The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 4/2012

Duesseldorf/Munich, **17 December 2012** 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 report about what the Federal Supreme Court (BGH) made out of the the Brüstle decision issued by the European Court of Justice in 2011, as well as about the latest development with respect to the European Community Patent - where things happen so fast lately that one can hardly keep track of it.

Despite industry concerns, Community patent seems to have entered home stretch

Tuesday, December 11, is likely to become the European memorial day of the Unity Patent, because this day the things happened so fast, you can't keep track of it all. So we will provide a brief summary of the things going on.

For establishing unity patent protection in Europe, 25 out of the 27 member states of the EU gathered together for an enhanced cooperation as Spain and Italy have refused to agree to a reasonable compromise concerning the rules of the Unity Patent and in particular to issues concerning the language(s) of the Unity Patent.

That Tuesday, the European Parliament approved the rules for a Unity Patent – also called EU unitary patent or Community patent – in three separate votings concerning (i) the Unity Patent, (ii) the language regimen and (iii) the Unity Patent Court.

Hence, the agreement on the Unity Patent and the language regimen will apply form January 1, 2014 or from the date when they enter into force, whatever is latest.

Hence from that date on, any inventor can apply for an EU unitary patent at the European Patent Organisation (EPO). The EU unitary patent will be valid in all 25 EU member stated taking part in the enhanced cooperation.

We expect that the proceedings for the Unity Patent are very much like the proceedings for the already existing European Patent as the application for a Unity Patent has to be filed with the European Patent Office, and search and examination will also be performed by the EPO. Most likely, the already existing application form for a European Patent will be amended such that the applicant may choose between the "conventional" European Patent designating states of the EPC, or the Unity Patent. More appropriately, said choice should not be a choice of alternatives as not all member states of the EPC are EU member states too.

BGH stem cell decision leaves loophole open for non destructive hEScell generation methods

On Tuesday Dec. 29, 2012, the Federal Supreme Court (BGH) made its long awaited decision in the so called "Brüstle case" (case Xa ZR 58/07, related to DE Patent 197 56 864 C1).

The BGH thus took over guidelines set forth by the European Court of Justice (ECJ) referral case C-34/10 (see The Rhineland Biopatent Gazette, Issue 5/2011).

The decision has not yet published; however, a press release has already issued, which is available here.

According to the latter, the BGH revoked professor Brüstle's main request, but accepted an auxiliary request.

As a result, the patent was maintained for neural progenitor cells derived stem cells provided they have been obtained without destroying an embryo.

Further, the BGH deemed it sufficient to add a respective disclaimer to the patent claims, but did not require that the patentee actually defines any suitable methods which meet this criterion.

Because, in its decision, the ECJ left it to the BGH to ascertain, in the light of scientific developments, whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a 'human embryo' within the meaning of Article 6(2)(c) of Directive 98/44/EC (the "Biopatent directive"), the BGH further ruled that pluripotent stem cells including pluripotent human embryonic stem cells (hES cells) *are not* embryos, and took thus over the definition set forth in the German Act for the

+ from our firm +

Dr. Andreas Hübel presented at the AIPLA 2012 Annual Meeting in Washington

MH associate Dr. Andreas Hübel gave a presentation on the European Patent Office's position concerning the patentability of therapeutic antibodies at this year's Annual Meeting of the American Intellectual Property Law Association (AIPLA), which was scheduled for October 25 to 27 at the Marriott Wardman Park Hotel in Washington, DC.

During the joint meeting of the "IP Practice in Europe Committee" and the "Biotechnology Committee", Andreas and two other speakers from industry (Lilly, UK) and a UK law firms shared their perspectives on antibody patenting strategies in Europe

MH patent moves to new and bigger premises effective of February 2013

We are exited to announce that, effective of February 2013, our headquarter will move to new and bigger premises in the Duesseldorf media

In their press release, the European parliament explained that the EU unitary patents will be made available in English, French and German. Applications will have to be made in English German or French. However, if made in another language, they will have to be accompanied by a translation into one of these three languages, which are in fact the three official languages of the EPA.

The press release emphasized that the translation costs will be fully reimbursed for EU-based SMEs, non-profit organizations, universities and public research organisations. The parliament also ensured that renewal fees will be set at a level that takes account of the special needs of small firms, so that they can benefit. In summary, a EU unitary patent is deemed by the EC to const only 4.725,00 €. It remains to be seen if and even if - then for how long this cost estimate will hold true.

The international agreement creating a Unitary Patent Court will enter into force on January 1, 2014 or after thirteen contracting states of the EU ratify it, provided that the UK, France and Germany are among those thirteen states.

