The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 3/2013

Duesseldorf/Munich, **17 September 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, MH Partner Dr. Andrease Hübel reports about the recent amendment of the German Patent Act, which brings with it an explicit exclusion of plants produced by essentially biological processes. Dr. Ulrich Storz discusses the (not-so-)recent Medeva decision and its impact on supplementary protection certificates (SPCs) on antibody therapeutics.

The Patentnovellierungs-gesetz - A case of anticipatory obedience

Based on the intention of improving prosecution of patent application before the German Patent and Trademark Office the so-called "Patentnovellierungsgesetz" brings us a surprise as a non-surprising anticipatory obedience, namely the explicit exclusion of plants and animals obtained from essentially biological processes for manufacturing animals or plants from patentability.

A patent can not be granted for essentially biological processes for the production of plants or animals. This legal provision of § 2a (1) 1 of the German Patent Act is virtually identical to Article 4 (1) (b) of Directive 98/44/EC (biopatent directive), and to Article 53 (b) EPC.

However, the term "essentially biological process" is neither defined nor explained in any one of these legal texts, and is by itself vague and unclear.

In their decisions G 2/07 (here) and G 1/08 (here), a.k.a. the "Broccoli case" and the "Tomato case", the Enlarged Board of Appeal (EBA) of the European Patent Office ruled that

> "A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC.
>
> Such a process does not escape

The Medeva case and its impact on Antibody SPCs

The Medeva case issued by the Court of Justice of the European Union (CJEU, Case C322/10) has often been critisized in the past, due to the fact that its guidance is, well, arguable. What has been overlooked in the past is that it also sheds doubts on Antibody SPCs. Here's the facts:

Art 3 of the respective regulation (EC) 1768/92 (now (EC) 469/2009) stipulates that a supplementary protection certificate shall be granted if […] the product is protected by a basic patent in force [...].

In Medeva, the basic patent related to a combination vaccine against *B. pertussis* comprising pertactin and filamentous haemagglutinin ("A" + "B"). SPC applications were filed, among others, in UK for A + B, plus four others for combinations of A + B with four other antigens.

The comptroller had doubts whether all these SPC requests were allowable. Therefore, the case went before court. Eventually, the Court of Appeal (England and Wales) referred, inter alia, the following question to the CJEU:

> "What is meant in Article 3(a) by "the product is protected by a basic patent in force" and what are the criteria for deciding this?"

The CJEU ruled in Nov 2011 that only the SPC for A + B could be granted, because SPCs relating ingredients which are "not specified in the wording of the claims" shall be excluded.

Said decision was subject to much criticism, particularly by UK Courts. It is astonishing that the CJEU sets the term "protected by a basic patent" equal with "specified in the wording of the claims", thereby discarding the well established "infringement test".

Further, the CJEU applies a very narrow interpretation of the term "protected". For example, according to well-established thinking a composition of A + B + X would be protected by a patent claiming A + B, although the former is not explicitly „specified" in the wording of the claims (which lack X).

+ from our firm +

MH partners attend conferences in the USA

MH partner Dr. Aloys Hüttermann attends the IPO Annual Meeting in Boston, September 15 – 17, 2013.

MH partner Dr. Andreas Hübel will attend the AIPLA Annual Meeting in Washington October 24 - 26, 2013.

MH partners Dr. Uwe Albersmeyer and Dr. Ulrich Storz will attend the LES annual meeting in Philadelphia, Sept 22 – 25, 2013.

Contact us here if you would like to schedule a meeting with either of them.

MH partner Dr Huebel now member of the AIPLA

Dr. Huebel, partner and one of MH patent's bio-tech attorneys, is now member of the American Intellectual Property Law Association (AIPLA).

Dr. Ulrich Storz to contribute at Pediatric Developments Expert conference

MH Partner Dr. Ulrich

the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.

If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC.

In the context of examining whether such a process is excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC, it is not relevant whether a step of a technical nature is a new or knownmeasure, whether it is trivial or a fundamental alteration of a known process, whether it does or could occur in nature or whether the essence of the invention lies in it."

Apart from providing insight of what the term "essentially biological" within the meaning of Article 53 (b) EPC comprises, the decisions of the EBA Appeal concerned only "essentially biological processes" for the production of plants, but did not address whether plants as such are also excluded from patentability if they are produced/producible by an "essentially biological" process. At least such product claims are allowed for grant by the EPO subsequent to the decisions G 2/07 and G 1/08.

On one hand, one might argue that the scope of protection provided by a process claim also comprises the product obtained by said process, and that it would be inconsistent and undue if a process is excluded from patentability whereas the product obtained from such a process is allowable.

