The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 6/2017

Duesseldorf/Munich, **28 August 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 report about yet another CRISPR player, and a recent strategic move related to Humira's IP portfolio.

Yet another CRISPR player

Headcount is now five

Quote 1 of the last Gazette: "The CRISPR Cas IP dispute has often made it into this Gazette". Quote 2 of the last Gazette: "3rd and 4th player on stage"

Well, today we can report about a fifth player who owns patents protecting the CRISPR basis, Sigma Aldrich, who remained under the radar of most or a long time.

Sigma Aldrich has recently received grant for an Australian patent (AU2013355214B1, and is about to get a European patent grated EP3138910A1).

As regards the priority date (Dec 6, 2012), Sigma Aldrich ranks fourth after Vilnius University (March 20, 2012), UCBerkeley/Vienna University (May 25, 2012) and Toolgen (Oct 23, 2012), but before Broad Institute, who however received granted patents first, due to expedited prosecution both in Europe and the United States.

What makes the Sigma Aldrich's portfolio so relevant is that it discloses and enables the use of CRISPR Cas 9 in eukaryotes, by means of a Nuclear Localization Sequence (NLS) already in the priority document.

This is what Broad Institute has always claimed to be its discriminating feature over the UC Berkeley portfolio, in which

AbbVie gives up Humira's European formulation patents

Still, Humira not yet open to generic competition in Europe

In an article that issued in 2017, we have discussed the patent strategy underlying the world's best selling drug, AbbVie's Humira. Please send an email if you want a copy.

One of the key families is the so-called Krause family, which protects Humira's established and approved formulation, comprising 40 mg/0.8 ml (hence 50 mg/ml) in a citrate/phosphate combination buffer.

The respective EP patent EP1528933B1 was revoked in 1st instance opposition proceedings on Oct 13, 2015 for lack of novelty. In fact, AbbVie had committed a fatal flaw during prosecution. Upon filing the underlying priority application, AbbVie forgot to submit the light chain/heavy chain variable domain sequences to which the formulation claims referred. Shortly after the priority date, the actual formulation was published, but only after that, AbbVie submitted the sequences with the USPTO. In the European prosecution, this issue escaped the attention of the examining division, but in subsequent opposition proceedings, the priority date of the application was re-dated to the date when the sequences were submitted, with the result that the published formulation became novelty-destroying prior art against the patent claims.

In an attempt to re-establish the earlier priority date, AbbVie then tried to replace the sequence by the term "D2E7". This attempt was found unallowable by the Opposition Division because of lack of clarity of that term, which furthermore was found to extend the scope of the claims post grant, and hence unallowable.

Not surprisingly, AbbVie appealed the decision, and, actually quite surprisingly, submitted an excerpt from the CAS registry database (entry No 331731-18-1) which discloses the full length heavy/light chain sequences of adalimumab, which was allegedly available to the public since April 18, 2001. This allegation was vigorously disputed by the opponents, who objected that said entry identified the chemical name "D 2E7" with a blank space between "D" and "2", whereas a search for "D2E7" (without blank space) did not deliver this register entry.

It almost appeared that AbbVie may have actually tried to conceal the full length sequence of adalimumab in

+ from our firm +

Save the Date: Our 2018 Patent Seminar will take place April 12, 2018

With our Patent seminar now scheduled for April 12, 2018, we will again return to the highly renowed Industrieclub in Düsseldorf, Germany.

And, as always, we will have high profile speakers from inhouse industry IP departments, plus attorneys from our firm.

If you want to receive all updates, please send an email to Mrs Felsner.

Lunch Seminar "IP strategies in Russia"

A new lunch seminar titled "IP strategies in Russia" will take place on Sept 5, 2017, in our premises in Düsseldorf. Speakers will be Denis Levchuk, Maria Lovtsova and Andrej Svistov from YUS Patent & Law Firm in Moscow.

The topics discussed will include "Patent prosecution in compliance with The Eurasian Patent Convention (EAPC)", „The Customs Register of Intellectual Property Objects and Requirements for Application Materials", „The Last Changes in Documentation Submitted for the purpose of the

such transfer from prokaryotes into eukaryotes was not yet disclosed or enabled at the priority date.

Actually, such transfer and use of NLS is also disclosed and enabled in the Toolgen portfolio's priority application, which however has not yet received grant, with the exception of Korea (KR101706085B1).

Hence, the recent development regarding Sigma Aldrich's portfolio could make an already complicated IP situation even more complicated.

said register simply by annotating it with a misspelled chemical name.

Further, AbbVie has recently received grant for a further divisional application (EP2359856B1) with amended claims that faithfully reflect the approved formulation in all details, with the exception that, again, the term "D2E7" is used. Here, the same clarity issues applies, less the issue regarding post-grant extension of scope, because the application was still pre-grant when the term D2E7 was introduced into claims.

Much to our surprise, Abbvie has last Monday (Aug 21, 2017) proactively revoked European patent EP2359856B1, still within the opposition term. On the same day, AbbVie has also withdrawn its appeal against the revocation of the parent patent, EP1528933B1.

Further divisional applications in the family (EP2361637, EP2363144 and EP2363145) are all finally withdrawn since 2016. This means that AbbVie has completely given up the European IP portfolio that protects its citrate phosphate buffer.

Humira as such is off-patent in the United States already. US patent US6090382 expired Feb 9, 2016, plus a PTE extension until Dec 31, 2016. However, its European counterpart, EP0929578B1 is still in force until Oct 15 or 16, 2018, due to a supplementary protection certificate plus pediatric extension.

Therefore, despite that step, Humira is not yet exposed to generic competition in Europe.

Still, the rationale behind AbbVie's tactics still remains enigmatic for us. According to US Philosopher Eugene T Gendlin, a key feature of guerilla warfare is to "borrow the enemy's resources, and to conquer and withdraw immediately". Now you would not actually qualify AbbVie as a guerilla – but we can't help to see similarities, tactics-wise.

recordal of assignment/ licence agreements in Russia" and „New developments regarding issues related to Parallel Import cases, 3-D Trademark Prosecution, Non-use cancellation actions, Powers and Authorization in the Court proceedings"

Please send an email to Mrs Felsner if you want to attend.

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.

EURIPTA® EEIG is getting personal... Today: Mario Bonfreschi – Studio Corradini

Mario graduated in Mechanical Engineering and started working in Intellectual Property in 1973 and joined the firm in 1986. His practice is devoted mainly to patent filing in Italy and abroad, patent searches, patent prosecution, court litigation and negotiations relating to Industrial Property and official technical consultant in court cases. Mario is an Italian and European patent attorney, and an Italian and Community Trade Mark and Design attorney. He speaks Italian and English.

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