

The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys

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Duesseldorf/Munich, 07 March 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, MH partner Dr Andreas Hübel discusses the existing problems regarding the filing of divisional applications at the EPO. MH partner Dr. Ulrich Storz reports, again, about what the Federal Supreme Court (BGH) made out of the the Brüstle decision, and discusses some surprising implications thereof.



The hassle of divisional applications – a relief in sight?!?

Filing divisional patent applications with the European Patent Office is often an issue, in particular in patent applications concerning biotechnological inventions and the issues of unity associated with these inventions. Even worse, back in 2009 Rule 36 EPC was amended to limit the time within which a voluntary divisional application could be filed to 24 month from the date or the first substantive examination report, or within 24 months from the date of the examination report, the Examination Division raised an objection as to lack of unity for the first time, provided that the parental application is still pending.

Fortunately, decision G 1/09 of the Enlarged Board of Appeals clarified that a European Patent Application is still pending after its refusal by a decision of an Examining Division until the expiry of the time limit for filing a notice of appeal. Hence, it is not necessary to file a divisional application shortly before oral proceedings in order to secure the Applicant's interest even if the application will be rejected during the oral proceedings. Nonetheless, usually it takes much longer than 2 years from the first examination report until oral proceedings or until patentable claims become visible. In such cases, wherein the time limit set forth in Rule 36 (1) EPC has been expired, the facilities provided by G 1/09 do not take effect.

The absolute cut-off of 24 months from the first examination report within which a divisional application could be filed with the EPO was subject to a lot of criticism from almost all European patent practitioners and professional

Now published BGH stem cell decision raises surprising implications

As discussed in the last issue of the Rhineland Biopatent Gazette, the Federal Supreme Court (BGH) had made its long awaited decision in the so called "Brüstle case" (case Xa ZR 58/07, related to DE Patent 197 56 864 C1) on Tuesday Dec. 29, 2012.

While until recently, a press release was only available, the full text of the decision is now online on the website of the [BGH](#).

As already discussed, the BGH took over guidelines set forth by the European Court of Justice (ECJ) referral case C-34/10 related to the patentability of human Embryonic Stem cells (hES cells). This event marks the rare coincidence that three of the highest jurisdictional bodies in Europe – the Court of Justice of the European Union (CJEU), the BGH, and the Enlarged Board of Appeal (EPA) of the European Patent Office in the oft-cited "WARF"-decision (G2/06) - have issued decisions on essentially the same subject matter.

However, the BGH decision has some remarkable aspects which we will shortly address here.

1. The BGH's interpretation of the Biopatent directive seems to be more liberal than that of the EBA. According to the latter, Rule 28(c) EPC forbids the patenting of claims directed to products which at the filing date could be prepared exclusively by a method necessarily involving the destruction of a human embryo, even if said method is not part of the claims. The EBA found it, in this context, irrelevant if after the filing date the same products could be obtained by non-destructive methods.

This finding has been interpreted by many as automatically excluding hES-cell-related patent applications from patentability if they were filed before non-destructive methods became public domain.

Oftentimes, Jan 1, 2008 is discussed as the key date, because this is the publication date of an article (Chung et al. 2008, Cell Stem Cell 7;2(2):113-7) describing the derivation of hES cells without Embryo destruction (so-called "Single Blastomere Biopsy", SBB).

Other articles issued by the same and other research groups discussing SBB (Chung et al. 2005, Nature 439,

+ from our firm +

Save the date: the 6th Rhineland Biopatent Forum will take place June 7, 2013

This year's Biopatent Forum, which takes place June 7 in our new premises in Duesseldorf, will again address actual Biopatent issues.

The agenda is not finalized yet, but topics to be addressed by external and in-house speakers will encompass (i) companion diagnostics, (ii) an overview of the pending Bowman case at the US Supreme Court, and (iii) legal frameworks concerning GM crops.

Confirmed speakers include, among others, Dr. Andreas Popp, Vice President Global IP, BASF SE.

Admittance to the Rhineland Biopatent Forum is free of charge, but, due to limited capacities the number of participants is restricted.

We are proud to welcome you in our new and bigger premises, which make an excellent venue for this forum.

