The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 3/2012

Duesseldorf/Munich, **31 August 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 on a recent SPC decision by the European Court of Justice (ECJ), which gives rise to hopes to change for the better, and we will highlight an aspect of the highly contested human embryonic stem cells which has never been an issue in Europe (where patenting is the major public topic), namely the discussion about funding of embryonic stem cell research in the USA.

Vet drug market authorisation does not count for human drug SPCs, ECJ rules

The development and authorisation of pharmaceutic drugs is a costly and time consuming matter. Because drug patent applications have to be filed at a very early stage (which sometimes predates the market entry by more than 15 years) it happens frequently that the patentee has only a very limited amount of time in which the eventually authorised drug is on the market under patent protection.

To compensate patentees in the pharmaceutic discipline for this disadvantage, which other technical disciplines (with the exception of herbicides) do not have, or at least not in such extent, a legal framework has been created in the European Union (EU) under which compound protection for an approved drug can be extended under Art. 63(2) of the European Patent Convention (EPC) and Regulation (EC) 469/2009 by means of a Supplementary Protection Certificate (SPC).

Under Art 3 of Regulation (EC) 469/2009, an SPC shall be granted if (a) the product is protected by a basic patent in force (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, (c) the product has not already been the subject of a certificate, and (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

The regulation (EC) 469/2009 leaves many issues unsolved. For this reason, the European Court of Justice (ECJ) dealt with quite a few SPC-related cases in the past.

One case our lawfirm was involved in is case C-130/11 (*Neurim Pharmaceuticals Ltd v Comptroller General of Patents)*, in which the ECJ issued a decision recently, and which dealt with the question whether the Market Authorization (MA) on which the request was based was the *first* one in the meaning of Art 3 (d) of Regulation (EC) 469/2009

Israel-based company Neurim has patented,

US appeals court finds funding for hES cell research legal

US case law saw recent decisions related to the patentabiliy of biological subject matter, and as such, of human emybronic stem cells (hES cells). An article adressing these developments is about to be published in Vol 3 of the book series "SpringerBriefs in Biotech Patents" (see also The Rhineland Biopatent Gazette, Issue 5/2011).

Essentially, human embryonic stem cells are nowadays considered patent eligible subject matter in the United States, even though according to the revision of the US Patent system in 2011 under the Leahy Smith Act, 35 U.S.C §101 will be amended by adding a passage according to which "no patent may issue on a claim directed to or encompassing a human organism." In an internal memorandum of September 20, 2011, the US Patent and Trademark Office (USPTO) informed it's employees that this new clause merely codifies existing USPTO policy that human organism are not patent-eligible subject matter. According to common understanding, this does not encompass human embryonic stem cells.

However, patent disputes are only one side of the medal in the USA. Another battle was, and still is, fought on the side of public financing.

According to the "Dickey Wicker amendment", which was an appropriation bill rider attached to a bill passed by the United States Congress during the Clinton administration, the Department of Health and Human Services (HHS) was banned from using public funds for the creation of human embryos for research purposes, or for research in which human embryos were

+ from our firm +

Dr. Andreas Hübel contributes to this year's AIPLA Annual Meeting in Washington

MH associate Dr. Andreas Hübel will contribute at the AIPLA Annual Meeting, which is scheduled for October 25 to 27 at the Marriott Wardman Park Hotel in Washington, DC

Together with other speakers from industry (Lilly, UK) and law firms (D Young & Co, UK), Andreas will share his perspective on antibody patenting strategies in Europe when the IP Practice in Europe Committee and the Biotechnology Committee are jointly meeting to discuss approaches to and issues surrounding Antibody Patenting from a US and European perspective.

Find the event's home page here.

Dr Ulrich Storz will give a speech at the 23rd Antibody Engineering conference in San Diego

MH partner Dr. Ulrich Storz will contribute at the 23rd Antibody Engineering conference

developed, and eventually authorized Melatonin as a treatment for primary insomnia in humans, sold under the brand name Circadin®.

