The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 3/2014

Duesseldorf/Munich, **23 September 2014** 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 Torsten Exner discusses the decision T1570/09, while our guest author, Dr. H. Kaspar Binz of Molecular Partners AG, explains the "Stelara" decision issued by the CAFC.

Preterm death of the Swiss-type claim at the EPO ?

Decision T 1570/09 is the latest blow

Recently a few decisions have been taken by EPO Boards of Appeal, which surprise us by deviating from what we had taken to be established practice at the EPO. One such decision is T 1570/09, dealing with a set of claims with two independent medical use claims, directed to the same medical use of the same active drug - one a Swiss-type claim, the other a purpose-limited product claim. The Board held that such a claim set is not allowable.

Since in 1984 the Enlarged Board of Appeal (EBoA) in G 5/83 gave its approval on medical use claims in the Swiss-style format, these claims have become very popular. Although nobody could exactly tell what subject matter Swiss-style claims cover, they were the gold standard for protection for medical inventions. A phrasing such as "*Use of [X] for the manufacture of a medicament for the treatment of [Z]*" was understood to be a legal fiction to circumvent the non-patentable subject matter ban on methods of treatment for the human and animal body.

With the drafting of the EPC 2000 the need for this legal fiction vanished, and so should have the need for Swiss-type claims. Nevertheless the EPO continued allowing such claims in a 'business-as-usual' manner. It took a decision by the EBoA again to end the "Swiss type age" - in the form of decision G 2/08. The EBoA set a final deadline: any European patent application with a relevant date that falls after 28 January 2011 is no longer entitled to the Swiss-type format.

Since the EPC 2000 had established a legal basis for a new claim format, the '*purpose limited product claim*', two claim formats have coexisted for patent applications with a relevant date up to 28 January 2011. The intention of the legislator had apparently been to provide equivalent protection for the new claim format in comparison to the established practice. In G 2/08 the EBoA had avoided any clear statement in this regard, but indicated

Functional antibody claims face new challenges

CAFC held Abbvie's IL-12 patents invalid

In decision AbbVie v. Janssen 2013-1338 (Fed. Cir. 2014), which issued July 1, 2014, the Court of Appeals for the Federal Circuit (CAFC) has declared so-called "functional antibody claims" in two US patents assigned to Abbvie invalid.

The term "functional antibody claims" describes patent claims that do not define an antibody, or a fragment thereof, by is structure or sequence, but by functional properties. This encompasses patent claims which merely define a theoretical antibody as binding against a given target, provided the latter is novel. Such claims are regularly granted by the USPTO (see Noelle v. Lederman, 355 F.3d 1343 (CAFC 2004), as well as by the EPO (see T0018/09), and are considered a fair reward to one who has described a new target for the first time, and in a way that antibodies can generally be made against said target by standard methods, as hybridoma technology or phage display.

In later stages such claims do for example describe a group of antibodies by their binding characteristics to a given target. These claims sometimes recite a minimum affinity to that target, and do thus encompass also follow-on developments by 3rd parties that have improved the affinity of the antibody protection was sought for in the respective patent.

In the underlying case, AbbVie had sued Janssen and Centocor, which are J&J subsidiaries, for alleged infringement of claims 29, 30, 32, and 64 of US6914128 and claim 11 of US 7504485, by Centocor's anti-IL12/anti-Il 23 antibody Ustekinumab (Stelara ®). The respective claims are as follows:

US6914128
29. A neutralizing isolated human antibody, [...] binds to human IL-12 and disassociates from human IL-12 with a K_{off} rate constant of $1*10^{-2}s^{-1}$ or less [...].
30. The neutralizing isolated human

+ from our firm +

Excel-implemented Software available that facilitates the drafting of sequence listings

We have created an VBA-based excel-implemented software that facilitates the drafting of sequence listings.

Simple as the software is, sequence listings can be created by copy pasting the sequences from another spreadsheet, plus a few mouse clicks.

The creation of sequence listing is thus less laborious than with sophisticated packages like Patent-In or Bissap.

The software comes with some limitations. For technical reasons, only 50 SEQ IDs can be processed. Further, the enumeration of nucleotides (in the right margin in intervals of 60) and the enumeration of the amino acid residues (under the line of the latter in intervals of 5), as set forth in items 14 and 21 of WIPO standard ST.25, has

that the new claim format was '*likely broader*' than the old one.

Previous decision T 250/05 had rejected the post-grant conversion of Swiss-style claims to the new product claim format as contravening Article 123(3) EPC by extending the scope of protection. Subsequent decision T 1780/12 set aside a double patenting objection by the Examining Division. The Board in this case de facto held that the legislator had not achieved their intention, and that the scope of protection afforded by Swiss-type claims and the new purpose limited product claims was overlapping, but different. Decision T 879/12, taken by an extended Board after decision T 1570/09, took the same view, namely that the scope of protection conferred by Swiss-type claims and purpose limited product claim is different.

The present decision prima facie takes the opposite view.

In this case an applicant had initially not followed the common practice of filing independent claims according to both the Swiss-type and the new purpose-limited product format. Without clear guidance on the scope having claims of both formats is commonly regarded the safest option. However, here the applicant had only Swiss-type claims on file, which were rejected by the Examining Division as obvious. It was only in response to the summons in appeal proceedings, that the applicant added an independent purpose limited product claim.

The Board admitted the claims into the proceedings, but rejected the presence of both claim formats in the same claim set as not allowable. The applicant thus had to delete the Swiss-type claims to succeed and have the Examining Division's rejection set aside.

