

The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys

Issue 3/2011

Duesseldorf/Munich, 31 May 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 partner Dr. Ulrich Storz reports on the first iPS-cell-related patent which is about to be granted by the European Patent Office. Yet the head article of this issue has been written by Scott D. Marty, J.D., Ph.D., who is a Patent Attorney with Ballard Spahr LLP, and who reports about the recent outcome of the *en banc* ruling by the Federal Circuit in the *Therasense* case, which addresses aspects of inequitable conduct.



Federal Circuit applies "But-For Materiality Test" in *Therasense*

Under U.S. law, the penalty for inequitable conduct is severe, as an entire patent is rendered unenforceable. Therefore it is important that courts maintain a high standard and have clear guidance on what actions rise to the level of inequitable conduct. The Court of Appeals for the Federal Circuit, knowing the importance of maintaining a high standard, recently delivered its *en banc* opinion on inequitable conduct (*Therasense Inc. v. Becton Dickinson and Co.*, Fed. Cir. *en banc*, No. 2008-1511, 5/25/2011.). In a split decision, the Federal Circuit stated:

"[t]his court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public."

Specifically, the Federal Circuit issued clear standards for establishing the inequitable conduct defense. Specifically, the court held that an omitted reference is a material reference only if "but for" its exclusion the claim or patent would not have issued. In addition, there must be clear and convincing evidence of a specific intent to deceive by the applicant. The court further held that a court cannot use a "sliding scale" to find inequitable conduct, *i.e.*, it cannot find sufficient a weak showing of intent based on a strong showing of materiality; both materiality and intent to deceive must be supported by clear and convincing evidence. And finally, the court held that courts should apply equity to ensure that the remedy is not imposed for misconduct that was "immaterial to the issuance of the patent." The court stated:

"To prevail on the defense of inequitable conduct, the accused infringer must prove that the applicant misrepresented or

First patent related to iPS cells to be granted by EPO, iPierian and Univ Kyoto sign deal

In the last issue of the Rhineland Biopatent Gazette, MH Associate Dr. Andreas Hübel reported about the recently issued opinion of the European Court of Justice's (ECJ) Advocate General in the Brüstle stem cell case.

Under said opinion (i) stem cells obtained by somatic nuclear cell transfer or parthenogenesis and (ii) human embryonic stem cells (hES cells) shall be excluded from patent protection either because they qualify as embryos (as is the case for the former two, due to their totipotency) or as their production involves the use of a human embryo (as is the case for the latter, because a blastocyst is used to obtain hES cells). Both embodiments are banned from patent protection for moral issues under the EU Biopatent Directive 98/44.

According to our analysis, induced pluripotent stem cells (iPS cells) are not encompassed by this proposed ban.

Interestingly, on May 16, 2011, the European Patent Office (EPO) issued a communication of intention to grant a patent with respect to European patent application 06834636.0, having the publication number [EP1970446](#). The inventor is Shinya Yamanaka of Kyoto university, who pioneered iPS methods. The claims as accepted for grant relate to a nuclear reprogramming factor which comprises an Oct gene/gene product, a Klf gene/gene product, plus either a Myc gene/gene product or a cytokine.

The acceptance came quite surprisingly, because initially, the EPO had objected the said claim under Arts 83 and 84 EPC (lack of clarity/lack of enablement), due to a prior publication by the inventor according to which the induction process could be accomplished only by treatment of cells with the four factors Oct, Myc, Klf and Sox.

However, the applicant has successfully put aside these concerns. Furthermore, moral issues have not been discussed during prosecution, which suggests that, after the Enlarged Board of Appeal decision

+ from our firm +

A number of journal articles by MH authors published

MH associate **Dr. Andreas Hübel** has published an article on the Essentials which discusses the recent EPO Decisions G2/07 (Broccoli Case) and G1/08 (Tomato Case). The Article has been published in European Intellectual Property Review 33 (5), 2011, 328. Please ask for a reprint [here](#).

MH partner **Dr. Aloys Huettermann** has authored an article which is the first of a series related to the protection of innovations in the pharma industry. The series is being published in "pharmind". Dr. Huettermann's contribution appeared in pharmind 4/2011, 714, and has the title "Was ist im Bereich der Pharmaindustrie schützbar?" Please ask for a reprint [here](#).

Just recently, the second article of this series has been published in "pharmind" 5/2011. The article is written by MH associate **Dr. Andreas Hübel** and

omitted material information with the specific intent to deceive the PTO. The accused infringer must prove both elements—intent and materiality—by clear and convincing evidence. If the accused infringer meets its burden, then the district court must weigh the equities to determine whether the applicant's conduct before the PTO warrants rendering the entire patent unenforceable."

From a patent prosecution standpoint, the Federal Circuit did not reshape the duty of disclosure. However, it is likely that many patent prosecution firms will be reassessing their information disclosure statement ("IDS") policies. The Federal Circuit did address the administrative burdens associated with IDS filings, but did not go so far as to provide new requirements.

