The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 6/2015

Duesseldorf/Munich, **21 December 2015** 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, Dr. Christoph Volpers, Senior Patent Manager in our firm, discusses the interesting recent District Court decision relating to biosimilars regulations in the US, and MH Partner Dr. Ulrich Storz provides an important update on the recently revised examination practice of the Australian Commissioner of Patents.

The Next Piece of the Puzzle

Florida DC rules that also biosimilars applicants who have engaged in the "patent dance" must provide 180-days marketing notice after FDA approval

The decision of the Florida District Court (DC) to grant Preliminary Injunction in *Amgen vs Apotex* (No. 15-61631, December 9, 2015) last week might represent another puzzle piece added on the long way to translate into practice the provisions of the US Biologics Price Competition and Innovation Act (BPCIA), or – as CAFC judges recently termed it – "to unravel the riddle, solve the mystery, and comprehend the enigma" of this statute.

The BPCIA had been enacted in 2009 in order to pave the way for regulatory approval of biosimilars, generic versions of biopharmaceutical drugs, in the US. As part of the Public Health Service Act, the BPCIA established a pathway for submission of an abbreviated biologics license application (aBLA) for such products, defined a procedure for patent dispute resolution between the originator, also termed reference product sponsor (RPS), and the biosimilars manufacturer, and provided for a 12-year marketing exclusivity period in favor of the originator drug. The patent dispute resolution procedure, also casually termed "patent dance", involves a complicated, multi-step patent information exchange process, aiming at a mutually agreed list of patents to be immediately litigated, and triggered by disclosure of the application dossier and manufacturing information to the RPS.

Last week's DC ruling is the first decision dealing with interpretation of the BPCIA patent dispute resolution provisions after the recent *Amgen vs Sandoz* landmark ruling of the Court of Appeals for the Federal Circuit (CAFC; see our *Biopatent Gazette* Issue 3/2015). In *Amgen vs Sandoz*, the panel had held that the biosimilar ("subsection (k)") applicant can decide *not* to engage in the information exchange procedure, i.e., that it *is not* mandatory for the applicant to trigger the "patent dance", even though the relevant section 42 U.S.C. §262(*l*)(2) of the BPCIA provides that within 20 days after acceptance of the application by the FDA for review,

> "the subsection (k) applicant *shall* provide to the reference product sponsor a copy of the application

AU Commissioner publishes revised examination policy

teachings of AU version of the Myriad decision

As envisaged in Issue 4/2015 of the Rhineland Biopatent Gazette, the Australian Commissioner of Patents has established a revised examination practice on December 15, 2015, taking into account the High Court's decision in *D'Arcy v Myriad Genetics Inc.* [2015] HCA 35.

This step follows public consultation on a draft published on 16 October 2015, in the course of which we have submitted our opinion towards the draft, which in our view makes the best out of the High Court's decision, quite contrary to the current situation in the United States in the aftermath of the Supreme Court decision *Ass' for Molecular Pathology v. Myriad* .

The established practice reflects the law as understood by the Commissioner of Patents to apply to the examination of patents and is intended to inform patent examiners pending the inclusion of guidance in the Manual of Practice and Procedure.

The revised examination practice can be found on IP Australia's website. In particular, the commissioner suggests that isolated naturally occurring nucleic acid molecules, whether DNA or RNA, human or non-human, coding or non-coding are excluded from

+ from our firm +

MH Patent's Christoph Volpers to speak at Biologics/Biosimilars Congress

Dr. Christoph Volpers, Senior Patent Manager at MH Patent, will be a speaker at the 2nd Biologics & Biosimilars Congress on February 1-2, 2016. The conference will take place in Berlin, in the Maritim ProArte Hotel.

Christoph will speak about „Chances and Challenges in Biosimilars IP". In his talk, he will address the complexities of biosimilar IP landscapes, focus on the interplay with commercial and regulatory aspects and discuss recent case law. Find the conference's website here.

