# The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 9/2016

**Duesseldorf/Munich**, **21 December 2016** 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, Dr. Ulrich Storz will shortly address a recent agreement between CRISPR Cas competitors, while Dr. Torsten Exner will comment on the announcement that the EPO will stay prosecution of patent applications comprising plant PbP claims.

## CRISPR Cas companies reach agreement

Yet, deal does not include Editas Medicine

On Dec 16, 2016, CRISPR Therapeutics, Intellia Therapeutics, Caribou Biosciences, and ERS Genomics announced that, together with their licensors, University of Vienna and UC Berkeley, they have signed a global agreement related to rights covering CRISPR Cas 9 technologies.

| Company | Country | Founders | Business model |
|---|---|---|---|
| ERS Genomics | Dublin | Emanuelle Charpentier et al. | Outlicensing |
| Caribou Biosci. | Berkeley | Jennifer Doudna et al. | Outlicensing |
| CRISPR Tx | Cambridge (USA) Basel | Emanuelle Charpentier et al. | Development of Therapeutics |
| Intellia | Cambridge (USA) | Jennifer Doudna et al. | Development of Therapeutics |

In their agreement, the parties have undertaken to streamline and coordinate prosecution and defense of what they call the "foundational patent portfolio" protecting CRISPR/Cas9, which is mainly based on WO2013176772, assigned to UC Berkeley and University of Vienna, with, *inter alia,* Jennifer Doudna and Emanuelle Charpentier as inventors.

All four companies have announced this agreement on their websites (ERS Genomics; Caribou; CRISPR; Intellia).

Yet, the agreement does not involve the major antagonist, Editas Medicine, which was founded by Broad Institute's Feng Zhang, and who has, in Europe alone, obtained 7 patents already, which all have a later priority date than the above mentioned WO2013176772.

Feng Zhang's patents are all subject to 3rd party oppositions, with between 7 and 9 opponents each. While most of the parties use strawmen for their oppositions (except CRISPR therapeutics), it can be assumed that some of the strawmen actually represent the

## EPO stays prosecution of plant/animal PbP claims

European Commission disagrees with findings of EBA decisions G 2/12 und G2/13

One should expect that patent eligibility of a plant or an animal obtained by an essentially biological process has been decided at the EPO once and for all. However, as explained in the following, it is not as simple as that.

Last year the Enlarged Board of Appeal (EBA) of EPO has decided in the combined cases G 2/12 and G 2/13 ("Tomatoes II" and "Broccoli II") that the exclusion of essentially biological processes for the production of plants in Article 53(b) EPC does not extend to the products obtained.

In the aftermath of this decision, there have apparently been discussions in the EU institutions on the topic. In December 2015, the European Parliament adopted a resolution asking the European Commission to look into the matter. The reason is the so-called Biotech Directive 98/44/EC of the EU, which entered into force on 30 July 1998. The member states of the EU had to implement this Directive into their national law by July 2000.

For the EPO, not being a EU member state, there is no need to implement or even consider the Directive. There is also no link whatsoever between the EU and EPC legal orders, as emphasized by the Advocate General of the Court of Justice of the EU, in Opinion 1/09 of 2 July 2010 at paragraph 71. Nevertheless Rule 26(5) EPC had been amended by the Administrative Council to match Article 2(2) Biotechnology Directive, a fact extensively discussed and taken into consideration by the EBA in its decision on cases G 2/12 and G 2/13.

In November 2016 the European Commission issued a Notice "on certain articles of the Biotech Directive", in which the Commission arrived at a different conclusion than the EBA: "The Commission takes the view that the EU legislator's intention when adopting Directive 98/44/EC was to exclude from patentability products (plants/animals and plant/animal parts) that are obtained by means

**+ from our firm +**

**Save the date: 10 Rhineland Biopatent Forum will take place June 8, 2016**

The 10th Rhineland Biopatent Forum will take place June 8, 2016, in our premises in Duesseldorf.

Some speakers have already confirmed, namely:

- Dr. Ranjit Ranbhor, Dy. General Manager IPR, Sun Pharmaceutical Industries Ltd, India,
- Tilman Breitenstein, Director DSM Innovation Center Intellectual Property, Delft, and
- Violeta Georgieva, LL.M., Legal and Regulatory Advisor, EuropaBio, Brussels

Further speakers will be announced soon.

We will send out invitations by February 2017. Those of you who are already interested to attend can however make a prenotation here.

above mentioned parties. The oppositions are currently pending.

Hence, the above agreement does not mean an end to the epic patent dispute related to CRISPR Cas patent – it simply suggests that Editas' competitors relying on Charpentier's and Doudna's IP close their ranks.

In the US, furthermore, a major interferece case is ongoing between UC Berkeley and Broad Institute. The whole dispute gave rise to calls for establishing a patent pool into which all parties involved throw their patents (Usdin S & Fishburn CS "Throw CRISPR into a pool" BioCentury Innovations, April 28, 2016).

Yet, we must disappoint those who thought that the above agreement would be a first step towards such pool, because the big adversary, Broad Institute, is not a member of the club.

You may also know that Charpentier's and Doudna's European regional phase application derived from WO2013176772, EP2800811, is currently under fire because of a negative examination report. See this Gazette, Issue 7/2016, for more details.