The market authorization was issued in the EU on June 29, 2007 under EMA product number EMEA/H/C/000695. The corresponding patent EP0518468 B1 had already been filed April 23, 1992, and has the following claim 1:

> "A pharmaceutical formulation, for use in correcting a melatonin deficiency or distortion in the plasma melatonin level and profile in a human subject, which comprises melatonin in combination with at least one pharmaceutical carrier, diluent or coating, wherein the melatonin is present in the formulation in controlled-release form adapted to release melatonin following administration to a human patient, over substantially the whole of a single nocturnal period of at least about 9 hours, such that melatonin release occurs according to a profile which, taking into account the existing nocturnal profile simulates a normal human endogenous melatonin nocturnal profile in plasma, in that administration of the formulation at the beginning of said at least about 9 hour single nocturnal period causes melatonin to be detectable in the plasma in an amount which increases to a peak in the course of said period and subsequently decreases to a post-peak minimum essentially at the end of said period."

However, an earlier MA dated March 2001 existed for the use of Melatonin in sheep as a reproductive tool in Sheep (brand name: "Regulin"). For this reason, the Comptroller General of Patents of the UKIPO rejected Neurim's request for granting an SPC on the grounds that the MA Neurim relied on for Circadin was not the "first one" in the meaning of Art 3 (d) of Regulation (EC) 469/2009.

Neurim appealed this decison to the High Court of Justice, which confirmed the Comptroller's decision, and referred to decisions under the earlier regulation (EC) 1768/92, in which the ECJ had adopted a 'one bite of the cherry' approach. According to this approach, the existence of an earlier MA of a given drug, yet for veterinary purposes, was considered prejudicial to the grant of an SPC relying on a later MA for the same drug, but for human administration (case C-31/03 *Pharmacia Italia*).

Neurim appealed again, and the Court of Appeal then referred to the ECJ the question whether an earlier marketing authorisation for placing an active ingredient on the market will bar the application for an SPC based on a later marketing authorisation, even in circumstances where the earlier authorisation iss for an indication of a different kind, and for animals.

In the meantime, the patent reached the end of its lifetime on April 23, 2012, thus leaving Circadin without protection on the European market, at least for the time being.

On May 3, 2012, the Advocate General issued his opinion, according to which, under Article 3(d) of Council Regulation (EEC) No 1768/92, the fact that the same product has previously been authorised as a medicinal product for human use or a veterinary medicinal product in the Member State for which the application is made does not preclude the grant of a supplementary protection certificate based on a later authorisation to place that product on the market as a new medicinal product, provided the first-

destroyed.

Under the Bush administration, the federal financing of research devoted to embryonic stem cells was then restricted to 21 already existing stem cell lines, in order to discourage the use of new embryos for the generation of new stem cell lines.

President Obama promised in his electoral campaign to lift these restrictions, in order to expand the number of hES cell lines eligible for federally-funded research. In an executive order of March 9, 2009, he instructed the NIH to remove existing limitations on scientific inquiry, and to expand NIH support for the exploration of human stem cell research.

Shortly thereafter the NIH published draft guidelines allowing funding for research on stem cells derived from donated embryos leftover from fertility treatments. Further, NIH would continue to fund research on adult stem cells and induced pluripotent stem cells. Research on embryos created specifically for research or on stem cells derived by research cloning techniques or by parthenogenesis would not be supported.

A large public discussion followed. In the final guidelines, which took effect July 7, 2009, it was set forth that previously-derived stem cell lines that follow the spirit of the new ethical guidelines would be eligible for funding, too. Further an NIH advisory panel would evaluate these older stem cell lines if needed.

On August 19, 2009, the NIH was sued by two researchers, James L. Sherley, an adult stem cell researcher at the Boston Biomedical Research Institute, and Theresa Deisher, R&D director at AVM Biotechnology in Seattle, before the US District Court for D.C. (case *Sherley et al vs NIH*, 1:09-CV-1575).

The claimants, who were backed, among others, by Christian organizations, contended that the funding of embryonic stem cell research would unfairly divert money from adult stem cell research.

