The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 2/2013

Duesseldorf/Munich, **06 August 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, Dr. Ulrich Storz discusses a strange thing called "Parthenotes", and a decision by the Supreme Court of India dramatized as "Novartis vs. India".

Stem cells revisited – ever heard of "Parthenotes" ?

Stem cell patents seem to be an evergreen topic in the Rhineland Biopatent Gazette.

In Issues 4/2012 and 1/2013, we have discussed the consequences of the long awaited BGH decision in the Brüstle case. The underlying decision by the CJEU was discussed in Issue 2/2011.

In Issue 3/2012 we have discussed the US debate which is focusing on funding issues rather than on issues of patentabilty, let alone morality, or ordre public, of patents related to stem cells.

In Issue 3/2011, we have discussed the underbidding race in patents related to induced pluripotent stem cells (iPSc).

Mission accomplished, and no more questions open, one should think. Nothing could be wronger than that !

A new case is now pending before the CJEU, which deals with the patentability of stem cells derived from parthenotes. Sounds familiar ?

Parthenotes are "activated" unfertilised oocytes, which allegedly are incapable of developing into a human being due to the absence of paternal DNA.

The underlying principle is parthenogenesis, which is a form of asexual reproduction in which growth and development of embryos occur

"Novartis vs. India": Case which could have only losers marks a new policy

A decision issued by the India Supreme Court has provoked diverging echoes from the originator industry, and from NGOs and generic companies from emerging markets, respectively. See the full decision here.

The decision dealt with Gleevec (INN: Imatinib mesylate), which is a tyrosine-kinase inhibitor used in the treatment of cancers, in particular chronic myeloic leukemia (CML). CML is a very malign orphan disease, but Gleevec has significantly increased survival rates (> 88 % after 8 yrs)

Gleevec has to be taken over very long periods as it effectively converts CML into a chronic disease. Although it qualifies as an orphan disease, the patient cohort thus grows year by year. In Germany, the patient costs for an annual dosis are about 35.000 €/yr.

The underlying compound, Imatinib, was first filed for patent as the free base (priority date: April 3, 1992), later as the mesylate salt (beta polymorph) which is now the marketed form

India joined the WTO, and established a patent law system, in 1995 only. Compounds predating said date were not eligible for patent protection. For this reason, the free base was never under patent protection in India. A patent law amendment with effect of 2005, necessary under Art 65 of TRIPS, eventually introduced compound protection for pharmaceuticals in India. Novartis could thus only file a patent application on the mesylate (IN1750CHE2005A, filing date: Nov 30, 2005), which was treated as a "mailbox application" and was only examined later.

The grant of the patent was opposed by Indian generic drug manufacturers and one NGO (Cancer Patients Aid Association). On April 1, 2013, the patent was eventually rejected by the Supreme Court on the grounds of alleged lack of inventiveness.

The legal basis was Section 3(d) of the patents act, according to which:

+ from our firm +

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Michalski · Hüttermann & Partner Patent Attorneys have been recommended in the "World's leading patent practitioners list", published by the Journal "Intellectual Asset Management".

The journal says that we are a "fast developing and growing a clutch of young, creative and responsive patent attorneys with excellent credentials in the pharmaceutical and biotechnology industries"

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without fertilization.

In animals, parthenogenesis means development of an embryo from an unfertilized egg cell. Such phenomena are for example commonplace in Lizards and water fleas.

Normal egg cells form after meiosis and are haploid, and thus require fertilization of a sperm which is likewise haploid, leading to a diploid zygote. Parthenogenetic offspring are, usually diploid, but without being fertilized by a sperm.

Parthenotes (also termed „parthenogenetic Embryonic Stem Cells, pESCs)" can be derived from eggs which have artificially been induced to initiate embryogenesis.

They can develop to the blastocyst stage over about five days (thus stem cells can be derived), but after that do not develop further, because they lack the genetic material from the father.

In the Brüstle case, the CJEU had already found that any non-fertilised human oocyte the division of which have been stimulated by parthenogenesis constitute a human embryo, and are thus excluded from patentability.

In a UK case (GB0621068 and GB0621069), US applicant International Stem Cell Corporation (ISCO), who has pioneered parthenogenetic methods to produce pESCs, now argued that the CJEU's finding that parthenotes are capable of commencing a process which leads to a human being is wrong.

ISCO argued that parthenotes are not totipotent (which the CJEU saw as one requirement to qualify as an embryo, and thus be exempt from patent protection), and thus claimed that their applications should be allowed.

The Comptroller urged the High Court to make a further reference to clarify the Brüstle ruling (Case No [2013] EWHC 807 (Ch) International Stem Cell Corporation v Comptroller General of Patents). Accordingly, Henry Carr QC, referred the following question to the ECJ on April 17, 2013:

„Are unfertilised human ova whose division and further development have been stimulated by parthenogenesis, and which, in contrast to fertilised ova, contain only pluripotent cells and are incapable of developing into human beings, included in the term „human embryos" in Article 6(2)(c) of Directive 98/44/EC on the legal protection of biotechnological inventions?"