It is furthermore interesting that, in connection with opposition proceedings against one of Broad Institute's EP patents licensed to Editas, Intellia has brought an action pursuant to 28 U.S.C. § 1782 to the District Court of Massachusetts, to take discovery

Intellia's concerns relate to an affidavit submitted to the EPO on behalf of Broad Institute from a US patent attorney, which states that the latter conducted an investigation into the inventorship of the CRISPR Cas 9 technology, concluding that the inventors were correctly designated.

Intellia believes that the submission of this affidavit may have violated the attorney-client privilege and demands to conduct discovery on the issue of the identity of the inventors. The case is ongoing under case number CV 1:16-91278-FDS.

Hence the legal uncertainties regarding to whom the rights on CRISPR Cas belong is ongoing.

of essentially biological processes." In the Commission's view only with this understanding the provisions of the Directive are consistent. The Commission's reasoning is based on exactly those documents that were also considered in detail by the EBA, namely the preparatory work to the Biotech Directive.

Note that Violeta Georgieva from EuropaBio will discuss this notice at the 10th Rhineland Biopatent Forum, June 8, 2017 (see right column).

It is certainly highly desirable to have a uniform approach on what type of biotechnological invention is patentable and what is not between grant and opposition proceedings on one hand and enforcement and nullity proceedings on the other hand. However, the Commission's view is not binding on anyone, certainly not on the EPO, but also not on the EU.

The European Commission does not have any jurisdictive powers. It is only within the competence of the Court of Justice of the European Union (CJEU) to interpret EU law, and take binding decisions for the EU member states (which still wound not be binding for the EPO, which is not a body of the European Union).

Nevertheless, the Administrative Council, representing the member states has the power to again amended the rules under the EPC and thus effectively override the EBA's decision in G 2/12 and G 2/13.

For this reason, the President's announcement to stay all respective proceedings came surprising, to put matter at its lowest. It seems that the President values a non-binding opinion of a foreign executive higher than decisions of the highest jurisdictive body of the European Patent Convention.

The President's decision effectively means that presently no patent on plants or animals can be issued at the EPO that can only be obtained by an essentially biological process, since the question of patent eligibility will ultimately cause a stay of proceedings.

It is all but clear how long this stay will last. Legally, there is no path to solve this issue, because the Commission has no authority over the Boards of Appeal at the EPO, and *vice versa*.

It may happen that a plant/animal PbP case, when granted, will be attacked in national invalidation proceedings, which could bring such case to the CJEU eventually. A decision by the CJEU which is in line with the Commission's opinion, although not legally binding, could have the power to affect the EBA's position.

However, it is impossible to predict when such thing will happen, in view of the fact that national invalidation proceedings can be long-lasting, and the point that the moratorium will stop plant/animal PbP cases to get granted – and hence challenged nationally.

This entire development is very unfortunate, because it entirely disrespects the jurisdictive role of the EBA. Further, because an end of the stay can not be foreseen yet, we are now facing a *de-facto* exemption of plant/animal PbP claims from patent eligibility, which is contrary to what the EBA decided.

**Article published in Nature Biotechnology**

MH partner Dr. Ulrich Storz has just co-published an article in Nature Biotechnology on obtaining and enforcing therapeutic antibody patent claims.

See the publication link here.

**MH attorneys speak at antibody conferences in 2017**

In the first half of 2017, MH attorneys will speak at the following antibody conferences:

- 9th Annual International congress on Antibodies (29 – 31 March 2017, Beijing)
- 7th World ADC summit (20 - 22 February 2017, Berlin)
- Antibody/Targeted Drug Conjugates 2017 (22 - 24 March 2017, LUMC, Leiden)

We would be happy to see you there !

**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: Agnieszka Kaminska – Kaminski & Partners

Agnieszka Kaminska has extensive experience in prosecution and enforcement of trademark rights, management of trademark portfolios, representation of clients in opposition and invalidation proceedings. Her expertise involves providing advice and opinions on both trademark registrability and infringement, drafting and negotiating agreements, representing clients in prosecution and contentious proceedings before OHIM, Polish Patent Office and administrative courts. Represented wide range of clients including owners of famous marks such as AKAI, SHARP, ESCADA, GUESS, NOKIA, CADBURY SCHWEPPES, ZINO DAVIDOFF and many others, managed border seizures for LYCRA, XEROX, EXPRESS, CANON counterfeits. Graduated from University of London, Queen Mary and Westfield College where she acquired Masters degree in Management of Intellectual Law, completed Intellectual Property Studies at Jagiellonian University in Cracow as well as studies in Civil and Administration Law at the European School of Law and Administration, Warsaw. Also a graduate of Lodz University of Technology (Master of Science degree in Textile Technology and Engineering) and of University of Lisbon, where she studied Marketing and Management. You can contact her under agnieszka@kaminskipatent.com

MICHALSKI · HÜTTERMANN & PARTNER

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

Hafenspitze - Speditionstrasse 21 - 40221 Düsseldorf - Tel.: +49 (0)211 159 249 0 - Fax: +49 (0)211 159 249 20
Nymphenburger Strasse 4 - 80335 München - Tel.: +49 (0)89 208 027 274 - Fax: +49 (0)89 208 027 275