On the other hand, one might argue that legal exceptions have to be interpreted narrowly, and that the legal provision only excludes "essentially biological processes" from patentability, but intentionally did not provide an explicit exclusion of products obtained/obtainable from an essentially biological process. Hence, referring to Rule 27 (b) EPC (here) and Rule 26 (2) EPC (here) it can be held that plants are patentable subject

The CJEU thus created a new terminology, because the term „to specify" has, among patent practitioners, never been used to refer to claim language, only to refer to specification language. What makes it even worse is that the CJEU also used the terms „identified in the claims" and „mentioned in the claims", with probably the same intended meaning as "specified in the claims".

We all know that patent professionals are extremely conservative as regards consistent language use. Consistent language, however, does not seem to be one of CJEU's virtues.

Why do we write about all this ? Because it matters. Consider case Novartis vs Medimmune (Case No HC09 C04770 [2011] EWHC 1669 (Pat) (see also Issue 1/2012 of the Rhineland Biopatent Gazette).

In short, Medimmune sued Novartis for infringement of claims 5-8 of Patent EP0774511, and claim 1 of Patent EP2055777, by producing and selling Lucentis, an Anti-VEGF antibody fragment.

Medimmune claimed that Lucentis was produced by a process of the claims, i.e., is a product obtained directly by means of any of the claimed processes.

The UK High Court dismissed the claim for non-infringement and invalidity. However, the court made a remarkable obiter dictum, by stating that, if Lucentis *was* actually produced by a process falling within the claims, then it was a product obtained directly by means of those claims and, on that hypothesis, Novartis would have infringed both Patents *if valid.*

Interestingly, the claims were drafted in such way that they recite a step of producing a library of bacteriophages displaying at their surface a population of antibodies. The claims are thus not restricted to mere screening steps – which in the eyes of the Court qualifies them for providing product protection under Section 60(1)(c) of the UK Patents Act (which corresponds, largely, to Art 64 (2) EPC). Consider Claim 5 of EP0774511 B1, which reads as follows:

"A method for producing a filamentous bacteriophage particle displaying at its surface a binding molecule specific for a particular target epitope or antigen, which method comprises the steps of:

a) producing a population of filamentous bacteriophage particles displaying at their surface a population of binding molecules having a range of binding specificities […]

b) selecting for a filamentous bacteriophage particle displaying a binding molecule with a desired specificity by contacting the population of filamentous bacteriophage particles with a target epitope or antigen

c) so that individual binding molecules displayed on filamentous bacteriophage particles with the desired specificity bind to said target epitope or antigen."

The decision thus overturns current thinking that phage display patents do not protect the actual products developed therewith.

To come back to the initial topic: Novartis also sought declaration that an SPC based on the Patent was invalid.

Novartis argued that even if (i) the Patent was valid and (ii) Lucentis was a product that was obtained directly by means of the claims, Lucentis was still not "specified or identified in the wording of the claims, which refer to a

Storz will contribute to an expert conference organized by Forum – Institut für Management GmbH, which is devoted to legal and intellectual property aspects of Pediatric Developments.

The conference will take place Oct 29, 2013, at the Maritim Hotel in Bonn, Germany. Dr. Storz will talk about Art 8 of the pediatric regulation, and the impact of the Neurim judgement on 2nd medical use patents, and he will highlight the question when does a patent qualify for SPC?

Find the event's homepage here.

Seminar on the community patent was a full success

MH partner Dr Aloys Hüttermann has successfully organized a seminar on the community patent, and the litigation system, which took place September 5, 2013, in our premises in Duesseldorf.

He was supported by Dr. Christoph Wilk, former head of IP with Henkel and now senior counselor with MH patent.

The seminar was extremely well attended, and all attendants agreed that the insights provided were unique, and very helpful for future decisions.

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

matter even though they are obtainable by an "essentially biological process" (note that Rule 26 (2) EPC defines "biotechnological inventions" as inventions concerning a product consisting of or containing biological material, whereas Rule 27 pertains to biotechnological inventions).

Hence, the question of whether the exclusion of essentially biological processes for the production of plants in Article 53 (b) EPC has a negative effect on the allowability of a product claim directed to plants or plant material was referred to the Enlarged Board of Appeal, and will be dealt with as cases G 2/12 (Tomato II) and G 2/13 (Broccoli II, here).

Notwithstanding the pendency of these questions with the Enlarged Board of Appeal, the German legislator provides an answer to this question with respect to the German ambit by amending the German Patent Act.

The law for amending the German Patent Act ("Patentnovellierungs-gesetz" passed the German Bundestag on June 27, 2013 and soon thereafter – July 05, 2013 – the Federal Council (Bundesrat). Thus, it remains that the president has to sign this law such that it will enter into force January 01, 2014.

The governmental draft of the law was passed to the legal committee in charge and other committees for discussion since late September 2012, and in late June 2013 the committee in charge recommended including an amendment of § 2a of the German Patent Act extending the exclusion of essentially biological processes for producing plants and animals to those plants and animals that are exclusively produced by such processes (here).