Perhaps the best news is that on May 30, 2011, the United States Patent and Trademark Office announced that it is carefully studying the important *en banc* decision to assess how it may impact agency practices and procedures. The agency also announced that it expects to soon issue guidance to applicants related to the prior art and information they must disclose to the Office in view of *Therasense*. It however remains to be seen whether this decision will solve the problems associated with practitioners "disclosing too much prior art of marginal relevance" or lead to any reduction in the number of inequitable conduct claims that are made. In addition to the PTO's public announcement, the United States Congress continues to debate possible legislative reforms aimed at inequitable conduct; however, the current outlook on patent reform remains uncertain.

In case of questions, please contact Scott Marty, J.D., Ph.D. [here](#).

G2/06 ("WARF", according to which hES cells are banned from patentability as long as their preparation involves the use of a human embryo), the EPO seems to accept that iPS cells do not fall under this exclusion – similar as implicitly suggested by the Advocate General of the ECJ.

Interestingly, the UK patent office (UKIPO), which is also bound to the provisions of the Biopatent Directive in case of patents the priority date of which ranks later than the implementation of the Biopatent Directive into UK law) has granted the first iPS-related patent outside of Japan already about one year ago (Jan 12, 2010) to iPierian. The inventor is Kobe-based researcher Kazuhiro Sakurada. The patent [GB2450603](#), which has a younger priority date than the Yamanaka patent, relates to an iPS method which involves the use of Klf-4, Oct-4 and Sox-2, but excludes use of c-Myc. The European counterpart of this patent, [EP2164952](#), is still pending. Provided the latter is granted with a similar scope, two conflicting patents would exist in Europe, having the following scope:

Yamanaka (Kyoto)	Sakurada (Kobe)
Oct and Klf and Myc and/or cyto-kine), Sox optional	Oct and Klf and Sox but not Myc

Groups working under the Yamanaka protocol would probably infringe the prospective Sakurada patent in case they use Oct, Klf and Sox, but not Myc (e.g., a cytokine instead).

Groups working under the Sakurada protocol would probably infringe the Yamanaka patent, at least as long as they use a cytokine instead of Myc.

In case Myc was left away, and no cytokine was used, the Yamanaka patent would probably not be infringed, but the prospective Sakurada patent, while in case all four factors (Oct and Klf and Sox and Myc) were used, the Yamanaka patent would probably be infringed.

Companies working with iPS cells should be aware of this confusing situation and ask for expert counsel before they enter the marketplace with their products.

In Feb 2011, iPierian announced that they have entered into a series of IP agreements with Kyoto University, home of iPS pioneer Shinya Yamanaka, under which iPierian assigns its iPS portfolio to Kyoto University, while the latter grants non-exclusive worldwide rights to its iPS portfolio for use in drug discovery and development. As part of the agreement, Professor Shinya Yamanaka has joined iPierian's Scientific Advisory Board.

This deal illustrates the complicated relationship between both patent portfolios. Further, the deal demonstrates that, at least today, the major goal of iPS technologies is drug development (rather than the oft-cited regenerative medicine).

has the title: "Patenterteilungsverfahren und internationale Anmeldestrategien". Please ask for a reprint [here](#).

MH partner **Dr. Ulrich Storz** has published an article on future antibody inventions in the journal "mAbs". The article titled "Intellectual property protection: Strategies for antibody inventions" appeared in mAbs 3 (3), 2011, 310. Please ask for a reprint [here](#).

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: Julia Wind-Falk

Dipl.-Ing. (FH) Julia Wind-Falk, born 1971, has a degree in biotechnology engineering. She worked 3 years at official authorities in the field of permission and monitoring of genetic tasks, laboratories and plants. In addition, she was consultant at the

University of Cologne, where she actively contributed the training of scientists regarding the Act on Genetic Engineering.

After another year with one of the largest German Biotech companies, where she supported the formation of a subsidiary, she started 2001 her expertise in Intellectual Property at a patent firm in Essen. In 2003 she changed to a Biotech Startup company in Cologne, where she developed the entire IP portfolio. In addition, FTO as well as the support of Due Diligence Reports during financing rounds belonged to her tasks.

Julia Wind-Falk joined Michalski & Hüttermann Patentanwälte in Düsseldorf in 2008. Her main practise areas include Patent Prosecution and FTO Reports as well as patent-strategic consultation, especially in the areas of biochemical engineering, biophysics, biochemistry and microbiology.

Julia speaks German and English. You can contact her under jwf@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

Imprint: Michalski · Hüttermann & Partner Patent Attorneys, c/o: Dr. Ulrich Storz
Neuer Zollhof 2 - 40221 Düsseldorf - Tel.: +49 (0)211 159 249 0 - Fax: +49 (0)211 159 249 20 – email: st@mhpatent.de

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.