We accept applications already - please write an email to st@mhpatent.de in case you know you

organizations. But it seems that all those complaints lead the EPO reconsidering the time-limits set forth in Rule 36 EPC, and appears to be willing to re-examine these time limits. In its 73rd meeting the *epi* Council approved sending an *epi* position paper to the EPO in which 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](#)).

In its reconsiderations concerning Rule 36 EPC, the EPO launched a transparent, inclusive and participative process to collect as much information as possible from all its users and other interested parties concerning the impact and effectiveness of Rule 36 EPC. To this end, the EPO opened an online consultation regarding divisional applications (Rule 36 EPC) and any interested party is invited to submit their views on current Rule 36 EPC and possible needs for further amendments [here](#).

In the open consultation, each participant is asked six rather simple questions:

1. How has the introduction of the time limits for filing divisional applications affected you? (It would be useful to learn about your background and / or your professional activity, as well as to get some insights into the extent to which your comments are the result of direct experience)
2. What is your overall assessment of current Rule 36 EPC?
3. What are, in your opinion, the most positive aspects of the current regime? Would it be possible to reinforce them? How?
4. Are there aspects of the Rule you think should be reconsidered? For example, should the time limits be extended from 24 to 48 or 60 months?
5. Do you think that further amendment of the Rule would help to optimise it? If so, could you please outline your preferred option?
6. What kind of action other than legal measures (e.g. administrative or financial ones) do you think the EPO could take that would effectively address the issue of divisionals filed merely in order to prolong pendency?

The open consultation will close on April 5th 2013.

Hence, you better hurry if you want to take the chance of helping to make a

216-219) and the so-called "Blastocyst Transfer", also known as BCT (Liao 2005, American Journal of Bioethics, 5 (6): 8-16), have, however, an even earlier publication date.

It seems, today, that the EPO examiners tend to stick to the 2008 date (see, e.g., case EP1844136). Some authors report that EPO examiners are even inclined to reject hES cell-related patent applications with an earlier filing date, even if applicants discuss therein non-destructive methods (Stolzenburg 2013, Transkript 1-2, 10), although this interpretation seems a little bit far fetched.

In contrast to this alleged policy exerted by the EPO, the BGH set forth, in his decision, that even hES cell related patent applications filed before that date can be successfully salvaged by restricting the claim in such way that destructive methods, or cells obtained therewith, are disclaimed.

Interestingly, the BGH emphasizes that it is irrelevant whether, at the filing date, such non-destructive methods existed, just like the application of Professor Brüstle, which claims a priority of Dec 19, 1997, when non-destructive methods were not yet developed.

The BGH thus applied a principle developed in the EBA decisions G 1/03 and G 2/03 (known as the "disclaimer decisions"), according to which a disclaimer which has no basis in the application as filed may be allowable under Art. 123(2), e.g., in order to disclaim subject-matter which, under Articles 52 to 57, is excluded from patentability for non-technical reasons.

2. It is another interesting feature that the BGH referred, in his decision, to scientific literature (Gavrilov et al. 2009, *Reprod Biomed Online*, 18(2):301-8; Gavrilov et al. 2011, *Stem Cells Int* 765378) in which methods for the derivation of hES-cells from non-viable embryos were disclosed. While this approach is strikingly different from SBB and BCT, to which EPO examiners often refer, it provides yet another solution to the ethical dilemma of obtaining hES cells, as non-viable embryos have lost their potential to develop into a full-grown human being. The BGH thus considers the derivation of hES cells from these embryos as not exempt from patent protection.

3. However, the more liberal position taken by the BGH compared to the EBA will unlikely provide any practical benefit to applicants. Like many other Biopatent cases, stem cell patent applications are in most cases prosecuted before the EPO, not before the German Patent and Trademark Office (GPTO).

This does not only apply to regional phase cases filed by applicants from overseas, but also to first filings made by European or even German applicants.

Professor Brüstle's application, which was prosecuted before the German Patent and Trademark Office (GPTO) – where the BGH is the highest instance in ex-parte appeal proceedings - is an example to this rule, although corresponding EP and US filings exist, among others.

Issues of patentability of hES cell-related patent applications are thus mainly dealt with by the EPO examiners and Technical Boards, which are bound to the guidelines set forth in the WARF decision, as well as by EPO president Battistelli's announcement in his Weblog shortly after issuance of the decision C-34/10, that "if the judges rule in favour of a restrictive interpretation of biotech patentability provisions, the EPO will immediately implement it".

