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The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 5/2011

Duesseldorf/Munich, **20 October 2011** 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 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 associate Dr. Andreas Hübel reports on the outcome the so called Brüstle case at the European Court of Justice. Further, MH partner Dr. Ulrich Storz reports on recent developments in the Cabilly patent legacy

ECJ decided on patentability of embryonic stem cells

The day before yesterday the European Court of Justice (ECJ) published its decision in Case C-34/10 with respect to the patentability of embryonic stem cells. The ECJ ruled that inventions are excluded from patentability where human embryos have to be destroyed, regardless of whether the destruction of a human embryo is part of the claim or not. Find the decision here.

In Issue 2/2011 of The Rhineland Biopatent Gazette we already reported about the opinion of the Advocate General, who recommended to answer the questions referred to the ECJ by the BGH with respect to Article 6(2)(c) of Directive 98/44/EC in that

- the concept of a human embryo applies from the fertilisation stage to the initial totipotent cells and to the entire ensuing process of the development and formation of the human body, which includes the blastocyst;
- unfertilised ova into which a cell nucleus from a mature human cell has been transplanted or whose division and further development have been stimulated by parthenogenesis are also included in the concept of a human embryo in so far as the use of such techniques would result in totipotent cells being obtained;
- pluripotent embryonic stem cells are not included in that concept because they do not in themselves have the capacity to develop into a human being;
- an invention must be excluded from patentability where the application of the technical process for which the patent is filed necessitates the prior destruction of human embryos or their use as base material, even if the description of that process does not contain any reference to the use of human embryos; and
- the exception to the non-patentability of uses of human embryos for industrial or commercial purposes concerns only inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it.

In his decision, the ECJ essentially agreed to the opinion of the Advocate General and ruled that any human ovum after fertilisation, an non-fertilised human ovum into which a cell nucleus

Cabilly III patent issued, immediately under attack

Much has been written about the history of the Cabilly patents, which cover key steps of therapeutic antibody production. After a long-winded prosecution involving interference proceedings and re-examination, US6331415 a.k.a. Cabilly II, the priority of which dates back to 1983, was eventually confirmed by a USPTO appeal decision in 2009. Because the patent was granted in 2001, its lifetime will expire in 2018.

Because Cabilly II protects a crucial step in the state-of-the-art production of therapeutic antibodies, major antibody drugmakers have acquired licenses, like Abbott, Johnson & Johnson, ImClone or MedImmune.

At the same time, Cabilly II has been subject to a number of lawsuits between Genentech and, among others, Medimmune, HGS, and GSK.

According to Genentech's Form 10K report filed with the SEC in 2008, annual royalties Genentech took in for Cabilly II were quantified as 256 million US$ in 2007.

On April 12 2011 the USPTO issued the youngest member of the "Cabilly" patent family, US7923221, which was quickly baptized "Cabilly III" by the antibody community. Due to a terminal disclaimer its lifetime is set to expire at the same day as Cabilly II.

The scopes of both patents overlap to a great extent. The following table shows the claim material to each patent.

Cabilly II	Cabilly III

+ from our firm +

MH patent attorneys host reception at Bio-Europe 2011

The BioEurope 2011 Partnering conference will take place from Oct 31 – Nov 2, 2011, in Duesseldorf, Germany. MH patent attorneys take this occasion to invite you, or your colleagues, to our firm's reception for Cremant d'Alsace and Amuse Gueules.

Please meet us on Tuesday, Nov 1, 6.45 pm in Duesseldorf's most exciting office building, the "New Zollhof" in the Duesseldorf Media Harbor. You may already know Frank O. Gehry's masterpiece, in which our firm's office is accommodated, from the headline of the BioEurope 2011 home page.

Transportation will be provided at 6.15 pm at the main entrance of the BIO-Europe 2011 venue, the CCD Congress Center Duesseldorf.

Please RSVP by email to wu@mhpatent.de, or call +49 211 159 249 0. We are looking forward to seeing you !

from a mature human cell has been transplanted, and any non-fertilised human ovum whose division and further development have been stimulated by the parthenogenesis constitute a human embryo and is thus excluded from patentability. An invention is also excluded from being patentable, if the technical teaching requires prior destruction of human embryos or their use as base material, whatever the stage at which that destruction occurs, and even if said destruction is not part of the claimed technical teaching and does not refer to the use of human embryos.

