The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 2/2012

Duesseldorf/Munich, **21 May 2012** 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, MH associate Dr. Andreas Hübel analyzes the case Bowman vs Monsanto, which is curently pending before the U.S. Supreme Court and deals with exhaustion issues in patents protecting self replicating technologies. MH Partner Dr. Ulrich Storz reports on a recent UK Court decison which relates to claim interpretation of antibody patents.

An Exception of Patent Exhaustion for crops and other self-replicating Technologies ?

Recently, the U.S. Supreme Court requested the views of the Solicitor General in Bowman vs. Monsanto (Court Docket No. 11-796, 2012) on whether self-replicating technologies are vulnerable to patent exhaustion or not. The Solicitor General's view is eagerly expected as it may provide an insight in how the Supreme Court might decide the case. The decision will have an impact not just on crops and seeds, but most likely on any self-replicating technology such as vectors, microorganism and cells.
So what had happen?

Monsanto Co. of St. Louis, MO developed its Roundup Ready® technology providing transgenic seeds for soybeans, corn and other crops, which are resistant to glyphosate. Hence, the transgenic plants are resistant to glyphosate, and allow a farmer to target non-transgenic weeds by using glyphosate. In the United States, Monsanto has its Roundup Ready® technology protected by U.S. Patent 5,352,605 and U.S. Patent RE 39,247E. Monsanto licenses its technology to seed producers, such as – for example – Pioneer Hi-Breed, and all Roundup Ready® seeds sold to farmers are subject to a standard-form license. Under this license, the farmer agrees to (i) use the seeds for commercially planting the purchased crop in a single season only, to (ii) refrain from supplying the seeds to another person or entity for planting, and (iii) to refrain from saving any crop produced from the seeds for replanting. However, the license agreement allows the farmer an unrestricted sale of the harvested crops and seeds thereof.

Mr. Bowman is a farmer in Knox County, Indiana, who purchased Roundup Ready® soybean seed from Pioneer Hi-Breed from 1999 to 2007, and planted the soybean seed under said license agreement as his first yearly planting. Starting in 1999, Mr. Bowman also purchased

UK court construes VEGF antibody patent as covering also fusion peptides

A case recently negotiated before the Chancery Division of the U.K. High Court of Justice dealt, among others, with questions of claim interpretation of antibody patents (Case No: HC 11 C00127). In this case, Regeneron, who has developed a fusion peptide targeting Vascular Endothelial Growth Factor (VEGF), had requested revocation of Genentech's European Patent (UK) No. 1 238 986, plus a declaration of non-infringement.

The '986 patent has been filed in Oct 1992 and protects the Anti-VEGF antibody Ranibizumab (Lucentis®) which is approved to treat wet age-related macular degeneration (AMD). Lucentis is, essentially, a truncated version of Genentech's Bevacizumab (Avastin®), namely a so-called "Fab Fragment".

Claim 1 of the patent reads as follows:

"Use of a hVEGF antagonist in the preparation of a medicament for the treatment of a non-neoplastic disease or disorder characterised by undesirable excessive neovascularisation, wherein the hVEGF antagonist is (a) an anti-VEGF antibody or antibody fragment; (b) an anti-VEGF receptor antibody or antibody fragment; or (c) an isolated hVEGF receptor."

In contrast to Lucentis, Regeneron's anti VEGF drug Aflibercept (Eylea®) is a fusion peptide consisting of a constant region (Fc) of human IgG1 fused to two extracellular domains of the human VEGF receptors I and II, (VEGFR I and II). Aflibercept is thus not an antibody in *strictu sensu*.

Regeneron thus argued that unlike items (a)

+ from our firm +

MH patent have founded "EURIPTA" European IP corporation

Michalski Huettermann & Partners Patent Attorneys are proud to announce that the European Economic Interest Group "EURIPTA" has now been registered.

