# The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 7/2016

**Duesseldorf/Munich**, **18 October 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, we report about a new patent troll approach in Europe, and recent developments in the CRISPR Cas patent dispute

## New patent troll in Europe

### exploits legal loophole and targets mainly pharma API patents

In our daily office routine, we came across a new pharma troll who has developed activities in Europe, exploiting a legal loophole, namely that pre-filed but post-published patent applications do only count as prior art for questions of novelty, not for questions of inventive step.

The approach is as follows:

- Originator files API application A
- 18 months later: Troll screens WO publication server in the morning hours for API applications, and finds newly published API application A
- Troll copy-pastes content of API application A, adds trivial 2nd generation features (e.g., packaging unit, combo with standard excipient, dosage regimen) and files 2nd generation application B at EPO the same day
- 2nd generation application B is novel over API application A because of novelty-conferring trivial 2nd generation features, and inventive if API is inventive
- This is because API application A does not count in determination of inventive step (2nd generation B has been filed the same day as API application A, not after)
- Troll can then ask originator for licenses if the latter wants to sell, e.g., the drug in a packaging unit)

Art 54 (2) EPC provides that the state of the art shall be held to comprise everything made available to the public (…) before the date of filing of the European patent application.

## new developments in CRISPR Cas IP dispute

Since late 2015, an international IP dispute is ongoing between Jennifer Doudna (UC Berkeley) and Emanuelle Charpentier (then Univ. Vienna) on one side and Feng Zhang of Broad Institute on the other. The dispute is focusing on nothing less than the legitimate intellectual ownership of the CRISPR Cas technology, and is fought with a poignancy unseen so far between academic institutions.

In the European Doudna/Charpentier application (EP2800811A1), the office has recently issued an objection based on lack of clarity.

In the examiner's opinion, the PAM sequence (Protospacer Adjacent Motif), which in the specification is discussed as essential, needs to be present in the claims.

The examiner thinks that omission of this feature cannot be accepted as admissible generalisation, because said sequence would be an essential feature.

Further, the examiner states that the PAM sequence feature would not be disclosed in the priority

## + from our firm +

**MH partner Dr. Ulrich Storz to organize a workshop on IP at World ADC Berlin**

MH partner Ulrich Storz organizes a World ADC masterminds workshop at the World ADC Berlin congress, 20-23 February, 2017. The workshop is titled "Intellectual Property Perspective on the Requirements for Successful ADC Drug Development".

Antibody-drug conjugates are highly complex entities that combine an antibody, a linker and a toxin. This complexity makes them demanding both technically and from a regulatory point of view, and difficult to deal with in their patent aspects. The workshop will discuss different issues of patent protection and freedom to operate with regard to this promising new class of drugs.

See the conference's website here.

**MH partners spoke at IP seminar at University of Siena**

On October 12, 2016, MH partners Dr. Andreas Hübel and Dr. Ulrich Storz

Hence, the trick is to file the troll application the same day the API application has published.

Thus, the API application has not been published before the date of filing of the API application and does, consequently, not count as prior art. In the meaning of Art 54 (2) EPC. It is still prior art in the meaning of Art 54 (3) EPC, but this excludes questions of inventive step.

We have identified said troll and detected a number of cases where he has acted like that, copying patent applications of some of the major pharma companies, and even got one granted claim related to a packaging unit of a given API.

It appears that the Troll has a good understanding of the value of individual API-related patent applications. For example, he has selected some API applications which claim polymorphs of a given compound. So far we are not aware that he has actively demanded a license.

As things stand now, the troll actually exploits a legal loophole, namely that prior art published the same day as a later application is filed does not count as prior art – and that the European Patent Offices jurisdiction on novelty is rather strict, demanding almost verbatim identity for a document to be novelty-destroying.

There are, however, a few possibilities for legal remedy one could think of, such as national nullity actions, where the national jurisdiction is less strict, or maybe vindication actions.