Moreover, the ECJ ruled that the exclusion from patentability concerning the use of human embryos for industrial or commercial purposes as set out in Article 6(2) (c) of Directive 98/44/EC also covers the use of human embryos for purposes of scientific research, because the grant of a patent already implies, in principle, its industrial or commercial application.

Still, patentability of inventions using human embryos are patentable for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it. However, what "use of a human embryo for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it" mean remains to be clarified in our opinion.

With respect to pluripotent stem cells which are not covered by the definition of "human embryo" as given by the ECJ, the court ruled that it is for the referring court 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.

As a result of this Decision, it is to be expected that the BGH will confirm the Germen Federal Court of Justice's declaration of the invalidity of claims 1, 12, and 16 of German Patent No. 197 56 864.
It is to be noticed that the decision ECJ with respect to the meaning of "human embryo" and patentable inventions in connection with human embryos is consistent with Decision G 2/06 of the Enlarged Board of Appeals of the European Patent Office.

Moreover, the Decision of the ECJ will have a tremendous impact on the research and development of stem cell therapy and pharmaceutical assays utilizing stem cells. At least, substantial non-public funding of research in the medicinal field can no longer be expected. Hence, the idea of patents as means for promoting technical progress has been thrown into reverse for one of the most promising therapeutic areas.

(1) A process for producing an immunoglobulin molecule or an immunologically functional immunoglobulin fragment comprising at least the variable domains of the immunoglobulin heavy and light chains, in a single host cell, comprising the steps of: (i) transforming said single host cell with a first DNA sequence encoding at least the variable domain of the immunoglobulin heavy chain and a second DNA sequence encoding at least the variable domain of the immunoglobulin light chain, and (ii) independently expressing said first DNA sequence and said second DNA sequence so that said immunoglobulin heavy and light chains are produced as separate molecules in said transformed single host cell.	(38) A method for making an antibody or antibody fragment capable of specifically binding a desired antigen, wherein the antibody or antibody fragment comprises (a) an antibody heavy chain or fragment thereof comprising a variable region sequence and a human constant region sequence and (b) an antibody light chain or fragment thereof comprising a variable region sequence and a human constant region sequence, the method comprising coexpressing the heavy chain or fragment thereof and the light chain or fragment thereof in a recombinant host cell.

While Cabilly II covers the production of practically all therapeutic antibodies on the market, Cabilly III does not extend to the production of antibodies devoid of a constant region or a light chain, for example. This excludes, for example, scFv formats. We will discuss these implications in a journal article which will issue soon.

On the day Cabilly III was issued, HGS filed a lawsuit at the Delaware District Court, asking for declaratory judgment of invalidity, unenforceability and non-infringement by Benlysta, an antibody which targets B-lymphocyte stimulator and is used for treating Lupus Erythematosus. Find the text of the complaint here.

While the US Patents benefit from their early priority date which dates prior to June 8, 1995 (thus resulting in a lifetime of 17 years from grant), the corresponding European patent EP0125023 has already expired in 2004, i.e., 21 years after the priority date.

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. Lars Müller

Lars Müller was born in 1975 in Cologne. He graduated in Chemistry at the University of Aachen in 2002. During his study period, he carried out research projects at the University of York as well as at DSM Research in Geleen. He received his PhD in 2005 at the University of Paderborn in the field of homogeneous catalysis. He is co-author of several scientific publications in the field of chemistry.

His work in Intellectual Property started in 2005 in a patent law firm in Düsseldorf. During this time, he additionally carried out

a traineeship at a court for patent cases of the Düsseldorf District Court. He passed the Patent Bar Examination in 2009, and has been registered in the list of representatives before the European Patent Office in 2011.

He speaks German and English. You can contact him under lm@mhpatent.de

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The information provided herein reflect the personal views and considerations of the authors. They do not represent legal counsel and should not be attributed to Michalski · Hüttermann & Partner Patent Attorneys or to any of its clients.

Please be invited to the MH Patent BioEurope 2011 reception

Join is for good talks, Cremant d'Alsace and Amuse Gueules

in Frank O. Gehry's Masterpiece

Duesseldorf, Tuesday 1, 2011, 6.45 pm

Neuer Zollhof 2, 40221 Duesseldorf

Please RSVP at wu@mhpatent.de or call +49 211 159 249 0

Transportation will be provided

MICHALSKI · HÜTTERMANN & PARTNER