EURIPTA is a network of IP law firms from different European countries who share the same commitment of providing excellent IP counsel services to clients from the European and International marketplace.

Under the new trademark, the member firms have access to shared resourcses and increased manpower plus broader technical expertise.

Invitations to membership are about to be sent to potential candidate IP firms.

We will keep you updated about this exciting development.

Review article about the Cabilly family of patents has been published in mAbs

In the March/April issue of mAbs, MH Partner Ulrich Storz has published an

commodity soybean seed from a grain elevator for a second yearly planting. As 94% of soybeans sold into commodity markets in Indiana in 2007 used Monsanto's Roundup Ready® technology, it was no surprise that he found the commodity seeds showing the same herbicide resistance to glyphosate as the Roundup Ready® soybean seeds. Mr. Bowman then began saving part of his commodity seed harvest for subsequent second plantings.
Mr. Bowman was candid with Monsanto about his use of the commodity soybean seed, but Monsanto investigated and – again not surprisingly – found out that the commodity soybean seed contained Monsanto's patented Roundup Ready® technology, and sued Mr. Bowman for infringing above-identified patent rights.

The district court ruled in favor of Monsanto and awarded 84,456.20 US$ in damages. In his appeal at the Federal Circuit, Mr. Bowman argued that the doctrine of patent exhaustion applies to the authorized sale of seeds into commodity markets and any downstream product of purchases from these markets which possess essentially the same characteristics as the sale to the commodity market, i.e. the glyphosate resistance in the instant case.

Monsanto, on the other hand, argued that its technology agreement explicitly did not allow the saving of harvested soybean seed and the sale of those seeds for planting purposes. Patent protection is independently applicable to each generation of soybeans containing the patented trait.

The Federal Circuit found that the doctrine of patent exhaustion does not apply to the next generation of seeds, even if Monsanto's patent rights in the commodity seeds are exhausted. By planting the commodity seeds a next generation of seeds is developed which contain Monsanto's Roundup Ready® technology. Thereby a newly infringing article was created to which the doctrine of patent exhaustion does not apply. Hence, the Federal Circuit denied Mr. Bowman's view that each seed sold is a substantial embodiment of all later generations. In its reasoning, the Federal Circuit considered that commodity seeds can be used in various ways, for example as feed. Using the commodity seed as feed or any other conceivable use wherein no replication of Monsanto's technology occurs would be free of liability for patent infringement. However, farmers can not replicate seeds including patented technology by planting them in the ground without creating newly infringing seeds.

In late October 2010, Mr. Bowman filed a petition for a writ of certiorari with the U.S. Supreme Court which has taken the court's interest as can be inferred from the recent request.

And what does that matter?

In its opinion, the Federal Circuit referred to "self-replicating" technologies, but it did not limit "self-replicating" technologies to seeds. Hence, the Bowman vs. Monsanto case will have implications to other "self-replicating" technologies such as nucleic acids, virus strains, microorganisms and cells. Thus, if the Supreme Court denies certiorari, it does not only strengthen protection for transgenic plants, but strengthens the rights of patentees in the field of

and (b) of the patent claim, which explicitly contemplate fragments, item (c), i.e., the term "isolated hVEGF receptor" should be construed to mean the complete VEGF receptor or, in the alternative, fragments that comprise the entirety of the extracellular domain (ECD) of the VEGF receptor – which isn't the case in Aflibercept. .

Regeneron further attacked the patent for lack of novelty, obviousness and insufficiency.

The latter was based on the allegation that the claims were directed to all non-neoplastic diseases and to all hVEGF antagonists, while enablement data had only been provided with respect to models of cancer and rheumatoid arthritis, and for an anti-hVEGF antibody.

In his decision, Judge Floyd J entirely rejected Regeneron's arguments.

With respect to the suggested narrow claim construction, he argued that he could see "no technical reason why the claim should be read as limited to any particular size of fragment provided that the fragment retains the essential ability to bind hVEGF and inhibit its biological activity". He went on by stating that the skilled artisan "would be surprised if the patentee had intended to leave the field open to anyone who could eliminate unnecessary domains, whilst still making use of the invention".

