

# The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 5/2017

**Duesseldorf/Munich, 26 July 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 two new developments in the CRISPR Cas dispute, and a decision of the UK Supreme Court in the notorious pemetrexed litigation.



## New developments in CRISPR Cas dispute

3<sup>rd</sup> and 4<sup>th</sup> player on stage, and Broad receives blow below the belt in Europe

The CRISPR Cas IP dispute has often made it into this Gazette. Today, we can report about two (not so-) recent developments which could become true game changers.

The Frontline as commonly perceived is between Broad Institute/Harvard/MIT on one hand side, and UC Berkeley/University of Vienna on the other. Irrespective of the outcome of this dispute, it was common perception that the CRISPR Cas cake would be more or less shared between these two consortia.

On May, 2. Mai 2017, the USPTO issued a patent to the University of Vilnius, which has an even earlier priority date than the Berkeley/Vienna estate, and which claims CRISPR Cas methods in general, yet without reciting or claiming the chimeric sgRNA (i.e., the fusion construct of crRNA and tracrRNA which is the key feature of the Berkeley/Vienna estate).

The Vilnius patent still claims the use of a crRNA and a tracrRNA, and hence could be considered to form the foundations on which the Berkeley/Vienna patent stands. It is difficult to judge whether or not methods using a chimeric sgRNA would fall under the scope of the Vilnius patent, because, strictly speaking, such methods still use a crRNA, and a tracrRNA, even when the two are combined to form the chimeric sgRNA.

It is in this context noteworthy that in a continuously updated press release, Broad Institute, who claims to have invented the transfer into eukaryotes, refers to a couple of patent applications having an earlier priority date than the Broad estate, with, inter alia, an application assigned to University of Vilnius, and the Berkeley/Vienna application, disqualifying them as „speculating about the potential utility of CRISPR“, showing „only that purified Cas9 protein and a certain purified RNA could cut a short piece of DNA in a solution in a test tube“.

With regard to the Vilnius application, Broad's press release goes on by stating that „the USPTO rejected the Vilnius application as not having significantly more than a study of the natural system and failing to describe the invention.“

## UK SC finds K<sup>+</sup> equivalent to Na<sup>+</sup>

Pemetrexed decision with similar outcome as the BGH

In an article that issued recently, MH partners Aloys Hüttermann and Ulrich Storz discussed the decision „Pemetrexed“ of the German Federal Supreme Court (BGH) (Hüttermann & Storz - Estoppel auch beim Scheitern funktioneller Patentansprüche ? Anmerkungen zu BGH „Pemetrexed“, Mitt. dt. Patentanw. 2017, 49). Ask [here](#) for a copy.

In a nutshell, we explained why it is a difference to (a) restrict a patent claim during prosecution in order to delimit the letter from prior art, than (b) restricting a patent claim which uses functional language in such way that the functional language is replaced by structural language.

While the former restriction serves to overcome the novelty or non-obviousness requirement (which we dubbed „hard requirements“), the latter serves to pacify an examiner who does not like functional language in a patent claim, because such language would not meet the sufficiency requirements (which we dubbed „soft requirements“, because different examiners and different jurisdictions judge this differently).

In the underlying case, the patent proprietor had started with a patent claim trying to protect a drug combination

+ from our firm +

### MH Patent is not on vacation, but....

...we are approaching what the Germans call the „summer hole“. Business as usual, with some individual vacations in between, but nothing special to report...

Enjoy the summertime, and the vacation, if you are lucky.

### Feedback please !

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### Archive

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

Indeed, the USPTO issued a final rejection against the Vilnius application in Oct 2015. However, in the subsequent prosecution, the applicant submitted amended claims which then were found patentable.

It is remarkable that Broad does not mention this change on their press release website.

The University of Vilnius has given an exclusive license to this patent to DuPont, who in turn have a cross license with Caribou – one of the organizations that license out the Berkeley/Vienna estate.

Still, this development adds one further patent estate to the scenario which has to be considered by potential licensees.

And there is more to come. In the opposition proceedings against Broad's European Patent EP2771468B1, with 9 (!) opponents, the Opposition Division (OD) has recently issued its intermediate opinion.

Therein, the OD takes the position that the subject patent would not be eligible to claim the priority of a number of priority applications (called P1, P2, P5, and P11), mainly because inventor Luciano Marraffini, a researcher of Rockefeller University is coinventor/coapplicant of these priority applications (which are US provisionals, hence inventors and applicants are the same), but has not transferred his priority rights to Broad's PCT application, which formed the basis of Broad's granted EP patent.

The loss of the priority claim could be fatal because it renders prior art applicable which otherwise would not count, for being post published. On the basis of this conclusion, the OD finds that the independent claim of said patent would be anticipated by the prior art, and hence not novel. Because the loss of the priority claim seems to affect other corresponding EP patents from Broad's family as well, which all refer to the same priority documents, an underlying controversy which so far has not really made it into the public could become fatal for Broad.

Indeed, Feng Zhan of Broad Institute did not only collaborate with Jennifer Doudna (Berkeley) and Emmanuelle Charpentier (Vienna) in the good old days, but also with Rockefeller's Luciano Marraffini – who was named coapplicant in the crucial priority filings. However, something seems to have gone wrong between Rockefeller and Broad – as Broad has not assigned Rockefeller as coapplicant in their non-provisional applications

This lack of coordination, between Broad and Rockefeller, or a conflict dwelling underneath, may turn out deadly for Broad's IP portfolio in Europe.

European law demands, in order to validly claim a priority, that either (i) the priority application is assigned to the same party as the actual application, or (ii) the right of priority has been transferred to the new applicant before the actual application is filed.

