The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 3/2018

Duesseldorf/Munich, **07 December 2018** 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. Ulrich Storz discusses two recent decisions by the EPO, one from the field of antibodies and one from the field of plant breeding, both of which are extremely relevant.

Amgen's blockbuster patent maintained in EP

Decisions strengthens functional antibody claims

In issue 2/2018 of this Gazette, we discussed different aspects of the global dispute regarding Amgen's patents protecting their anti PCSK9 antibody Repatha.

Therein, we also referred to Amgen's European Patent EP2215124B1, which is opposed by 5 parties, among them Sanofi, Eli Lilly and Regeneron.

Oral proceedings took place on November 29 and 30, 2018, and the outcome and some other aspects are now diffusing out, although the grounds for the decision have not yet been published.

It seems that the Opposition Division remained true to itself, and maintained the patent in amended form, i.e., on the basis of a new main request that was already put on file in May 2017 – as already suggested in the Division's preliminary opinion, which issued December 13, 2017.

Claim 1 as maintained is as follows:

> 1. A monoclonal antibody or fragment thereof that binds to human PCSK9 and is neutralizing in that an excess of said antibody or fragment thereof is capable of reducing the quantity of PCSK9 bound to LDLR in an in vitro

Board of Appeal declares Rule 28 (2) EPC invalid

EPO's jurisdiction takes sweet revenge

On 5 December 2018, the Board of Appeal 3.3.04 issued a groundbreaking decision - T1063/18 – in which it declared Rule 28 (2) EPC as to not comply with Art. 53 (b) EPC. The case relates to the long-dwelling dispute as to whether or not plant products produced by essential biological processes are patent-eligible

The decision under appeal related to EP application EP2753168A1 assigned to Syngenta, and concerning pepper plants. Claim 1 recites a pepper plant characterized by specific quantitative trait loci as obtained by a conventional breeding method, but supported by the use of specific markers („smart breeding"). The application was rejected on 22 March 2018 under Art. 53 (b) EPC in conjunction with Rule 28 (2), on the grounds that the subject matter of claim 1 was excluded from patentability.

Art. 53 (b) sets out that European patents shall not be granted to plant or animal varieties or essentially biological processes for the production of plants or animals. Rule 28 (2), which was introduced into the Implementing Regulations only in 2017, further clarifies that, under this article, European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process.

The amendment of Rule 28 was a response on a notice the European Commission issued in November 2016 on certain articles of the "Biotech Directive", in which the Commission took „the view that the EU legislator's intention when adopting Directive 98/44/EC was to exclude from patentability products that are obtained by means of essentially biological processes." (see this Gazette, Issue 6/2016). As we all know, the Commission's view is not binding on anyone, and certainly not on the EPO, and the Commission does not have any jurisdictive powers either.

+ from our firm +

EQE seminar 2018

As in previous years, we will offer two two-day free preparatory courses for the C and D part of the European qualifying examination.

The courses take place on Monday / Tuesday, 26./27. November, and Saturday / Sunday, 8./9. December 2018 (which is probably a bit late now to apply for).

The courses content focuses on appropriate techniques and error prevention strategies to successfully to successfully pass the C and D parts of the EQE exam.

According to our experience, well-prepared examination documents significantly increase the chances of success.

Therefore, we want to furnish the participants with the necessary knowledge.

In this respect, the course should be understood as an addition to a content-related preparation of the legal foundations of the EPC.

The courses take place in Dusseldorf in our premises

competitive binding assay,

wherein said monoclonal antibody or fragment thereof competes for binding to PCSK9 with

(a) an antibody comprising a heavy chain variable region of the amino acid sequence in SEQ ID NO: 49; and a light chain variable region of the amino acid sequence in SEO ID NO: 23; or

(b) an antibody comprising a heavy chain variable region of the amino acid sequence in SEQ ID NO: 67; and a light chain variable region of the amino acid sequence in SEQ ID NO: 12.

Surprisingly, Claim 1 of the amended main request is hence identical to claim 1 as granted. Modifications Amgen effected applied only to other claims with less br9oad scope.