This brings us pretty much to the point, namely that Judge Floyd considered that the invention lies in the concept of providing a VEGF antagonist of a disorder characterised by undesirable excessive neovascularisation, not in the provision of a very specific, well-defined antagonist. Judge Floyd considered the provided prior art as not pertinent (probably due to the early priority date), which made him accept such broad concept of invention.

With respect to the insufficiency argument, Judge Floyd countered that it is quite "possible to extrapolate results showing that VEGF antagonists slow the progression of tumors to at least some non-neoplastic angiogenic diseases, including diabetic retinopathy". Further, he concluded that the biotech industry is "one where careful experimentation with a degree of trial and error, sometimes extending over months and years, is entirely normal". He closed by stating that "the refinement of the inventive concept to its most elegant embodiment, does not make earlier constructs insufficient".

The decision brings back into mind how important it is, in case a new therapeutical target has been found or a new medical indication has been assigned to a known target (i.e., where the invention lies in the disclosure of a target) to draft broad antagonist claims.

Even in case enablement data are available only for an antibody against said target, applicants should try to encompass, by the claim langage, other classes of antagonists,

article discussing the status quo of the Cabilly patents, their scope of protection and the role these patents play for the therapeutic antibody industry in Europe and the US.

Find the link to the recent issue here.

Storz, U: The Cabilly patents: Status quo and relevance for antibody companies; mAbs 4:2, 274-280

2nd Volume of SpringerBriefs in Biotech Patents has issued

We are pleased to announce that the 2nd volume of SpringerBriefs in Biotech Patents has issued recently. This volume is devoted to IP issues related to therapeutic antibodies, Vaccines and Molecular Diagnostics, and contains three contributions written by MH partner Ulrich Storz, Dr. Wolfgang Flasche, who is director of IP with Immatics Biotechnologies GmbH, and Dr. Johanna Driehaus, who is a patent attorney with Viering Jentschura & Partner.

Find the respective link 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.

biotechnology. However, if the Supreme Court will reverse the Federal Circuit on the question of whether the doctrine of patent exhaustion is applicable to self-replicating technologies, any consumer and any competitor is able to avoid patent infringement by simply duplicating patented technology by means of growing or cultivating a sample purchased in the stream of commerce. The latter outcome would require rethinking of established strategies for protecting business investments in biotechnology, life sciences and agriculture.

like alternative antibody formats, fusion peptides, antibody mimetics, aptamers and even small molecules, while of course also mentioning the actual antibody as a fall back position.

Judge Floyd accepted that such broad type of claims are justified in the present case, even in case enablement for most of the active substances falling thereunder was lacking. Nota bene, he considered anti VEGF treatment of non-neoplastic diseases as novel at the priority date, and thus accepted said extrapolation.

The decision issued March 22, 2012, and is thus still open to appeal. However, the patent will expire Oct 2012. The full text of the decision can be found here.

Michalski Huettermann & Partner are getting personal... Today: Dr. Aloys Hüttermann

Aloys Hüttermann, born in 1972, studied Chemistry at the University of Freiburg and received his degree in 1997. His doctoral thesis was completed in 2001 and related to synthetic organic chemistry. Aloys Hüttermann is co-author of the textbook "Das Basiswissen der Organischen Chemie" (The basic knowledge of organic Chemistry, published at Wiley-VCH) and of several juridical publications in the field of intellectual property.

He passed the German Patent Bar Examination in 2005. Since 2005, he has been admitted to practice as European Trademark Attorney at the European Trademark Office (OHIM), since 2006 he is European Patent Attorney. In his legal practice, he is involved in prosecution, opposition and litigation proceedings. His technical expertise covers a broad span from anorganic material science over organic chemistry and detergents to nucleic acids.

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