MH Partner speaks at "Basel Intellectual Property Lecture"

MH Partner Ulrich Storz will contribute to Roche's "Basel Intellectual Property Lecture" on February 23, 2016 with the following

> submitted... and such other information that describes the process or processes used to manufacture the biological product…"

Furthermore, the CAFC had ruled that the 180-day pre-launch notice set forth in 42 U.S.C. §262(*l*)(8), which triggers a second, late-stage round of litigation, *is* mandatory:

> "The subsection (k) applicant *shall* provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)."

and that this 180-day notice period does not begin before the FDA has issued marketing approval for the biosimilar.

The present DC decision relates to a putative biosimilar version of Amgen's Neulasta®, a pegylated filgrastim, which was jointly developed by Canada-based Apotex and the Indian company Intas Pharmaceuticals. The FDA accepted Apotex's biosimilar application for review in December 2014, but has not approved it yet. In contrast to Sandoz before with its filgrastim biosimilar, Apotex complied with the BPCIA and disclosed its aBLA and information about its manufacturing process to Amgen pursuant to §262(*l*)(2). As a result of the following patent information exchange process, the parties agreed on a list of two patents (US 5,824,784 and US 8,952,138). In April 2015, Apotex also provided a notice of commercial marketing to Amgen – long before any possible FDA approval –, but informed the RPS that it was not intending to send Amgen a 180-days commercial marketing notice according to §262(*l*)(8) after FDA approval of the biosimilar product.

Amgen sued Apotex on August 6, 2015, for infringement of the two listed patents. On October 16, 2015, Amgen filed motion for a Preliminary Injunction enjoining Apotex from marketing its pegfilgrastim product until 180 days after notification to Amgen of FDA approval, based on alleged violation of §262(*l*)(8). The Florida DC concluded that the only issue before the Court was whether the BPCIA requires a company such as Apotex to give a company such as Amgen 180-days notice of its intent to market a licensed biosimilar product or not, as the parties actually agreed that all other requirements needed for issuance of a Preliminary Injunction were met.

In its counterclaims, in addition to bringing non-infringement and invalidity defenses, Apotex argued that the notice provision was *not* mandatory, but optional at the discretion of the applicant, *when* the applicant did comply with the information disclosure provision of §262(*l*)(2):

> "Where a biosimilar applicant has provided the reference product sponsor with the required information pursuant to § 262(*l*)(2)(A), the BPCIA gives such biosimilar applicant the option to either provide the reference product sponsor a Notice of Commercial Marketing under 42 U.S.C. § 262(*l*)(8) (A) or to face an action…for a declaration of patent infringement. Any other interpretation of the BPCIA would render superfluous subsection (*l*)(9)(B)... The BPCIA expressly contemplates and provides for the situation where a biosimilar applicant declines to provide a Notice of Commercial Marketing, which triggers a reference product sponsor's right to bring suit under BPCIA subsection (*l*)(9)(B)."

Apotex also referred to wording in the CAFC *Amgen vs Sandoz* decision arguably distinguishing an applicant who complies with paragraph (*l*)(2)(A) from one who does not.

The Florida DC noted in its decision that the CAFC had addressed the meaning of "shall" as used in §262(*l*)(8) in the *Sandoz* case – where the applicant did not comply

patent eligibility because they relate to genetic information that is not "made", i.e., created or modified by human action.

Claims to cDNA and synthetic nucleic acids, probes and primers, and isolated interfering/inhibitory nucleic acids are excluded where they merely replicate the genetic information of a naturally occurring organism.

Subject matter of the latter type may be patent eligible where the utility of the invention lies in genetic information that has been "made" (e.g., non-naturally occurring chimeric nucleic acid).

Other biological inventions should be considered according to the same general principles above. If what is claimed properly falls within the requirements for existing categories of products and processes (e.g., is not for or merely replicates the genetic information of a naturally occurring organism) it will be patent eligible.

lecture topic:

"2nd medical use claims – new indications for an old claim category".

