

The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 2/2019

Duesseldorf/Munich, 29 July 2019 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 two events that cast new light on the notorious CRISPR Cas patent debate.



CRISPR Cas in Diagnostic applications

Is a new patent war looming ?

You know that CRISPR Cas is a powerful tool for genome editing, and, as a frequent reader of this Gazette, subject of a multilateral patent dispute.

Now, CRISPR Cas has also become a tool for advancing diagnostics – and it may happen that we all experience a déjà vu, i.e., a new patent battle.

It's all about CRISPR Cas12a, which uses a pathogen specific guide RNA. In a sample to be tested, an isothermal recombinase polymerase amplification (RPA) is carried out, and then Cas12a is added together with its guide RNA. If present, Cas12a finds its target sequences and starts chopping it – together with nearby ssDNA-fluorophore/quencher probes that were added to then reaction mix, and are unspecifically cleaved. Increase of fluorescence hence signals presence of the pathogen.

The technology, called DETECTR, has been developed by Mammoth Biosciences, which is a spinoff from UC Berkeley and, has licensed the technology from the lab of Jennifer Doudna.

A similar technology, using Cas13 (C2c2) instead (which cuts RNA rather than DNA), is called SHERLOCK, and has been developed by a group from Broad Institute in Boston, based on Feng Zhang's IP.

(Wait a minute: Zhang, Doudna – do these names sound familiar ?)

Both approaches are highly sensitive and specific, and can be used in items as simple as mere paper strips. They hence hold great promise in particular when it comes to the diagnosis of viral diseases in less developed countries, like Zika, Lassa and Dengue.

CRISPR Cas dispute flares up again

USPTO initiates new interference

In a recent [press release](#), MPEG LA, the company that is well known for patent pools in the telecom industry, but is also in a process of establishing a pool for CRISPR Cas patents, has summarized recent developments in the ongoing patent debate.

One of the reasons for said press release is the [announcement](#) of Broad Institute and MilliporeSigma to offer joint licenses for their respective CRISPR Cas patent portfolios – a step which came unexpected because already in 2017, Broad has committed itself to discussions to contribute to the patent pool coordinated by MPEG LA.

The new coalition between Broad and MilliporeSigma does not come surprising though. Already a few years ago, Sigma Aldrich mentioned, on their [website](#), that the CRISPR Cas Kit products Sigma was offering for sale then were covered under a license between the Board Institute and Sigma Aldrich, including, *inter alia*, Broad's US patent 8,697,359.

Another event that may have triggered MPEG LA's press release is the fact that the Patent Trial And Appeal Board (PTAB) of the USPTO has initiated on June 24, 2019, on its own motion, a new [interference \(No. 106.115\)](#) against a set of patents and patent applications assigned to Broad Institute (US8697359 et al.) based on a series of patent applications assigned to University of California (15/947,680 et al.).

This move came unexpected, too, because the earlier interference initiated by UC Berkeley (covered repeatedly in this Gazette) was finally decided on September 10, 2018.

The Court of Appeals of the Federal Circuit (CAFC) confirmed a decision of the 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 1/2018 of this Gazette).

+ from our firm +

MH partner to speak on CRISPR Cas patents

MH partner Dr. Ulrich Storz will speak on CRISPR Cas patents this autumn on several occasions.

On 7./8. November, he will attend the annual [Conference on European Patent Law](#) in Brussels, organized by ERA Academy of European Law, and speak about "patent engineering in the light of CRISPR".

On 15./16. October 2019, Ulrich will speak at the [C5 Life Sciences IP Summit](#) in Munich on "Exploring Controversies Surrounding the Patentability of Gene-Editing Processes".

New article on epitope based claims accepted by Human Antibodies

We are proud to report that a new article authored by MH Partner Dr. Ulrich Storz has been accepted for publication in [HUMAN ANTIBODIES](#). The article is called "The nine lives of epitope based antibody patent claims."

While both groups have declared to make the technology available as a scientific platform in particular in the developing world, the situation sparks memories to the current patent battle in CRISPR Cas9. Another name for Mammoth's Cas12a is Cpf1, which Broad filed for patent in 2015 ([WO2016205711A1](#) et al.), and later licensed to Editas, the spin-off cofounded by Feng Zhang.

It is so far not clear whether Mammoth's decision for Cas12a will interfere with Broad's patent estate, meaning whether or not the latter also covers applications like diagnostics – rest assured, we are working on it.

New York professor Jacob Sherkow, who has frequently commented on the CRISPR Cas dispute, has commented that "a similar, almost mirror-image scenario" would actually be possible.

We will wait. And see. And report.

MilliporeSigma has now come to Broad's aide and filed a [petition](#) to the USPTO on July 19, 2019 in which it demanded declaration of a parallel interference against UC Berkeley, based on MilliporeSigma's applications 15/188,911; 15/188,924 and 15/456,204 (the "Chen" portfolio).

In their press release, MPEG LA appeals to the parties to settle their disputes and contribute to the suggested patent pool, stating that "among all the parties involved in CRISPR patent licensing, MPEG LA is unique in its independence and neutrality", and would hence be able to "maximize the benefits of CRISPR, as the market needs a patent pool option in which all stakeholders participate and the market's confusion and uncertainty concerning".

This is indeed an honorable approach.

Yet, in a conflict situation thus complex, the prospects of this initiative remain difficult.

Actually, the title is quite self-explaining. Send us an [email](#) if you would like to receive a reprint once the article is published.

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...

It's summer break - n new arrivals to report !



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