The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 5/2013

Duesseldorf/Munich, **23 December 2013** 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 provide 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 actual decisions issued by European Patent authorities for the Biopatent community, and provide expert insight into what's going on behind the scenes. In this issue, we will briefly report on a new SPC decision issued by the CJEU, as well as about the next envisaged amendment to US patent law.

Still digesting the AIA ? Here's HR 3309 !

On December 05, 2013, the US House of Representatives passed H.R. 3309 (the "Innovation Act") by a 325 : 91 vote. For those of you who are still in the process of digesting the AIA, here's the essentials:

The Bill is 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").

As set forth in a summary published by the US congress the Bill requires "a party alleging infringement in a civil action involving a claim for relief arising under any Act of Congress relating to patents to include in the court pleadings, unless the information is not reasonably accessible, specified details concerning:

- each claim of each patent allegedly infringed, including each accused apparatus, feature, function, method, service, or other accused instrumentality;
- the person alleged to be the direct infringer for each claim alleged to have been infringed indirectly;
- the principal business of the party alleging infringement;
- each complaint filed that asserts any of the same patents; and
- whether the patent has been declared essential, potentially essential, or having potential to become essential to any standard-setting body as well as

Eli Lilly vs HGS: Return of the Infringement Test in SPCs ?

Thursday, December 12, 2013 saw a couple of SPC-related decisions issued by the Court of Justice of the European Union (CJEU), namely Cases C 484/12 (Georgetown University v Octrooicentrum Nederland), C 443/12, (Actavis v Sanofi and BMS), and C 493/12 (Eli Lilly vs HGS).

As regards the foreplay to the latter, we have reported earlier (Issue 6/2011) that Lilly and HGS (now Glaxo) have a long lasting dispute about EP patent EP0939804 B2. The claims of the latter relate to nucleic acids encoding for Neutrokine-α, and an antibody that binds specifically to Neutrokine-α.

Neutrokine-α (now: BLyS or BAFF) is a member of the TNF-α superfamily, and was novel at the time of filing, but no experimental data were given as to therapeutic use, nor was a real antibody made (only tissue distribution of Neutrokine-α mRNA).

HGS is marketing Belimumab (trade name Benlysta), while Lilly's competing product is Tabalumab. Both parties were involved in legal disputes before the EPO and UK courts. The patent has a changed history, but was eventually maintained both by the EPO Technical Board (case T0018/09) as well as by the UK Court of Appeals (Case No [2011] UKSC 51 HGS vs Eli Lilly).

The Patent claims define the claimed antibody merely by the amino acid sequence of the target, not by the amino acid sequence of the antibody itself. The antibody is thus not explicitly specified, as, e.g., required by the European Court of Justice in the Medeva decision (Case C322/10), in which it was found that Supplementary protection certificates (SPCs) relating to ingredients which are "not specified in the wording of the claims" of the underlying patent shall be excluded.

As we have reported in Issue 3/2013, Lilly intended to apply for a marketing authorization (MA) for Tabalumab, and thus wanted to avoid that, if granted before expiry of EP0939804 B2, the former could be used by HGS to obtain an SPC ("MA ownership issue").

Lilly further seeked to clarify whether the patent

+ from our firm +

MH whishes you all the best for the new year !

We had an exciting year, which brought with it, among others, the relocation of the entire office from Neuer Zollhof to Speditionstrasse.

Further, we received awards, among others, from Focus newsmagazine and IAM.

With Dr. Hans Christoph Wilk, former head of IP of Henkel, Professor Möbius, Dr. Verena Maren Jaeger and Dr. Stephan Hettstedt we were able to acquire four new firm members, which bring further expertise into the firm, and thus allow us to continue our growth strategy.

The 6th Rhineland Biopatent Forum was a huge success, and we are already in the process of planning the 7th Rhineland Biopatent Forum.

Hence, we are confident that 2014 will be a successful year. We hope that you feel the same, and that you find the opportunity to catch some breath in the coming holidays.

We wish you the best for the coming days, and a happy and successful 2014 !

whether the United States or a foreign government has imposed any specific licensing requirements."

The bill also introduces a "loser pays it all" cost scheme under which it will be easier for a victorious defendant to recover the costs of defending against an unsuccessful patent lawsuit.

One other goal is, in order to reduce the tremendous costs involved with IP litigation, to delay discovery until the courts have construed the patent claims. The idea behind this is that so-called frivolous lawsuits mainly triggered by Patent trolls will be resolved prior to discovery.

One other troll-related goal is to protect end users (e.g., the coffee shop that offers WiFi services), in that technology vendors may indemnify them and take over the defendant's position in a lawsuit triggered by a troll.