There is also a couple of steps applicants can take to avoid being trolled like that. One possibility is to add omnibus clauses covering trivial 2nd generation embodiments into an API application. Such approach may yet end up in a „cat-and-mouse game“ with the Troll.

Another possibility is to publish the API application one day prior to WIPO, e.g., on an internet platform with changing URL or in a publicly accessible room, and care for proper documentation. Hence, the API application would become fully applicable prior art against the troll application.

One might also consider to change Art 54 (3) EPC to say “The state of the art shall be held to comprise everything made available to the public (…) before or on the date of filing of the European patent application”

Note that rule 64 PCT has a similar regulation (“prior to the filing date of the international application”).

However, the change of these legal provisions is very unlikely at least in the short run.

Another possibility would be that the WIPO publishes the A1 or A2 document in the evening hours instead of morning hours. This would make the Troll’s life much more difficult.

Be it as it may, it appears that there is a need for action for pharma companies to keep their application, leading to a de-facto loss of the priority claim and, hence, making a Science paper from the group (Jinek et al, August 2012) prior art.

The applicant’s attempt to explain that, at the priority date, the key role of the PAM sequence was sufficiently established and formed part of the common knowledge (based on specific prior art documents, that were already on file, i.e., Sapranauskas et al, 2011, and Makarova et al, 2011) was rebutted by the examiner, who stated that these documents would relate to other technical fields, i.e., not to the field of genetic engineering.

In fact, these two documents discuss the CRISPR Cas system in bacterial self defence, and hence would address the microbiologist rather than a person interested in genetic engineering. Therefore, the examiner concluded that these documents could not be construed as forming part of the general knowledge in this technical discipline, and can hence not compensate the alleged defects of the priority application.

One may wonder how Doudna’s and Charpentier’s work could have become so influential though it was allegedly not sufficiently described. However, the examiner’s objection focuses on what’s in the patent application, not what was written in Doudna’s and Charpentier’s papers.

The applicant has replied on this office action with a 37 page submission, but without substantially amending the claims. We will wait and see what happens.

In the meantime, the number of Feng Zhang’s EP family members has risen to 25, out of which 7 are granted. Zhang has filed later than Diudna/Charpentier, but due to expedited examination in the US and EP was quicker to receive granted patents.

Against four patents of this portfolio, several oppositions have already been lodged, while three are still in the opposition period.

have spoken at an IP seminar at the University of Siena, Italy. The University was founded in 1240, and is hence said to be the 4th oldest University in the world.

The seminar was titled “Biopharmaceuticals: Challenges in Intellectual Property and Patent-ability“, and was organized by Prof. Maurizio Taddei, Prof. Annalisa Santucci, Prof. Stefano Mangani and Prof. Elena Petricci, from the department of biotechnology, chemistry and pharmacy.

Also speaking were three examiners from the EPO in Rijswijk. Enrique Molina gave an Introduction to the European Patent Office, Maria Giuseppina Covone-van Hees spoke about patent issues related to therapeutic antibodies, and Giovanni Macchia generally addressed the patentability of biotech-nological inventions.

Dr. Hübel spoke about the Role of IP in Chemistry and Biotech Startups, and Dr. Storz spoke about International IP Strategies in the Chemistry and Biotech fields.

**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.

API applications from being hijacked by said Troll, or by other (probably better funded) entities copying his approach.

Please come back to us if you need more information, or a list of API applications that we could identify to have been targeted by the Troll.

It is however to be expected that these three will not remain unopposed, while, furthermore, other applications from the family will probably be granted soon.

## EURIPTA® EEIG is getting personal... Today: Cesare Corradini - Studio Corradini

Since 1997 Cesare has been working at studio Corradini focusing on: patent filing procedures in Italy and abroad, priority searches, opposition procedures to European patents, infringement and validity opinions on patents and models, litigations and out of court disputes related to Intellectual Property, patent licensing and transfer agreements, official technical consultancy in national court cases.

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