A pretty suggestive question. It remains to be seen what the CJEU

„the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance [...]"

are not inventions within the meaning of the Patent Act

Novartis had claimed enhanced efficacy of the mesylate by showing better physico-chemical properties (better flow properties, better thermodynamic stability, lower hygroscopicity etc.) over the free base form. However, the Supreme Court denied that these properties, which can give better processability, storability, stability etc., can result in enhanced efficacy in the meaning of Section 3(d). The court said that

"Efficacy means the ability to produce a desired or intended result [...] Therefore, in the case of a medicine [...] the test of efficacy can only be "therapeutic efficacy" [...] Not all advantageous or beneficial properties are relevant, but only such properties that directly relate to efficacy, which in case of medicine, [...] is its therapeutic efficacy."

In other words: 2nd generation patents which relate to an improved formulation, galenic or derivative can only be protected by a patent if the modification directly affects the therapeutics efficacy of the drug, that is, interaction between the molecule and its target. Indirect effects, which relate to physiochemical properties (solubility, pharmacokinetics, shelf life, etc.) will no longer be considered.

The decision was mourned by the originator industry, but acclaimed by NGOs and generic companies from emerging markets, who called the decision a "victory for the poor"

It has been overlooked, in the entire discussion, that Novartis has contributed to the Gipap programme (Gleevec International Patient Assistance Program) run by the Max Foundation, which supplied about 60.000 Patients in 79 countries with Gleevec free of charge. Allegedly, said programme reached 90 % of all CML patients in India. And: If the mesylate form is no better than the free base, why don't generic manufacturers distribute the latter, which is off patent now in most countries, and has always been off patent in India.

Could the true reason be that a Market Authorisation for the mesylate exists (to which generic manufacturers would like to refer, as it has been sponsored by Novartis), while no such authorisation exists for the free base ?

It is further disturbing that Generic manufacturers from India do not only serve the domestic market or foreign emerging markets – they also export to western markets. Thus, the term "pharmacy of the poor" is heavily euphemistic. The Canadian Internet pharmacy Northdrugstore, for example, offers the originator version side by side with generic Imatinib mesylate versions from Indian manufacturers, which however come at 1/10 of the originator price.

In the meanwhile, the Gleevec decision seems to mark a new line of decisions which reflects India's patentee-unfriendly policy.

On March 4, 2013, the Patents Appeal Board confirmed a decision according to which a compulsory license was granted to local generic manufacturer Natco, to legally make and sell a low-cost version of Bayer's Nexavar (sorafenib), which is used to treat kidney and liver cancer. On July 17, 2013, the patent office has revoked divisional patents for Roche's Herceptin (trastuzumab), because, allegedly, they had not been properly submitted. On Aug

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makes out of it.

See the referral here. The matter is now pending as Case C-364/13 before the CJEU. A decision will most probably not be expected earlier than in a year's time.

2, 2013, the Indian patent board revoked GSK's patent for Tykerb (lapatinib ditosylate), calling it an incremental improvement of the original compound (lapatinib), and thus not inventive enough to deserve patent protection.

As a result of the Gleevec decision Novartis has announced that they will reconsider their activities in India. Others may follow. The United States have placed India on the special 301 blacklist as not providing "adequate and effective" protection of intellectual property rights. The decision could also affect the recently opened negotiations between India and the European Union on a free trade zone.

The decision, which has been applauded by many, could thus turn out into a case with only losers.

Michalski Huettermann & Partner are getting personal... Today: Dr. Hans Christoph Wilk

We are pleased to announce that Dr. Hans Christoph Wilk, who used to lead the IP department of Henkel KGaA, has now joined our firm as a counselor.

Christoph Wilk, born 1948 in Ulm, holds a diploma in Chemistry and a PhD in polymer science. In 1977 he joined Henkel KGaA, a multinational adhesive and consumer good company, based in Düsseldorf, working as a research chemist and making some inventions in the field of adhesives and lacquers. In 1982 he switched to the patent department of that company, and passed the European Qualification Exam as well as the German Patent Bar Exam.

From 1997 to 2012 he was head of the patent department, supervising more than 35 attorneys in Germany, the USA, China and Japan. Starting in 2013, he now is working in free practice for Michalski · Hüttermann & Partner Patent Attorneys.

The main practice areas of Christoph Wilk in IP are patent law (especially Chemistry), licensing, inventor compensation, patent valuation and patent portfolio management

You may contact of Christoph Wilk under info@mhpatent.de

MICHALSKI · HÜTTERMANN & PARTNER

Imprint: Michalski · Hüttermann & Partner Patent Attorneys, c/o: Dr. Ulrich Storz - email: st@mhpatent.de

Hafenspitze - Speditionstrasse 21 - 40221 Düsseldorf - Tel.: +49 (0)211 159 249 0 - Fax: +49 (0)211 159 249 20
Nymphenburger Strasse 4 - 80335 München - Tel.: +49 (0)89 208 027 274 - Fax: +49 (0)89 208 027 275