The future § 2a (1) 1. will read:

> "Patente werden nicht erteilt für Pflanzensorten und Tierrassen sowie im Wesentlichen biologische Verfahren zur Züchtung von Pflanzen und Tieren und die ausschließlich durch solche Verfahren gewonnenen Pflanzen und Tiere"

It is remarkable that the new version of § 2a (1) 1. Is in contradiction to § 2a (2) 1. Which provides that patent can be granted for inventions concerning plants or animals if the feasibility of the invention is not confined to a particular plant variety or animal variety.

Wherein the intention of the "Patentnovellierungsgesetz" was improving prosecution patent applications with the German Patent method rather than to an antibody) and thus not "protected by the Patent" in the meaning of Article 3(a) of the Regulation.

Judge Arnold did not make a further reference to the CJEU as, due to invalidity of the patent, the SPC was also invalid. However, he expressed that the CJEU was not sufficiently clear in Medeva, and that further references will be required to clarify what is meant by "specified in the wording of the claims".

In another case (Lilly vs. HGS, see also Issue 6/2011 of the Rhineland Biopatent Gazette), the implications of Medeva on Antibody SPCs become even more obvious.

Lilly and HGS 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 (now: BLyS or BAFF).

Neutrokine-α 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 (now GSK) 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 EPO Technical Board judged that the tissue distribution data disclosed in the specification suffice for industrial application and may be used to develop appropriate means for diagnosis and treatment, and thus maintained the patent on Oct 21, 2009 (case T0018/09).

The UK Court of Appeals referred to Directive 98/44/EC and found the patent invalid for lack of industrial applicability, insufficiency and obviousness, but the Supreme Court established industrial application on Nov 2, 2011, and remanded the case. The Court of Appeals then established validity on Sept 5, 2012 (Case No [2011] UKSC 51 HGS vs Eli Lilly).

Interestingly, the Patent claims define the claimed antibody merely by the amino acid sequence of the target it binds, i.e the antibody is not explicitly specified. These types of claims are regularly granted by the EPO and the USPTO in case the target is novel, well enough defined (e.g., by sequence), and when it is at least plausible that the target, and blocking the latter, has a physiological effect.

As Lilly intended to apply for a marketing authorisation for Tabalumab, they 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 ("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).

Judge Warren described his motivation as follows:

> "Whilst sharing Arnold J's puzzlement with the reasoning in Case C-322/10 Medeva [...] it is not

Archive

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and Trademark Office in order to make filing German national phase patent applications – for example as priority applications – more attractive for applicants, this is definitely not true for plant breeding companies as they have to rely on plant variety protection.

However, given that the Enlarged Board of Appeal before the EPO will rule that the exclusion of essentially biological processes for producing plants is restricted to said method, but does not affect allowability of plants obtained by such processes, an applicant might obtain a European patent with validity in Germany as Article II, § 6 IntPatÜG defines the reasons for declaring revocation of a European Patent in German nullity suits.

Hence, it appears that strategic considerations of protecting the intellectual property of plant breeders in Germany will be severely impacted by the upcoming decisions of the Enlarged Board of Appeal in the EPO in the Broccoli and Tomato cases. We will watch and keep you updated in this bulletin.

possible to disagree with what he says at to the effect that the test laid down in Medeva and its progeny is unclear save […] with his statement in that it is inevitable that there will have to be further references to the ECJ."

In the referral, which has the case No C-493/12 (Eli Lilly and Company Ltd vs Human Genome Sciences Inc) he asks the follwoing questions:

(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?

Does question (i) sound familiar to anybody ? Remember the referred question in the Medeva case, which was as follows:

"What is meant in Article 3(a) by "the product is protected by a basic patent in force" and what are the criteria for deciding this?"

Some commentators have joked that the true question Judge warren wanted to ask the CJEU was "This time, could you please do you homework ?"

Michalski Huettermann & Partner are getting personal... Today: Dr. Verena-Maren Jaeger

Dr. Verena-Maren Jaeger was born in 1979 in Flensburg and studied Biology at the University of Cologne and at the Oxford University (UK). She prepared her diploma thesis at the Max-Planck-Institute for Neurological Research in Cologne. Then she worked on her doctoral thesis at the Institute for Biochemistry, Medical Faculty of the University Hospital of Cologne and Durham (UK) and received her Ph.D. in Biochemistry in 2009. She is author and co-author of several scientific publications in the field of medical biology.

Verena-Maren Jaeger began her professional career in intellectual property in 2009 in a law firm and after passing the Pre-Exam she was sitting the European Qualifying Exam in 2013.

In 2013 Verena-Maren Jaeger joined Michalski Hüttermann Patentanwälte in Düsseldorf. Besides competent knowledge of medical biology, Verena-Maren has experience in pharmaceutical chemistry, human genetic diseases, antibody technology, diagnostic assays, and screening methods.

She has particular expertise in preparation and prosecution of German and European patent applications, patent infringement proceedings, nullity proceedings and opposition proceedings, and evaluation of the validity and infringement of European patents.

You can contact her under vj@mhpatent.de

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