Once the agreement has been ratified, the Unitary Patent Court will be set up, having it main seat in Paris, accompanied by two divisions which will be specialized with respect to the technical fields: Munich for mechanical engineering and London for life Sciences and pharmaceutics.

The Unitary Patent Court will enable enforcing or challenging a unitary patent in a single action everywhere in the EU apart from Spain and Italy, and is thereby believed to provide a significant advantage compared to existing system, wherein a European Patent fall apart into national rights once it has been granted, and wherein the patent rights have to be enforced or challenged –apart from the opposition – in each country separately.

Whether this system will become that successful as almost everyone wants it to be looking at numerous official press releases appears to be uncertain to me. I wonder whether an applicant having interest to gain patent protection in a few European countries only would indeed use the Unity Patent, or whether that applicant keeps using the existing European patent.

In addition, the Unity Patent poses the risk of loosing patent rights throughout Europe in a single law suit. Are the benefits of the Unity Patent worth this risk. Wouldn't it be less risky for a - let's say pharmaceutical company – having its competitors to challenge the patent rights in a plurality of European countries, and not loosing patent protection for one of its drugs throughout the entire EU when they are going to lose the law suit ? At least, the Unity Patent puts new aspects for strategic considerations onto the table.

The Council has authorized the enhanced cooperation between those 25 EU member states by a decision adopted in 2011. However, Spain and Italy requested the Court of Justice to annul the Council's decision, because (i) the Council was alleged not to be competent to adopt the decision because creating a unitary patent falls within the EU's exclusive competence, (ii) the Council misused its power, (iii) the Council failed to respect the judicial system of the EU, and (iv) that the enhanced cooperation is detrimental to the internal market, the economy, the social cohesion, the territorial

Protection of Embryos, which, under § 8, requires totipotency (which hES cells aren't).

First reactions from the stem cell community interpret this decision as leaving a loophole for non-destructive methods, like Single Blastomere Biopsy (SBB) or Blastocyst Extraction, which have been developed in the context of preimplantation genetic diagnostics (PGD).

In the former, a blastomere is separated from the embryo at the six to eight cell stage (i.e. about 72 hrs after fertilization). While the remaining embryo survives this treatment and can be returned to the incubator, hES cells can be derived from the thus separated blastomeres.

In the latter, a cell is separated from the blastocyst, which forms at day 5 after fertilization and has 70-100 cells comprised in the outer trophoblast (which later forms the placenta) and the inner embyroblast (which later forms the fetus). While for PGD, cells from the trophoblast are preferably taken (because this is the safest approach with least effect on embryo survival), it seems that hES cells can only be derived from embryoblast cells - which comes at lower survival rates for the embryo.

While the BGH decision now brings these two approaches back into the spotlight, it seems that the EPO has already accepted them as a feasible bypass solution to the ECJ ban.

Remember that, although ECJ jurisdiction has no legal bearing for the granting practice of the EPO, the latter's president Benoît Battistelli announced in his Weblog shortly after issuance of the decision C-34/10, namely on November 3, 2011, that "if the judges rule in favour of a restrictive interpretation of biotech patentability provisions, the EPO will immediately implement it".

One example of EPO's recent examination policy is pending case EP1844136, which has the following independent claim on file:

"A method for maintaining SC in an undifferentiated state, the method comprising incubating said cells with a culture system comprising feeder cells expanded from human umbilical cord cells, and wherein said culture system is free of antibacterial agents and anti-fungal agents"

Interestingly, the recent office action under Art 94 (9) EPC, sets forth that the first approaches of SBB required co-culture with "conventionally" obtained hEScell – a fact which would render such approaches unpatentable. Only later approaches demonstrated SBB without the use of hEScells. The examiner cites Chung et al., Cell Stem

harbor.

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

The mail address will be "Speditionstrasse 21, 40221 Duesseldorf". See an actual picture of the complex here.

Although the decision to leave the iconic Gehry Building, which was our domicile for the last 6 years and helped us tremendously to develop our brand, did not come easy to us, we realized that we need more space and state of the art infra-structure to further pur-sue our growth strategy. We believe that we have now found a decent, yet probably slighly less spectacular, replacement for our existing domicle.

This relocation does not affect our telephone or fax numbers nor our email adresses. Further, normal mail sent to our old adress will be for-warded to the new adress automatically.

However, we urge you to update your respective records.

