The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 4/2013

Duesseldorf/Munich, **21 October 2013** 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 provide 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 actual decisions issued by European Patent authorities for the Biopatent community, and provide expert insight into what's going on behind the scenes. In this issue, we will briefly report on the envisaged re-amendment of Rule 36 EPC, as well as about the first mAb biosimilar approved in the EU.

Reconsider your strategies, please: 24 months term for divisional applications will become obsolete

In Issue 1/2013 of the Rhineland Biopatent Gazette, MH partner Dr Andreas Hübel discussed the existing problems regarding the filing of divisional applications at the EPO.

Andreas reported that, in its 73rd meeting, the *epi* Council approved sending an *epi* position paper to the EPO in which it is proposed to revert to a Rule 36 which allows filing divisional applications any time during pendency of the parent European patent application (the report of the 73rd Council Meeting is available here).

Well, Andreas' analysis was not without merits. On Oct 16, 2013, the Administrative Council of the EPO took the decision to change Rule 36, together with Rules 38 and 135. The proposed amendments can be found here.

Under new Rule 36 (1), a divisional application can again be filed as long as the parent application is pending. The notorious 24-month time limit is then obsolete.

There will however be an additional fee for 2nd or higher divisional applications, which will increase with each generation, and will become a flat fee after a certain number of divisionals.

Filing divisionals has always been a costly matter, because, in addition to the filing fees, applicants have to pay all annuity fees which accumulated in the parent application at once.

Under the new rule, the filing a series of subsequent divisionals will become increasingly expensive. in respect of earlier divisional applications will be subject to an additional fee.

Under Rule 36 as it still stands now, the number of divisionals increased (rather than decreased, as officially intended by the EPO), as applicants were often forced to file preemptive divisionals shortly before the 24 months time window closed. This policy thus produced remarkable additional income for the EPO.

First mAb biosimilar approved in the EU – but why did holders withdraw patent oppositions ?

On September 10, 2013, the European Commission issued the first approval of a biosimilar antibody. Inflectra, which was developed by Celltrion and will be marketed by Hospira under the brand name Inflectra®, is a biosimilar to J&J's infliximab (Remicade®), a chimeric IgG targeting TNFα. The respective entry of Inflectra® in the EMA database can be found here.

In 2012, Remicade® had global sales of more than 7.67 bn USD.

The approval of Inflectra® came after a respective recommendation by the Committee for Medicinal Products for Human Use (CHMP) in June 2013. The CHMP is a division at the European Medicines Agency (EMA) that is responsible for preparing opinions on questions concerning medicines for human use.

What is startling is that both Celltrion and Hospira have withdrawn their oppositions against a couple of European Patents assigned to the Kennedy Institute of Rheumatology, who has licensed them to J&J.

The opposed patents, EP1593393B1 and EP1941904B1, are true 2nd generation patents which cover the use of infliximab in combination with methotrexate, while the basic patent protection for infliximab has, in Europe, expired March 18, 2012 (EP0610201B1). A supplementary protection certificate has been obtained and a paediatric extension has successfully been claimed, thus extending the effective term of protection until February 13, 2015. Check the entry into the German patent register here.

Surprisingly, Hospira withdrew their oppositions on July 23, 2013, while

+ from our firm +

MH patent named one of Germany's leading firms in Patent law.

The German News magazine "Focus" has, in a a special November issue, named MH Patent as "one of Germany's leading law firms in Patent Law".

The study is based on an analysis of recommendations given by colleagues, as well as coverage in Germany's business press.

It is noteworthy that our firm, being founded in 2006, is the youngest patent law firm that made it into the ranking, which has 20 entries consisting of firms having mostly general lawyers, and patent attorney firms like ours.

See a commentary to the article here.

Amended Rule 36 (1) will likely enter into force on April 1, 2014, and will apply to divisional applications filed on or after that date.

The new regulation will thus also apply to pending applications which currently do no longer qualify for divisionals, because the 24 months window has expired.

This means that (i) applicants which have a pending application which is about to be granted may want to consider to delay the grant until April 2014, in order to be able again to file a divisional prior to the grant. Likewise, (ii) existing FTO opinions in which a given patent family has been found to no longer qualify for new divisionals may have to be reconsidered.

Celltrion did so on July 30, 2013. The respective entries can be found here (EP1593393B1), and here (EP1941904B1).

The combination of infliximab and methotrexate, which is subject of the two patents, is yet recommended both in the label of Remicade® and Inflectra®.

It thus appears that some kind of a deal has been made between J&J and Celltrion/Hospira, which might have resulted in a license to the latter with respect at least to the two patents.

Feedback please !

What do you think about this newsletter ? Let us have your comments here.

Archive

In the future, you may find prior issues of the Rhineland Biopatent Gazette here.

Michalski Huettermann & Partner are getting personal... Today: Markus Schatz

Markus Schatz, born in 1972, completed his studies in physics at the University of Bochum and since 2006 has worked in the field of intellectual property law. His admission as a German Patent Attorney and as European Trademark and Design Attorney was in 2010. Since 2012 Markus Schatz works for the law firm Michalski Hüttermann & Partner.

Over his years of office work Markus Schatz has acquired a broad knowledge in various fields of intellectual property law. Besides his work in general engineering its main activities are among others in the fields of medical technology, automotive engineering, manufacturing engineering and optics.

Markus Schatz speaks German and English. You can contact him under ms@mhpatent.de

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