In their reasons the Board explains that for both claim formats "*the notional novelty … relies on the novelty of the medical indication specified* …". There would be no objective reason for justifying the simultaneous presence of independent claims of both forms. They continue that "*G 2/08 does not give applicants an absolute right to draft two independent claims in one single set of claims …, one claim following the praetorian rule introduced in view of the old provisions of EPC 1973, and the other claim following the new provisions in Article 54(5) EPC 2000.*"

According to the Board, "*the Swiss-type form was conceived as an exception under the old law.*" There would no longer be any legal reason in the present case for allowing Swiss-type claims.

Examiners have so far allowed both claim types within the same claim set. Applicants may in the future find themselves confronted with an objection based on the present decision, especially in case it finds its way into the version of the Examination Guidelines expected to be released in 2015.

Decision T 1570/09 appears to stand in contrast to decisions T 1780/12, T 250/05, and T 879/12. We may thus see requests for a referral to the EBoA on this issue in the future. It also remains to be seen whether other

antibody of claim 29 [...] which dissociates from human IL-12 with a K_{off} rate constant of $1*10^{-4}$ s^{-1} or less. 32. The neutralizing isolated human antibody of claim 29 [...] which disassociates from human IL-12 with a Koff rate constant of $1*10^{-3}$ s^{-1} or less. 64. A pharmaceutical composition comprising the antibody [...] of claims 1, 16, 21, 27, 29, 41, 44, 45, 48, 50, 51, and a pharmaceutically acceptable carrier.
US7504485
1. A pharmaceutical composition comprising an isolated human antibody [...] which is capable of binding to an epitope of the p40 subunit of IL-12, and further comprising an additional agent. 11. The composition of any one of claims 1-4, wherein the antibody [...], dissociates from the p40 subunit of IL-12 with a Kd of $1*10^{10}$M or less or a K_{off} rate constant of $1*10^{-3}$ s^{-1} or less [...].

While both patents have also claims that define antibodies by their sequences, among them AbbVie's competing anti-IL 12 antibody Briakinumab, which was however withdrawn from FDA and EMA approval on January 15, 2011, the claims at stake in the litigation were mere functional claims.

Interestingly, the two patents disclose the amino acid sequences of about 300 antibodies identified by phage display, which cover a broad range of different affinities to IL 12, among them. The starting point was AbbVie's Joe-9, which had a low affinity for IL 12., and which was further developed by mutagenesis, resulting in a flock of antibodies the V_H3 heavy chains and Lambda light chains of which are identical to Joe-9, and which share about 90% similarity in their variable regions.

Stelara® has V_H5 type heavy chains and Kappa type light chains, and has about 50% sequence similarity in the variable regions compared to Joe-9.

In summary, the CAFC confirmed a jury decision that the respective claims failed to fulfill the written description requirement (35 U.S.C. §112) to cover antibodies to IL-12 as substance class, mostly as no enabling structure (composition) – function (affinity) correlation was disclosed. Thus Centocor's antibodies would not be anticipated from the disclosures and descriptions, and were thus considered as not infringing the patents.

The decision of the CAFC in favor of Janssen could reflect a paradigm shift in US antibody patenting. Claiming antibodies as unified substance class with a certain function (like affinity to/competition with/neutralization of a target) appears merely impossible, as a set of antibodies of diverse compositions would have to be described to fulfill the written description requirement 35 U.S.C. §112. In case an applicant has invented a limited set of antibodies, like in the case of the Abbvie patents, focusing the efforts around building a strong protection around the antibodies that are effectively disclosed may be a more advisable strategy going forward. This strategy is typically used for well-known targets to not yet been accomplished. Support to overcome these limitations is welcome !

In any case, filing a sequence listing created with this software should meet the requirements to obtain a filing date. Later formal objections can then still be overcome.

We would be happy to share with you the beta version of the software free of charge, to learn about your experiences.

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In the future, you may find prior issues of the Rhineland Biopatent Gazette here.

boards will follow the present ruling or not.

Nevertheless it is difficult to see in practice what effective difference the presence or absence of Swiss type claims, in addition to the new purpose-limited product claims, would make. We are not aware of a national court that has distinguished these medical use claims.

which prior art antibodies exist.

As a consequence, Centocor can continue to sell Stelara on the US market. According to business intelligence provider FiercePharma, Stelara's sales amounted to 717 mn USD in the first half of 2013, while analysts estimate annual sales in 2018 to be as high as 2,1 bn USD. Not exactly a niche product.

Michalski · Huettermann & Partner are getting personal... Today: John Hans Tsay

Dipl.-Ing. John-Hans Tsay was born 1975 in Mülheim an der Ruhr. He studied mechanical engineering at TU Braunschweig with the specialization chemical engineering. During his studies he worked as a research assistant for the Institute for tooling machines and fluid dynamics. He supervised and constructed a testing stand for studying vibrations on a portal arm for circuit board assembly.

In 2002 he graduated from the university and went for a half a year to Taiwan to study mandarin at the Taiwan Normal University. Afterwards he worked for seven years as a development engineer for electrical cooling solutions in different companies.

In 2009 John-Hans Tsay started his qualification in intellectual property rights at Michalski Hüttermann & Partner Patent Attorneys. During this time, he additionally was an intern at the Higher Regional Court of Düsseldorf. In 2013 he passed the Patent Bar Examination. Afterwards he worked afterwards for a patent firm in cologne. In July 2014 he started to work for Michalski Hüttermann & Partner Patent Attorneys

John-Hans Tsay is admitted as European Trademark and Design Attorney.

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