Claim 1 is of the notorious „competes with" style that is keeping the entire community upset, as the scope of such claim is extremely difficult to determine, and hence creates large uncertainties amongst competitors.

We have discussed these claims in panel discussions at the BioConvention, May 2018 in Boston, as well as at the C5 Life Science Summit in Munich in October, with, *inter alia,* representatives of Eli Lilly and Sanofi, both of which have developed a very critical position regarding these claims. See also Issues 4/2016 and 2/2017 of this Gazette.

Unfortunately, these claims have so far not made to a Board of Appeal, at least to our knowledge. This may now change, because, not surprisingly, two of the opponents, namely Sanofi, and a strawman-lawfirm, have submitted appeals against the decision on the very same 2nd day of the oral hearing, directly after the Opposition Division declared its decision.

Hence, time will hopefully bring more clarity with regard to the patentability of these claims.

It is only within the competence of the Court of Justice of the European Union (CJEU) to interpret EU law, and take binding decisions for the EU member states (which still would not be binding for the EPO, which is not a body of the European Union).

Nevertheless, shortly thereafter, the Administrative Council, overrode the Enlarged Boards of Appeal (EBA) decisions in "Tomato II" (G 2/12) and "Broccoli II" (G 2/13), according to which such claims were patent eligible, and implemented the Commission's findings into new Rule 28 (2) EPC. Before that, the President of the EPO had already ordered to stay all respective proceedings – a move which came (not so) surprising to many, as it, too, stood against decisions G 2/12 and G 2/13.

It seemed, at that time, that the President valued a non-binding opinion of a foreign executive higher than decisions of the highest jurisdictive body of the European Patent Convention – which was considered a slap in the face of the Boards of Appeal in general.

Back to the present case: Syngenta appealed the decision, arguing that Rule 28 (2) would be in conflict with Art. 53 (b). Since, under Art. 164 (2) EPC, the articles prevail the rules, Syngenta demanded that Rule 28 (2) must be declared inapplicable or otherwise interpreted. In the alternative, Syngenta requested to refer the case to the Enlarged Board of Appeal.

While in its provisional opinion, the Board had still declared that it would likely reject the appeal, it then decided otherwise, and declared Rule 28 (2) to be in conflict to Art. 53 (b), and hence inapplicable under Art. 164 (2). The Board then ruled that claim 1 is not subject of the patent exemption of Art. 53 (b), and remanded the case back to the examining division, to continue the examination for clarity and inventive step.

The reasons for the decision have not yet been published, but will certainly be studied intensively. According to rumors, the Board did not see any need to refer to case to the Enlarged Board of Appeal, as its decision is in line with EBA's precedent.

The decision somehow reflects the deep disruption between the EPO's executive, with the President as it's spearhead, and the Boards of Appeal, and is the first one in history in which a Board of Appeal draws the nuclear option of Art. 164 (2).

It will have to be seen whether this decision will endure, and how the executive bodies of the European Patent Office, as well as the European Commission, and primarily the examiners and opposition divisions, will deal with this decision.

in the Speditionstr. 21 and are free of charge. Speakers of the course are Dr. Torsten Exner, Dipl.-Ing. Andreas Gröschel and Dr. Aloys Hüttermann.

Registration is possible immediately. Please mention your full name, employer and the desired date, and send your application to eqe@mhpatent.de.

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.

MH Patent is getting personal... Today: Deborah Meyer

Deborah Meyer studied chemistry at ETH Zurich and complemented her studies with a Master degree in the field of nuclear magnetic resonance in 2011. Her fascination of magnetic resonance led her to join the Institute of Physical Chemistry of the University of Freiburg, where she started working in 2012 in the field of electron

paramagnetic resonance. She received her Ph.D. in 2017 on light-induced states in materials of relevance in organic electronics.

Due to her high attention to detail and her ability to clarify the nature of a problem she embraced IP and decided in early 2018 to start her training as a patent professional at the law firm of Michalski Hüttermann & Partner. Deborah Meyer speaks German and English as well as reasonable French. She likes to nurture her green thumb and her hobbies include the preparation and indulgence of excellent food as well as dancing.

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