claims that protect the amino acid sequences of trastuzumab. The patent has expired June 16, 2012, but corresponding SPCS were granted in some EPC member states (among others, SPC/GB04/015 (UK); C300145 (NL); 04C0007(FR); 04900080.L (SWE); A 2004 00004 (DK) and 91067 (LU)), The SPCs are set to expire July 28 or 29, 2014, depending on the respective jurisdiction.

Thus, pending the outcomes of the appeals in the EPO oppositions, and of possible appeals against the High Court decisions, it appears that the time for a 2nd antibody biosimilar in Europe is coming closer.

We have received overwhelming feedback by the attendees, and are looking forward to next year's Rhineland Biopatent forum already.

MH patent has again been mentioned in the 2014 issue of Intellectual Asset Management

MH patent has again been mentioned in the 2014 issue of the publication "The World's Leading Patent Practitioners"., edited by iam (Intellectual Asset Management).

Therein, we are described as "a fast-developing team of young, dynamic patent attorneys with excellent contacts and activities in the life sciences space", while our partners are said to be "very creative and responsive." Honestly, doesn't this sound nice ? Find the respective entry here.

Feedback please !

What do you think about this newsletter ? Let us have your comments here.

Archive

In the future, you may find prior issues of the Rhineland Biopatent Gazette here.

Michalski · Huettermann & Partner are getting personal... Today: Dr. Torsten Exner

Torsten Exner, born in 1965, studied Biochemistry at the Universities of Bayreuth and Hanover, Germany. After his master thesis in the area of natural substance synthesis in Organic Chemistry, he joined a Max-Planck group for asymmetric catalysis in Rostock, Germany. In 1999 he received his Ph.D. for research on a heterotrimeric G protein at the Institute of Pharmacology of the University Medical Center Benjamin Franklin, Free University of Berlin, Germany. Subsequently, Torsten was research scientist, first in a Lead Discovery section in the pharmaceutical industry in Sweden, and then at the Bioprocessing Technology Institute in Singapore. He is the author and co-author of several scientific publications in the fields of pharmacology, biochemistry und analytics.

Torsten started his education in intellectual property law in Singapore in 2003, where he also began his practice in IP, which he continued in Germany since 2006. He is registered as a German Patent Attorney since 2009 and as a European Patent Attorney

since 2011. He is also admitted at the Office for Harmonization in the Internal Market.

His main practice areas are the world-wide prosecution and enforcement of patent applications/patents, FTO analysis and legal opinions, in particular in the fields of pharmacology, pharmaceutics, biochemistry, chemistry, biology, and biochemistry.
Torsten is an appointed member of an examination committee for the European Qualifying Examination for admittance of European Patent Attorneys.

Torsten joined Michalski Hüttermann in January 2014. He speaks German, English and Swedish.

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