During the debate, a couple of amendments were pushed through:

(1) 35 U.S.C. § 145, which allows a patent applicant to sue in district court to obtain a patent after a USPTO rejection, is maintained,
(2) claimants are required to provide additional disclosure information in any pre-suit notification to be entitled to claim willful infringement.
(3) a study shall be conducted regarding the economic impact of provisions of the Innovation Act on the ability of individuals and small businesses owned by women, veterans, and minorities to protect their "constitutionally guaranteed exclusive right"

Not surprisingly, concerns have already been expressed, 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".

They further said that "Provisions in the legislation would erect unreasonable barriers to access justice for innovators, especially small start-ups that must be able to defend their businesses against patent infringement in a timely

("antibody that binds to Neutrokine-α") could be held to "specify" Lilly's antibody in the meaning of Medeva ("specification issue").

Lilly thus applied for the UK Patents Court to make an immediate reference to the CJEU for a preliminary ruling. The Court stayed the decision with respect to the MA ownership issue, pending a decision of the Court of Appeals in the corresponding invalidity case, but made a reference to the CJEU in the specification issue (Case No [2012] EWHC 2290 (Pat) Eli Lilly & Company vs Human Genome Sciences Inc).

> (i) What are the criteria for deciding whether "the product is protected by a basic patent in force" in Article 3(a) of Regulation (EC) 469/2009) ? […]
>
> (ii) In the case of a claim to an antibody […], is it sufficient that the antibody or antibodies are defined in terms of their binding characteristics to a target protein, or is it necessary to provide a structural definition for the antibody or antibodies, and if so, how much?

On December 12, the CJEU issued its decision, which, with respect to the specification issue stated that

> Article 3(a) […] must be interpreted as meaning that […] it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula. Where the active ingredient is covered by a functional formula in the claims […] Article 3(a) […] does not […] preclude the grant of a supplementary protection certificate for that active ingredient, on condition that it is possible to reach the conclusion on the basis of those claims […] that the claims relate […] to the active ingredient in question.

In other words: To act as a basic patent for an SPC, the patent does not have to "specify", *expressis verbis*, the active ingredient that is to be made subject of the SPC. It is sufficient if the claims "relate" to the active ingredient in question, whatever that means. It thus seems that the CJEU re-establishes, through the backdoor, the well-known infringement test that was deemed obsolete after the Medeva decision.

Although the referral related only to the specification issue, the CJEU also opined on the MA ownership issue, at least vaguely, by stating that:

> The refusal of an SPC application for an active ingredient which is not specifically referred to by a patent […] relied on in support of such an application may be justified […] where the holder of the patent […] has failed to take any steps to carry out more in-depth research and identify his invention specifically, making it possible to ascertain clearly the active ingredient which may be commercially exploited in a medicinal product […]. In such a situation, if an SPC were granted to the patent holder, even though – since he was not the holder of the MA granted for the medicinal product developed from the specifications of the source patent – that patent holder had not made any investment in research relating to that aspect of his original invention.

Thus, it appears that situations may exist where a patentee can not rely on a MA obtained by another party. It remains to be clarified by the UK Patents court whether such constellation actually applies to the underlying case.

Feedback please !

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

Archive

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and cost-effective manner, and without needless and numerous procedural hurdles or other obstacles."

A coalition of American Universities has expressed similar concerns, mainly addressing a similar bill developed by the U.S. Senate (Patent Transparency and Improvement Act of 2013), In a press release they stated that "some refinements should be made to ensure that its language is not overbroad in parts and does not impose unreasonable or unnecessary burdens on legitimate patent owners "

It seems that HR 3309 will become a topic at the 7th Rhineland Biopatent forum which will take place in May or June 2014. We will keep you updated.

It is, however, certainly unfair to state that HGS has "not made any investment in research relating to ascertaining clearly the active ingredient which the patent "relates" to, though not "specifying" it. Belimumab has been approved in the EU in July 2011, so HGS should be capable of founding an SPC request in their own MA.

Although the patent expires in October 2016, no such requests could yet be found in the registers of the UKIP and the GPTO.

Michalski Huettermann & Partner are getting personal... Today: Professor Möbius

Professor Andreas Möbius was born in 1948 in Leuben near Meissen, Germany. He studied chemistry at the Technical University Bergakademie in Freiberg, where he received his PhD and was promoted to professorship in the field of technical electrochemistry. He rounded off his academic education with stays in Hungary, England and Austria.

1984 he was appointed lecturer at the Technical University Dresden and relocated to the Academy of Science in Berlin-Adlershof in 1989. There he was appointed as professor for inorganic chemistry.

1991 he began his work in LPW-Group Neuss as head of the R&D on plant engineering. Later, he also became head of the chemistry department. After acquisition of the LPW-Group by Enthone he worked as European technology director until 2003 and was responsible for the company´s patent portfolio. He is a co-inventor of more than 50 patents. From 2003 until 2013 he could concentrate on new technologies all over the world as Enthone R&D Fellow. He is an adjunct professor for industrial electroplating at the RWTH Aachen University.

Professor Möbius is working as a consultant for Michalski · Hüttermann & Partner since September 2013.

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