As a result, Judge Lamberth of the US District Court for D.C. issued a preliminary injunction on August 23, 2010, banning federal spending on human embryonic research. The US Government quickly filed an appeal, but in the meantime the NIH had already shut down part of their hES cell research, and stayed grants to researchers that had not yet been paid out. On September 9, 2010 the Appeals Court for the D.C. Circuit allowed the request to stay the injunction, and the NIH could resume its hES cell programs.

On September 27, 2010, the Appeals Court ruled that the federal funding could go on while the appeals process

which takes 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 will contribute to a session called "Intellectual Property Issues that Impact Antibody Engineering".

His talk will address "European IP Perspectives in the Therapeutic Antibody Space". Find the event's home page here.

MH patent has published in Nature Biotechnology

The July issue of Nature Biotechnology features an article written by Colin Sandercock of Perkins Coie and Dr. Ulrich Storz of MH patent, which addresses recent US case law related to antibnody patents, and lessons learned thereof

Sandercock CG, Storz U: "Antibody specification beyond the target: claiming a later-generation therapeutic antibody by its target epitope".

Nature Biotechnology 30(7), 615 – 618. 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.

authorised medicinal product is not within the scope of protection conferred by the patent designated by the applicant as the basic patent.

Because the Circadin patent related to a pharmaceutical formulation for use in a human subject, its scope did not encompass Regulin.

It is a common (yet not very convincing) tradition of the ECJ that the court does, in most cases, adopt the opinion of the Advocate General. The ECJ made no exception from this rule in the present case. In his decision which issued July 12, 2012, the ECJ thus ruled that "the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of a supplementary protection certificate for a different application of the same product for which a marketing authorisation has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate".

This decison has been praised as "a step in the direction of a more fit for purpose SPC regulation" and a "liberalization of the SPC system". In any case, it faithfully reflects the teleological approach the ECJ was urged to apply by the Advocate General, in that a reasonable balance of interests was found, and a realistic asessment of the financial burden an innovator has to tackle even if his drug was already approved for use in animals was made

The German Patent and Trademark Office (GPTO) reacted quickly, in order to avoid that Circadin is even longer without protection, and granted an SPC on August 7, 2012.

The full text of the decision can be found here.

moved forward, and on April 29, 2011 blocked the decision in a 2-to-1 ruling, and remanded it back to the District Court. Notably, the dissenter of said decision, Judge LeCraft Henderson, said her colleagues had performed "linguistic jujitsu". Following this prejudice, Judge Lamberth dismissed the lawsuit on July 27, 2011, thus paving the way for federal funding of hES cell related research. For 2011, the NIH allotted $358 million for non-embryonic stem cell research, and $126 million for embryonic stem cell research.

On August 24, 2012, the Appeals Court for the DC circuit eventually confirmed this decision. Judge Sentelle stated that the Dickey-Wicker act permits federal funding of research projects that utilize already-derived embryonic stem cells , which the court considered are not themselves embryos, because no "human embryo or embryos are destroyed" in such projects.

Thus, the court came at least in one aspect to the same finding as the European Coiurt of Justice in the "Brüstle" decision (case C-34/10and the Enlarged Board of Appeal of the EPO in the "WARF" decision (case G2/08) – namely that embryonic stem cells are not embryos as such.

Michalski Huettermann & Partner are getting personal... Today: Hartmut Elias

Hartmut Elias obtained a master degree in Physics in 1985, his diploma thesis being in the field of radio frequency superconductivity. This is followed by experience in R&D and product development of High-Tech products such as SQUID magnetic field sensors, fiber optic sensors, and polymer electrolyte membrane (PEM) fuel cells in industry for many years, both as a project lead and manager. He got into Intellectual Property Rights in 2007.

Hartmut Elias is a technical expert for fuel cells, energy technology, fiber optics, vacuum technology, cryogenics, radio frequency, and electronics. He joined the patent law offices of Michalski, Hüttermann & Partner in 2011.

Hartmut Elias speaks German and English, and has basic skills in French and Italian. You can contact him under he@mhpatent.de.

MICHALSKI · HÜTTERMANN & PARTNER

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