# The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 1/2018

**Duesseldorf/Munich**, **28 September 2018** Here we are again – after clarifying the uncertainties the General Data Protection Regulation (EU) 2016/679 left us with quite unprepared, we are proud to present the latest issue of the Rhineland Biopatent Gazette. 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 focus on two recent decisions that issued in September 2018, namely the Appeal decision in the CRISPR Cas9 interference, and a 1st instance opposition decision regarding a patent protecting Gilead's anti HCV drug Sovaldi.

## Broad prevails in CRISPR Cas9 interference

CAFC: Broad's patent claims separately patentable from the claims of UC Berkeley's patent application.

On September 10, 2018, the Court of Appeals of the Federal Circuit (CAFC) issued a long awaited decision, and confirmed a decision of the Patent Trial and Appeal Board (PTAB) of 2017, in which the latter denied that Broad's patent portfolio covering CRISPR Cas9 technologies would interfere with UC Berkeley's earlier patent portfolio, covering similar subject matter (see issue 1/2017 of this Gazette).

In a nutshell, UC Berkeley, with inventors Jennifer Doudna and Emanuelle Charpentier, established a simplified way to use the bacterial system CRISPR Cas9 as a genome editing tool, though they could demonstrate the use of this tool only in prokaryotes. Broad Institute, with Inventor Feng Zhang, claims to have invented a way to use the tool in eukaryotes, too.

The CAFC now confirmed that the claims of Broad's patents are sufficiently distinct as to be separately patentable from the claims of the Doudna/Charpentier group's patent application.

We have discussed the underlying patent dispute in two articles (Les Nouvelles (2018), 123 – 131 and J Biotech 265 (2018), 86-92). Please write us here for copies.

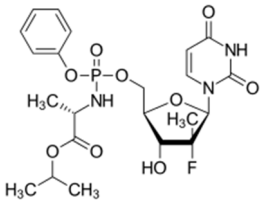
UC Berkeley used its then pending application US20140068797 as a basis for the interference. However, examination thereof was stayed when the interference began, so the final scope of this application remains unclear until to date.

When the application went into hibernation, the then pending set of claims was however not restricted to neither prokaryotes nor eukaryotes – the major restriction then was the chimeric sgRNA

## European Sovaldi patent stands attack by NGOs

Patent maintained in amended form, but Gilead says: still string enough

Gilead's Sovaldi (Sofosbuvir) is a nucleotide analogue that is being used for the treatment of Hepatitis C, in a combination with other drugs.



It is generally considered to be a breakthrough therapy, and a true gamechanger in the treatment of HCV – a disease with otherwise may lead to liver cancer, and often a painful death after years of suffering.

Hence, a blessing for humankind, one would think, if there weren't the price tag. Sovaldi made its way through the media as the „1000 Dollar" pill.

Treatment costs for a 12 week therapy in the United States were reported to be up to 84,000 USD, while in India Gilead sells the drug for 300 USD per therapy, and has granted licenses to leading Indian generic companies. Still, Gilead's pricing policy in the industrialized markets has been subject to much criticism.

This seems to be one of the reasons why Doctors of the World, Doctors without Borders, and the European Public Health Alliance (EPHA), filed an opposition against Gilead's EP patent EP2604620.

Oral proceedings took place on Sept 11, 2018, and, as a consequence, the patent was maintained in amended form. The decision is

**+ from our firm +**

### MHP has opened satellite office in Frankfurt

As already announced earlier, we have now opened a satellite office in the Gateway Garden campus close to Frankfurt Airport, to improve our presence and availability in the Rhein/Main and Rhein/Neckar area.

Important Biotech hubs, like the Mainz/Ingelheim region, the Langen region, the Bad Homburg region and the Mannheim/ Heidelberg region, are now within easy reach for Biotech attorneys from our firm.

Further, we increase the visibility and reachability for our international clientele.

Our new office is within walking distance from Terminal 2, and just a 5 min cab ride from Terminal 1 and the airport train station that serves high speed trains.

Your contact partners in Frankfurt will be Dr. Torsten Exner and Dr. Christoph Volpers.

We trust that this new satellite helps to improve our services to our clients in these regions.

which is generally accepted to be Doudna's and Charpentier's invention.

Now, with the interference proceedings terminated, the examination of US20140068797 can be resumed.

In the meantime, UC Berkeley has filed a divisional application (14/685,502), which was granted on June 19, 2018 as US10000772.

The independent claim of this patent relates to a method of modifying a target DNA molecule using Cas9, but is restricted to

„contacting the target DNA with the CRISPR Cas9 complex *outside of a bacterial cell and outside of an archaeal cell*"

So what does this mean? The language is actually quite ambiguous as, strictly speaking, it excludes *in vivo* use in bacteria and archea, meaning it could encompass *in vitro* and *in vivo* use in eukaryotes.

