The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 7/2017

Duesseldorf/Munich, **06 October 2017** 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, we discuss a brand new decision by the CAFC affecting the validity of epitope based antibody patent claims.

CRISPR patent dispute makes it to down under

As we discussed in Issue 6/2017 of this Gazette, Sigma Aldrich has recently received grants for an Australian patent (AU2013355214B2), and a European patent (EP3138910 B1).

The scope of the two patents is essentially identical, covering the integration of a donor/exogenous sequence into a chromosomal sequence of a eukaryotic cell by an RNA-guided endonuclease comprising at least one nuclear localization signal.

Interestingly, the EP patent is restricted to CRISPR/Cas type II systems, while the AU patent isn't.

In the EP patent, the opposition term will end June 20, 2018. In the AU patent, the opposition term has already ended Sept 15, 2017.

Not entirely surprisingly, three strawmen have filed oppositions against the Australian patent.

Hence, the CRISPR patent dispute has now eventually made it to down under.

CAFC calls epitope based antibody patents in question

But, swan song on epitope based claims not yet sung

In Issue 4/2016 of this Gazette, we reported about a district court decision in which Amgen had received a 1st instance win against Sanofi at and Regeneron (1:14-cv-01317). The dispute circled around Sanofi's and Amgen's anti PCSK9 antibodies, which bind to the receptor for low-density lipoprotein (LDL) that are used in the treatment of hyperlipidemia.

The two antibodies, alirocumab (Praluent®, Sanofi) and evolocumab (Repatha®, Amgen) received FDA approval in 2015 for lowering cholesterol where statins and other drugs were insufficient.

The patents Amgen relied upon are US8829165, claim 1 of which is as follows

> 1. An isolated monoclonal antibody, wherein, when bound to PCSK9, the monoclonal antibody binds to at least one of the following residues: S153, I154, P155, R194, D238, A239, I369, S372, D374, C375, T377, C378, F379, V380, or S381 of SEQ ID NO:3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.

and US8859741, claim 1 of which is as follows:

> 1. An isolated monoclonal antibody that binds to PCSK9, wherein the isolated monoclonal antibody binds an epitope on PCSK9 comprising at least one of residues 237 or 238 of SEQ ID NO: 3, and wherein the monoclonal antibody blocks binding of PCSK9 to LDLR.

The court found (i) that Sanofi's Praluent would fall under the scope of these claims and (ii) that the claims are valid. As a consequence, the court granted an injunction against Sanofi, forcing the latter to withdraw Praluent from the market.

The injunction, in particular, sent shockwaves through the pharma community, because there had already been patients who had a prescription for Praluent, and who would have been deprived them of their actual heart medication.

We discussed this decision as the "return of the epitope-based antibody claims". This claim species is often used

+ from our firm +

MH Partners to attend GIPC conference in Bangalore.

Dr. Torsten Exner and Dr. Ulrich Storz will attend the GIPC conference in Bangalore.

The conference is Asia's leading Conference on Innovation and IP, and will take place on 23-25 January, 2018, in Bangalore, India.

Torsten will speak in Session VII (IP prosecution best practice), and discuss aspects of the possession of the invention at the priority date.

Ulrich will speak in session IX (IPRs in the field of Biotechnology) with a talk entitled "Biosimilar masterclass: How AbbVie tries to fend off world's blockbuster No 1 from generic competition"

See the conference website here.

Feedback please !

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

as a fallback position for antibody protection in case the target as such is already prior art, because it provides broader protection scope of protection then antibody claims protecting the mere antibody sequence.

For this reason, epitope-based antibody claims are still quite popular among antibody companies. See e.g. U.S. patent 8,779,105 assigned to Ono and licensed by BMS, which claims "a monoclonal antibody or an antigen-binding portion thereof, which cross-competes for binding to PD-1 with a reference antibody" specified by a given sequence (we discuss this patent in an article that can be found here).

Not surprisingly, however, Sanofi went into appeal to the CAFC. In the respective suit, both sides were aided by amicus curiae briefs from different parties, including Eli Lilly (to support Sanofi's position) and AbbVie (to support Amgen's position).

On February 8, 2017, the CAFC decided to stay the injunction for the duration of the appeal proceedings, hence allowing Praluent to remain on the market. While this was considered to be a stage win for Sanofi, the question whether or not the Amgen's claims were valid was still pending.

Until yesterday, Oct 5, 2017, to be precise, when the CAFC issued its decision to remand the case back to the first instance.

The decision vacated the permanent injunction and ordered that Sanofi's lack of written description and lack of enablement defenses are to be reconsidered. In the eyes of the CAFC, the District Court had erred by categorically excluding evidence regarding those defenses. The CAFC emphasized that the District Court must allow the jury to consider Sanofi's post-filing evidence in determining whether Amgen's patent specification discloses a "representative number of species" sufficient to show possession of the claimed genus of PCSK9 antibodies binding a particular epitope.

Ok, what do we learn from this ?

Considering that the case is not yet finally decided, epitope based claims can be valid in case the applicant provides a sufficient number of antibodies that bind to the respective epitope – probably to different subsections thereof, and probably combined with a non-working example of an antibody that binds outside of that epitope – to demonstrate true intellectual possession of the claimed epitope

In case the applicant has just one candidate antibody, and claims all antibodies that compete with that respective reference antibody for binding to the target (as it has been done in Ono's anti PD-1 antibody patent discussed above), said written description will hardly be fulfilled.

Archive

To obtain a neat overview of the quickly changing world of Biopatents, find prior issues of the Rhineland Biopatent Gazette here.

EURIPTA® EEIG is getting personal... Today: Hans Bracquené – IP Lodge

After 10 years of being an in-house counsel in industry, including at the renowned micro-electronics research center IMEC, Hans became an independent legal consultant in 1991.

At IMEC, Hans Bracquené was responsible for the legal and financial aspects of contract research. IMEC has more than 200 bilateral research contracts, with the major European electronics companies as well as with SMEs, and is the most important Belgian participant in the ESPRIT program. IMEC is also participating in RACE, BRITE, Joule, in different EUREKA projects and in projects of the European Space Agency.

In relation to IMEC's participation in the projects of the Framework Program, Hans Bracquené dealt with all financial and

legal aspects. Hans was also responsible for IMEC's patent policy. As an independent consultant he is still advising IMEC on these questions.

Both at IMEC and as a consultant, Hans Bracquené has been involved in the legal and financial organization of spin-off companies.

From May 1988 until September 1991, Hans Bracquené was Adviser of the Belgian Deputy Prime Minister, Minister of the Budget and of Science Policy, responsible for international scientific cooperation (EU, ESA, Eureka, Airbus) and industrial R&D. In this capacity he negotiated as a member of the Belgian delegation the Third Framework Program. Special attention was thereby devoted to the pre-competitive character of the Framework Program and the relationship between Eureka and the Framework Program.

Hans Bracquené was also responsible for improving the participation of the Belgian industry in the ESA projects. In close co-operation with the Belgian delegation at ESA, a new policy, aimed at emphasizing Belgium's position in some ESA programs (e.g. telecommunications), was laid down.

Hans holds a master's degree in law and a master's degree in Economics, both from the University of Leuven.

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