This relocation does not affect our Munich subsid-iary either, which stays where ist is, at Nymphenburger Strasse 4, 80335 München

Third volume of SpringerBriefs in Bio-tech Patents issued

The current volume of this book series which is edieted by MH partner Ulrich Storz is titled "Limits of patentability", and features articles of MH partners Andreas Hübel, Ulrich Storz and Aloys Hüttermann, relat-ed to (i) current issues in the patentability of plants produced by essentially biological processes including the controversy between farmer's privi-lege and patent exhaus-tion with respect to seeds in the US, (ii) the pat-entability of human em-bryonic stem cells in

cohesion, and that it builds barriers to trade between Member States, and discriminates trade between the Member States.

The Court of Justice joined the two cases Kingdom of Spain (C-274/11) vs. Council of the European Union and Italian Republic (C-295/11) vs. Council of the European Union. The memorable Tuesday, December 11, 2012, the Advocate General's Opinion was released.

The Advocate General Yves Bot proposes that the Court of Justice dismisses the actions brought forward by Spain and Italy against the Council's decision of authorizing the enhanced cooperation concerning the Unity Patent.

As this is the first time that the Court of Justice has been called on the legality of a decision authorizing enhanced cooperation, the Court may carry out only a limited review of legislative measures adopted by the council by virtue of the principle of the separation of powers.

The Member States may establish an enhanced cooperation solely in matters that are within the EU's non-exclusive competences. The Advocate General considers that the Treaty on the Functioning of the European Union (TFEU) establishes an exhaustive list of the areas in which the Union has exclusive competence. Although the rights deriving from a patent affect trade and competitive relationships within the internal market, this is insufficient making it a right relating to the competition rules. Thus, the TFEU provides an appropriate legal basis for the creation of intellectual property rights within the framework of the establishment and functioning of the internal market, an area which comes within the competence shared between the EU and the Member States. Hence, the enhanced cooperation is not within the EU's exclusive competencies, and the Council was therefore competent to adopt the decision of enhanced cooperation.

The Advocate General observes that an enhanced cooperation must aim to further the objectives of the Union, protect its interests and reinforce its integration process. The establishment of an enhanced cooperation mechanism for the unitary patent was inspired by the growing heterogeneity of the Member States and their respective interests or specific needs. Thus, by first noting the absence of unanimity with respect to the language arrangements for the unitary patent and then deciding to deal with that deadlock by establishing enhanced cooperation, the Council merely made use of a tool available to it under the Treaties.

The Advocate General further observes that in the two actions for annulment the Court is called on to determine whether the conditions for the proper implementation of enhanced cooperation have been fulfilled. He notes that the creation of a specific judicial system for unitary patents is not among the conditions required by the Treaties for the implementation of enhanced cooperation. The Council's authorisation for the setting up the enhanced cooperation only provides the premises for the adoption of other legislative acts which will then have to give specific effect to that cooperation. Thus, the judicial system of the EU is respected.

Advocate General then points out that the decision authorising the setting up of enhanced cooperation defines the procedural framework within which other acts will subsequently be adopted. The Council did

Cell (2008), 1 – 5.

Accordingly, the examiner concludes that, in case the applicant does not exclude the use of hEScells, the application will be rejected – which in turn means that if he excludes the use of hEScells the application may at least not violate Art 53 (c) and Rule 28 (a) EPC – which however is less than the loophole the BGH now seems to suggest.

With respect to the BGH decision, however, some crucial questions remain open:

1. What do you have to do to meet the criterion that the embryo is not destroyed by such process? Is this a practical requirement , i.e., does it mean that, after the extraction of the blastomers or embryoblast cells, the surviving embryo has to be put back into the freezer or even carried to term by a host mother, or is it sufficient that the derivation process as such does not invariably and always result in the destruction of the embryo, regardless of what happens with him afterwards ? (In the former case it is hard to imagine that parents would agree with such treatment only to allow researches to obtain hES cells from their embryo)

2. The ECJ ruled that the exclusion from patentability also covers the use of human embryos for purposes of scientific research. It is thus not unlikely that the use of a blastomere or blastocyst to obtain hES cells would still be considered such insutrial use of an embryo (even if the latter survives) and thus exempt from patent protection by the ECJ.

3. According to current knowledge, it appears that blastomere cells are still totipotent (and thus embryos according to German law), while embryoblast cells have lost their totipotency and do thus not qualify as embryos.

Deriving stem cells by SBB even without destroying the entire embryo would thus still qualify as use of an embryo for commercial purposes, which is excempt from patentabilty under Art 6 (c) of EU directive 98/44/EC.