Such claim construction would however directly interfere with Broad's patents portfolio (US8697359 et al.) that was subject of the interference, and would collide with the CAFC's finding that Broad's patents which specify that the CRISPR-Cas9 system is used in eukaryotic cells would be separately patentable from Broad's patent claims

In other words: In view of the new decision, UC Berkeley's patent could prove unenforceable. The problem seems to be written description, which UC Berkeley actually has not provided for the use of the new technology in eukaryotes. These more sophisticated organisms require that the enzyme is shuttled into the nucleus – for which purpose Broad used so-called NLS sequences, which are lacking in the UC Berkeley applications.

However, what looks like only a prelude to a whole series of further lawsuits could also be a trigger for settlement.

This is because UC Berkeley has recently obtained a double success in Europe, with their key patent EP2800811 being granted (although already under opposition) with relatively broad scope (note Europe does not have a written description requirement), and the first of Broad's patents being revoked in 1st instance opposition, due to a priority problem – which It shares with its other EP members from the same family.

Hence, both parties have had their successes and their losses – sounds like a good starting point for a settlement, doesn't it? If there weren't the other players, and the exclusive licenses that have already been granted.

not yet publicly available, but we will keep you tuned.

The three NGOs joined forces and submitted identical opposition briefs, which comprised the admissible grounds for revocation (lack of novelty and inventive step, added matter, insufficient disclosure), but also an introductory section where Gilead's drug pricing policy was denounced.

Without knowing the exact outcome, it appears that the attacks were not strong enough. Or, in other words: Drug pricing is not a ground for opposition at the EPO.

However, Gileads IP position on Sovaldi is under higher pressure in other jurisdictions. The corresponding patents in Brazil and China were recently revoked. And on March 14, 2018, the NGO Knowledge Ecology International (KEI) launched an initiative against Gilead, by demanding the Department of Health and Human Services (HHS) to investigate a potential failure to report NIH funding for research that lead to Gilead's Sovaldi patent US7964580. Such failure would violate regulations set forth in the Bayh Dole act, and hence force Gilead to forfeit its title to the patents.

And, Sovaldi is not the only patent front Gilead is fighting at. On May 15, 2018 the Federal Patent Court of Germany (BPatG) declared the supplementary protection certificate (SPC) DE122005000041 for Gilead's combination drug Truvada, (tenofovirdisoproxil and emtricitabine), which is an anti HIV treatment, invalid, hence opening the market for generic versions thereof.

The SPC was declared invalid because, while emtricitabine is also protected by the basic patent, the combination isn't. The Court argued that an SPC may only include what is also protected in the basic patent.

In this decision, one of the many unclarities of the EU's SPC regulation comes again into focus, with the Court of Justice of the European Union (CJEU) having proven unable to clarify matters despite the fact that it has already issued more than a handful of decisions addressing this question (see issue 5/2013 of this Gazette).

The BPatG decision is not yet published. Yet on July 5, 2018 the CJEU decided a referral by a UK court, which related to the corresponding UK SPC. Like the German counterpart, the latter was based on EP patent EP0915894. The CJEU revoked the SPC for the same reasons as the BPatG. This decision can't be appealed and will also have a bearing on a potential appeal in Germany.

P.S. Gilead's Truvada SPC in Switzerland has been declared valid in June 2018. Do I here someone complaining about lack of harmonization? Well, you are right. Welcome to our world. We call it Europe.

If you have a stopover in Frankfurt airport, or at the railway station, or if you are from the region, please stop by for a coffee or talk.

Find driving directions here.

**MH partner will contribute to LES Webinar**

On October 10, LES USA/Canada will host a webinar titled

"Enhancing antibody patent protection using epitope mapping information"

MH partner Dr Ulrich Storz will be one of the speakers, and will discuss the current state of case law regarding epitope based antibody claims.

This webinar is aimed at IP lawyers with biotech/pharma interests

LES Members can attend the webinar free of charge. Please find more details here.

**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: Dr. Kevin Lamberts

Kevin Lamberts studied chemistry at RWTH Aachen University and completed his studies in 2012 with his master's thesis in the field of complex chemistry. After a research stay at Tsinghua University in Beijing, he received his doctorate in Aachen in 2015 at the Institute of Inorganic Chemistry with a thesis on the coordination chemistry of amino acids.

He then worked on the development of feedstuff in industry and found his enthusiasm for IP through his dedicated and successful work on patent topics during that time.

By the end of 2017, he decided to start his training in intellectual property law at the law firm of Michalski Hüttermann & Partner. Dr. Lamberts is a member of the German Crystallographic Society and speaks German and English as well as reasonable Portuguese and French. His hobbies include dancing, sailing and speed cubing.

MICHALSKI · HÜTTERMANN & PARTNER

Imprint: Michalski · Hüttermann & Partner Patent Attorneys, c/o: Dr. Ulrich Storz - email: st@mhpatent.de

Tel.: +49 (0)211 159 249 0 - Fax: +49 (0)211 159 249 20
Hafenspitze - Speditionstrasse 21 - 40221 Düsseldorf
Perchtinger Strasse 6 - 81379 München
Hufelandstrasse 2 - 45147 Essen
De-Saint-Exupéry-Strasse 10 - 60549 Frankfurt a.M.