

# The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 4/2017

**Duesseldorf/Munich, 14 June 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 will discuss a recent blow against the Unitary patent, and a new US Supreme Court decision related to the biosimilar patent dance.



## Patent Dance revised

US Supreme Court makes an end to the  
“6 months myth”

According to a recent decision by the US Supreme Court of last Monday, biosimilar companies will no longer have to wait further six months, starting from FDA approval, to get their biosimilar to the market.

In Issue 3/2015 of this Gazette, DMH associate Christoph Volpers reported about the underlying case, *Amgen Inc. vs Sandoz Inc.* which related to some specific clauses in the Biologics Price Control and Innovation Act (BPCIA).

In 2014, the FDA accepted to review Sandoz's application to market a biosimilar version of Amgen's Neupogen® (filgrastim, granulocyte colony stimulating factor).

As Sandoz refused to disclose its application and to participate in the “patent dance”, Amgen sued Sandoz in October 2014, and subsequently appealed the District Court's decision from March 19, 2015, which was in favor of Sandoz, to the CAFC.

The latter's majority concluded that it was *not* mandatory for the biosimilar applicant to disclose its aBLA and manufacturing information, and thus trigger the “patent dance”, in spite of the use of “*shall*”, because other sections of the BPCIA gave context that the disclosure was not mandatory. Section 42 U.S.C. §262 (f)(9)(C) considered the situation and consequences when the biosimilar applicant would *not* make the disclosure.

In the subsequent appeal, the Supreme Court now gave its decision. One issue at stake was whether biosimilar companies need to wait 6 months, starting from FDA approval before they can launch their biosimilar product, as Amgen pleaded –

## Unexpected Blow against the Unitary Patent

German Federal Constitutional Court asked President to not yet sign the ratification act

In the past, the Brexit and the subsequent turmoil in the UK administration was considered the biggest obstacle towards enactment of the Unitary Patent system. Germany has now shown that it can do, too.

On Monday, the Federal Constitutional Court asked President Frank-Walter Steinmeier to not yet sign the UPC ratification act already approved by the Bundestag and Bundesrat. The Court explained its request with a pending constitutional complaint against the ratification act that was already lodged on April 3, 2017.

As a consequence, the President has suspended its signature until a decision be taken by the Court.

According to the newspaper report, the underlying complaint was lodged by a private individual. According to the President's Office, the Court had justified its request on the grounds that the complaint would not be “completely hopeless” from the outset, and that it would therefore take time to decide.

Unfortunately, neither the identity of the complainer nor the complaint as such have been made public so far.

It may yet be that the grounds for the complaint lie in some specific constitutional problems.

Allegedly, the referral of the ratification act to the Bundesrat may have violated principles of the German Constitution.

In a press release, the Christian Democrat's parliamentary group had stated that, on May 25, 2016, the Federal Government presented the draft to the Bundesrat and qualified the matter as “particularly urgent”.

However, in cases where a new act to be passed transfers sovereign rights to intergovernmental bodies – as it is the case, with the Unitary patent Court taking over jurisdiction from the national courts - German law excludes such expedited pathway, to allow the Bundesrat more time to discuss and comment on such acts. It may well be that the complaint addresses this point.

Another possible claimant may be the author of [this article](#), which is, unfortunately, in German. In a nutshell, the

+ from our firm +

**MH Partner finalizing marking this year's EQE**

MH partner Dr. Torsten Exner will attend this year's marking meeting of the European bar examn (EQE) committee marking paper C at the EPO in Munich from June 19 to June 21, 2017.

At the meeting, the committee will decide on the marking results that will be suggested to the Examination Board.

**MH Partner to speak at Stem Cell conference in Halle**

MH partner Dr. Ulrich Storz will give a presentation at the Interdisciplinary Conference “Stammzellen, iPS-Zellen Genomeditierung”, June 23, 2017, at the Martin Luther University Halle.

The title of his talk is: „iPS cells and Genome editing – a patent perspective“

See the programme of the conference [here](#).

while Sandoz countered that this mandatory break would effectively create 6 months of additional exclusivity.

In their unanimous decision, the judges opined that an applicant may provide notice of commercial marketing before obtaining a license (the term meaning that the product has obtained regulatory approval)

The judges further emphasized that the word "licensed" merely reflects the fact that, on the date of the first commercial marketing, the product must be licensed in the above meaning – much to the satisfaction of Sandoz.

Sandoz has indeed taken the rocky road in patent dance proceedings, and was the first to accept this challenge. It appears that such endurance has granted them a considerable competitive advantage, by knowing how to dance the patent dance.

author complains about the point that the Unitary Patent Agreement would not be compliant with European Union law, and concludes that, because the German Government would not have any interest in blocking the road to the Unitary Patent Court System, any incentive to have the Federal Constitutional Court consider the ratification act would have to come from private persons.

This is now another blow against a quick enactment of the Unitary patent system. The recent re-elections in the UK had already delayed the enactment, slowing down the legislative process in the UK, and hence the ratification by the UK government, which the UKIPO had envisaged in late 2016.

At the 10. Rhineland Biopatent Forum, organized by our firm last week, speakers and attendees, including Mrs. Bettina Wanner of Bayer Intellectual Property GmbH, had discussed that they would expect the system to go active in mid 2018.

With the new development now public, it may well be that, once again, we all need a little bit more patience.

#### 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: Ariane Bird - IP Lodge

Ariane Bird (née Goën) is an engineer specialized in electronics, computer technology, and telecommunications. She is qualified as a European patent attorney and a French intellectual property counsel. She specialized in intellectual property at the University of Strasbourg, worked for two years as a consultant in the field of patent information based product development, worked at Bardehle Pagenberg (München) from 1988 until 1996, and founded the patent department of a telecom multinational in Paris.

Together with William Bird, she founded the successful patent firm Bird Goën & Co. in Belgium, where she remained active as a patent attorney until the acquisition of the firm by the Gevers Group. Ariane joined IPLodge in September 2015.

Ariane is a qualified European and French patent attorney. She is also a registered professional representative before OHIM, the European trademark and design and office. Her professional working languages include Dutch, French, and English.



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