Ulrich will discuss the changes over time that 2nd medical use claims went through in the last decade. He will not only discuss the change from Swiss type claims to purpose limited compound claims, and the resulting implications as to enablement requirements and patent infringement, but will also address the transfer of this concept to medical devices, where 2nd medical use claims are still relatively novel.

Further, Ulrich will discuss a phenomenon that is sometimes disrespectfully called "nonsense indications".

The lecture will take place in the Auditorium of the Pharmacenter of the University of Basel, Klingelbergstrasse 50/70, Feb 23, 2016, 6:15 p.m.

If you want to attend please contact Dr Marita Wasner of Niizuma Wasner GmbH under BIPL@niizumawasner.com.

New round of amicus curiae briefs in the Sequenom case opens soon – will you subscribe ?

As published in a press release recently, US NIPT company Sequenom is considering an appeal to the US Supreme Court after their request of *en banc* rehearing ijn their US 6258540 case was dismissed by the CAFC (see Rhineland Biopatent Gazette, Issue 5/2015)

This opens the possibility to file a new round of amicus curiae briefs. Our US colleagues, including Hans Sauer, Chief IP counsel of BIO, strongly encourage German companies to also play a role in the debate. We will thus shortly launch

with §262(*l*)(2)(A) –, but "left some ambiguity which this Court must now address".

Doing so, the DC came to the conclusion that the BPCIA would not give the subsection (k) applicant the discretionary power to nullify the RPS's statutory right to 180-days notice of approval prior to marketing:

> "Neither the statute nor the *Sandoz* decision condition the 180 day notice provision of §262(*l*)(8)(A) upon a subsection (k) applicant's compliance with §262(*l*)(2)….Requiring that a product be licensed before notice of commercial marketing … provides a defined statutory window during which the court and the parties can fairly assess the parties' rights prior to the launch of the biosimilar product… That defined statutory window exists for *all* biosimilar products that obtain FDA licenses, regardless of whether the subsection (k) applicant complies with §262(*l*)(2)." [Emphasis added]

The DC concluded that Amgen had a substantial likelihood of success on the merits, and granted its motion for Preliminary Injunction; if the FDA approves Apotex's aBLA, Amgen must be provided with at least 180 days notice before the first commercial marketing of the licensed product.

As could be expected, the Florida DC ruling is not going to be the final word on this matter. Apotex has already appealed this decision to the Federal Circuit on December 10. It remains to be seen as to how far the CAFC, having recently denied rehearing *en banc* with regard to their *Amgen vs Sandoz* decision, will share the DC's interpretation of the 180-day pre-marketing notification as being mandatory after FDA approval for all biosimilar applicants, regardless of whether "patent dancing" or not. Some more certainty on the construction of the "late-stage" end of the biosimilar regulatory pathway might be desirable for various stakeholders in this relevant segment of the world's largest pharma market.

an initiative, and invite you to subscribe to a respective letter.

Feedback please !

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

Archive

To obtain a neat overview of the quickly changing world of Biopatents, find prior issues of the Rhineland Biopatent Gazette here.

Michalski · Huettermann & Partner are getting personal... Today: Andreas Gröschel

Dipl.-Ing. Andreas Gröschel was born 1973 in Lima/Peru. He studied Mechanical Engineering and Technical Communication at the RWTH Aachen University of Technology, obtaining his degree 2002 with a diploma thesis on process engineering in the field of mechanical engineering.

From 2002 to 2005 he worked in the Law Firm von Kreisler, Selting, Werner in Cologne. He passed the Patent Bar Examination in 2006. Since 2006, he has been admitted to practice as European Patent Attorney at the European Patent Office (EPO) and European Trademark Attorney at the European Trademark Office (OHIM).
He speaks German and English and with basic knowledge Spain and French.

Main practice areas include German, European and International Intellectual Property Law; Patent Prosecution; Patent Infringement; Trademark Prosecution; Trademark Infringement; Design; Licensing, Automotive engineering, Process engineering, Mechanical engineering; Chemical engineering, Software engineering, Automatic control engineering and Medical engineering.

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