Neither of the two seems to be the case in the Broad portfolio, because, as it seems, Mr. Marraffini did not transfer his priority rights to Broad. Because, under US law, in a provisional applications the inventor is the applicant, inventorship disputes (which play a minor role at the EPO) can easily escalate into applicantship issues – which in the worst case may result in the loss of a priority claim – and, as a consequence, revocation of the patent for lack of novelty.

comprising an antifolate - which is a class of drugs being used in cancer therapy. In fact, it is the oldest class of cancer chemotherapeutics, having entered the clinic about 70 years ago, and as such well known to the skilled person.

However, the European examiner did not like that term because it was functional, and covered molecules which were not yet discovered at the filing date - a position which is shared by some examiners, but by others not.

Unfortunately, the patent specification mentioned only one specific antifolate, namely the disodium salt of Pemetrexed. This hence was the actual fallback position the patent proprietor was restricted to.

While, fortunately, the product which the patent proprietor actually used was the disodium salt, a competitor started marketing the dipotassium variant of Pemetrexed.

The patent proprietor considered this to be an equivalent infringement, while the competitor argued that, because of the restriction to the specific embodiment, the patent proprietor could no longer claim any scope of equivalence (so-called "estoppel"). The OLG Düsseldorf shared the competitors view, while, on appeal, the Federal Supreme Court (BGH), came to findings not considered by the OLG, and remanded the case back.

In our article we explained the BGH's view, and placed an emphasis on the fact that there are hard and soft patenting requirements, and while it is probably justified that, in case a restriction was made due to satisfy a hard requirement (like novelty), a patentee has lost the legitimate interest to reclaim subject matter that has been surrendered before, by means of an equivalence claim, the same estoppel cannot automatically be applied in case of a restriction due to a soft requirement.

The UK Supreme Court (UKSC) now came to a similar conclusion in the corresponding UK decision "[Actavis vs Eli Lilly](#)" [2017] UKSC 48], which issued July

Quite surprisingly, Rockefeller filed a couple of US non provisional applications and EP applications on their own initiative, in which the priority of Broad's provisional applications which name Mr. Marraffini as a co-applicant was claimed, and Broad and MIT were named coapplicants, allegedly without informing them.

In their non-provisional US application US2015184139, Rockefeller has simply copied the claims of Broad's US patents US8697359 and US 8771945, which fail to name Mr Marraffini as a coinventor, or Rockefeller as a coapplicant, although relying on a provisional application which names Mr Marraffini as a coapplicant.

One of Rockefeller's US applications has been objected by the USPTO examiner for double patenting in view of the two Broad patents, for improper naming of inventors and for being anticipated by a Berkeley/Vienna's application US2014068797 – which is surprising, because Broad's US8697359 and US 8771945 were granted irrespective of said reference. Rockefeller has countered, inter alia, that it would not be the USPTO's role to resolve the underlying inventorship dispute ex parte.

Apparently, Broad is not happy about these parallel filings. Accordingly, although the opposition terms are still pending, oppositions have already been lodged against both patents by a strawman – which does not necessarily mean that Broad is the party behind.

However, because Rockefeller is named in these patents as coapplicant, the priority problem that threatens the validity of Broad's other European patents would likely not apply before the EPO.

Two European patents were already granted based on these filings, namely EP2840140B1 and EP2825654B1, while the US counterparts are still pending. Although, in the two EP patents, the opposition term is still pending, oppositions have already been lodged against both by a strawman.

So it seems that two further players – Rockefeller University and University of Vilnius – which have been below the public radar so far – made it into the scene, and into the licensing scenario.

12, 2017.

The Court referred explicitly to the BGH decision which stated that "it is permissible ... to use statements made by the applicant [and the examiner] during the grant procedure as an indication of how the person skilled in the art understands the subject matter of the patent" but "such indications cannot be readily used as the sole basis for construction".

In passage 74 of its decision, the UKSC stated that "the addressee of the Patent would [...] understand that the reason why the claims were limited to the disodium salt was because that was the only pemetrexed salt on which the experiments described in the specification had been carried out", while it would "not follow that the patentee did not intend any other pemetrexed salts to infringe". Hence, it would be unlikely that "the notional addressee would have concluded that the patentee could have intended to exclude any pemetrexed salts other than pemetrexed disodium, or indeed pemetrexed free acid, from the scope of protection."

Could have been our own words, right ? We do not add more – except that we are excited to see what the OLG Düsseldorf makes out all this.

## **EURIPTA® EEIG is getting personal... Today: Isabelle Surdej - IPLodge**

Isabelle Surdej is an engineer with a PhD in Physics. In 2004, she joined the European Southern Observatory (ESO) in Munich, where she completed her master's thesis in physical engineering.

She was subsequently employed by ESO as an engineer in wave front control, where she worked for the European Extremely Large Telescope (E-ELT) project, a European telescope project with a primary mirror of 39 meters. Her responsibilities on this project were to evaluate, design and test different wave front sensors aimed at improving the alignment precision of the nearly 1000 mirror segments composing the primary mirror of this telescope. In this context, she defended her PhD thesis (Co-phasing segmented mirrors: theory, laboratory experiments and measurements on sky) in October 2011 at the Physics faculty of the Ludwig Maximilians Universität München.

After the completion of her PhD thesis, she worked at the Université Libre de Bruxelles to conduct post-doctoral research in the field of active and adaptive optics for space-based telescopes. She gained hands-on experience in programming (C, Matlab) by realizing various optical simulations, and in optics, both theoretical and practical, by designing, commissioning, and conducting experiments on an optical bench both in laboratory and at the telescope.

After working as a postdoctoral researcher at the Université Libre de Bruxelles, she entered the field of intellectual property. She joined IPLodge in 2015. Isabelle's professional working languages include French, English, and German.



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