4. However, the derivation of totipotent stem cells by SBB without destroying the embryo could represent cloning of a human, which is illegal under German Law.

§ 6 of the German Act for the Protection of embryos sets forth that even trying to artificially create a human embryo which has the same genetic information as another embryo can be fined with up to 5 years prison (while § 2 defines that steps to promote extracorporal development of a human embryo can be fined with up to 3 years prison, unless they are intend to induce pregnancy in a woman)

Europe and the US, also considering alternative technologies with respect to their practicability and patentability, and (iii) the patentability of genes and nucleic acids, especially the issue of patenting of encoding genes and nucleic acids.

You can preview and buy or download the volume, or single chapters, here.

Ulrich Storz has given a speech at the 23rd Antibody Engineering conference in San Diego

MH partner Ulrich Storz has contributed to the 23rd Antibody Engineering conference which took place Dec 2 – 6 at Hilton San Diego Bayfront Hotel.

Together with other speakers from major US law firms (Fish and Richardson, Sterne, Kessler, Goldstein & Fox, Jones Day and Duane Morris) Ulrich contributed to a session called "Intellectual Property Issues that Impact Antibody Engineering".

His talk addressed "European IP Perspectives in the Therapeutic Antibody Space".

If you want to have copies of Ulrich's slides please don't hesitate to ask here.

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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.

indeed refer in the decision to what the language arrangements for the unitary patent might be but that question is not a condition that determines the validity of the decision authorising enhanced cooperation. That question would have to be addressed at a later stage and form the subject-matter of a separate act to be adopted unanimously by the participating Member States. The Advocate General is of the view that a mechanism intended to create a unitary patent would have the effect of conferring uniform protection on the territory of several Member States and of contributing to the harmonious development of the Union as a whole by reducing the existing disparities between those Member States. Moreover, all economic operators could enjoy the benefit of such a patent, since the place of origin of the applicant for a unitary patent is irrelevant for the purpose of obtaining it.

Finally, with regard to the alleged infringement of the obligation to respect the competences, rights and obligations of those Member States which do not participate in the enhanced cooperation the Advocate General considers that the question of the language arrangements is not a condition that determines the validity of the decision authorising enhanced cooperation.

The Advocate General therefore proposes that the Court should reject all the pleas put forward by Spain and Italy and, consequently, dismiss both actions". Owing to our experience, that the Court usually agrees with the Advocate General's opinion, it is very likely that the Court will indeed reject the pleas. However, no decision is made yet.

This could lead to a paradox situation in which, to obtain a patent, the claimed method must yield that the embryo survives, but, in order to escape imprisonment, a co-development of stem cells and remaining embryo should be avoided. This would mean that (i) a legal method (i.e., the Brüstle method which used hES cells legally obtained under the deadline solution) which had went through an Ethics Comittee and enjoyed publich funding can not give rise to a patent because of violation of ordre public of the practised method, while (ii) an illegal cloning method in which the embryo is not destroyed, practising of which can result in imprisonment, actually could give rise to a patent.

Only as an aside, the fact that any active or passive destruction of an embryo after cell extraction is illegal anyway renders the above described approach to avoid illegal cloning obsolete.

5. In contrast thereto, extracting stem cells form an embryoblast by Blastocyst Extraction would probably not qualify as illegal cloning, as the extracted cells are no longer totipotent.

Particularly the three latter issues, which for god's sake are not related to patent law, require, obviously, diligent legal clarification.

Michalski Huettermann & Partner are getting personal... Today: Dr. Caroline Schall

Dr. Caroline A. Schall was born 1977 in Schwandorf/Bavaria. She studied Chemistry and Biology at the University of Regensburg as well at the University of Aberdeen, UK. In 2003 she graduated with a Diploma in Chemistry and started afterwards her PhD thesis in the Institute for Organic Chemistry at the University of Regensburg and at the University of Kansas, USA (Bioinorganic Chemistry) in the field of "Chiral Oxazoline and Bis(oxazoline) Ligands – New biomimetic Models for Iron containing nonheme Proteins and their Application in Catalysis".

In 2007 she started her Postdoc career at the Columbia University Medical Center New York, USA in a new challenging research area (Institute of Genetics and Developmental Biology). Since 2010 she worked as a lab manager in the Institute of Experimental Medicine at the University Hospital of Cologne and in 2011 again as a Postdoc in the Institute for Genetics at the Heinrich-Heine University of Düsseldorf. Since September 2012 she has started her training as a patent attorney in the field of intellectual property at Michalski Hüttermann & Partner.

Dr. Caroline A. Schall speaks German and English.

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