Thus, the vast majority of hES cell patent applications is examined by the EPO, and may be challenged by third

want to attend. Further information including an agenda will follow soon.

MH Patent sponsors Biotech and Pharmaceutical Patenting Conference 2013 in Munich

MH Patent sponsored the Biotech and Pharmaceutical Patenting Conference 2013 in Munich. Further, MH attorneys gave a joint speech with US attorneys from Sterne Kessler Goldstein Fox einen focusing the examination policy of the EPC and the USPTO with respect to therapeutic antibodies.

MH patent partner Dr. Ulrich Storz further acted as chairman for day 2 of the congress.

Find the event's home page [here](#).

MH patent has moved to new and bigger premises !

We are excited to announce that we have now completed our relocation to new and bigger premises in the Duesseldorf media harbor.

Our new domicile is in the Hafenspitze Tower, which is next to the brand new Hyatt Hotel and within walking distance from our old building.

The new building offers state of the art facilities and a fantastic view on the Duesseldorf Altstadt and on River Rhein. Further, our lease provides the option to access further office space, in order to continue our growth strategy.

The postal address is "Speditionstrasse 21, 40221 Duesseldorf", while all other contact details (telephone or fax numbers and email addresses) remain unchanged. Further, normal mail sent to our old address will be forwarded to the new address automatically.

Come and visit us in our exciting new building !

better Rule 36 EPC. Don't waste the open-mindedness of the EPO in reviewing controversial provisions and taking the user's needs, critics and suggestions into account for providing regulations.

parties by way of a post grant opposition procedure.

Patent applications rejected, revoked or restricted through that pathway can not be brodedended again by the BGH, because in granted EP patents, the BGH has only jurisdiction in invalidity lawsuits concerning the German part of an EP patent. Further, Art 123 (3) EPC excludes post-grant amendments which extend the protection the patent confers

Prosecuting hES cell patent applications before the GPTO, trusting that one may take benefit of the more liberal position exhibited the BGH, makes however no sense at least today, because with respect to applications filed after the public availability of non-destructive methods, the EPO will accept similar disclaimers as those suffggested by the BGH. However, it is highly recommend in any case to add respective enabling disclosure into the patent specification.

4. The stem cell community has acknowledged the BGH decision as making the best out of the quite narrow guidance given by the CJEU, thus leaving a loophole for non-destructive methods. It remains to be clarified if this alleged loophole can keep such promise, because the derivation of totipotent stem cells from an embryo without destroying the latter could represent cloning of a human, which is illegal under German Law (§ 6 of the German Act for the Protection of embryos), and can be fined with up to 5 years prison, and is further exempt from patentability under Art 6 (2)(a) of the Biopatent directive, which is the overarching code that has been implemented into German and European patent law.

Thus, even though already considered by three of the highest jurisdictive bodies in Europe, hEs cell related patent applications leave many questions unanswered.

Together with Timo Faltus, who is at the Translational Center of Regenerative Medicine in Leipzig, we will publish an article on this decision, and its implications, within short.

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: Dr. Stephan Hettstedt

Dr. Stephan Hettstedt was born 1976 in Neustadt a. Rbge. He studied chemistry at the University of Hanover and by an Erasmus/SOKRATES-scholarship at the University of Cambridge (UK). In 2007, he obtained his doctoral degree from the University of Göttingen with a thesis on enantioselective catalysis of domino reactions. During this time, he was guest researcher at the University of Szeged (Hungary).

Stephan Hettstedt obtained his training in intellectual property law in an internationally active law firm in Cologne and at a special chamber for patent litigation at the district court of Düsseldorf. In 2012, he passed the Patent Bar Examination and was admitted to practice as European Patent Attorney at the European Patent Office (EPO) as well as a European Trademark and Design Attorney at the Office for the Harmonization in the Internal Market in Alicante (OHIM).

After an engagement at a law firm in Düsseldorf specialized in handling litigation and nullity proceedings he joined Michalski Hüttermann in 2013.

He speaks German and English, with basic knowledge of French. You may contact him under sht@mhpatent.de



M I C H A L S K I · H Ü T T E R M A N N & P A R T N E R

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