The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 4/2011

Duesseldorf/Munich, **02 August 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 highly anticipated decision of the U.S. Court of Appeals for the Federal Circuit in the Myriad case.

"isolated DNA"-claims held patentable by CAFC in Myriad

Fears that therapeutic proteins/antibodies isolated from nature no longer patentable dispelled

On July 29, 2011, the U.S. Court of Appeals for the Federal Circuit (CAFC) has issued his highly anticipated decision in the Myriad case (Assn Mol. Path. vs. USPTO).

The history of this case dates back to March 29, 2010, when Judge Sweet, who is a senior United States federal judge at the District Court for the Southern District of New York, ruled that Myriad Genetics' patents related to breast cancer genes BRCA1 and BRCA2 were invalid for the reason that genes do not constitute patentable subject matter. One of Judge Sweet's major arguments was that

> "DNA's existence in an 'isolated' form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes. Therefore, the patents at issue directed to 'isolated DNA' containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter."

The case was appealed before the CAFC, where oral hearings were held on April 4, 2011. Although the U.S. Patent and Trademark Office (USPTO) is one of the defendants, the US Department of Justice (DOJ) interfered by means of an amicus curiae brief, in which federal attorneys argued against the patentability of genes isolated from nature, and suggested the meanwhile notorious "magic microscope test", according to which any natural molecules which one could find with a magic microscope that could look deep inside of cells should be excluded from patent protection. Interestingly, this analogy was referred to by Judge Moore, who presided the proceedings together with Judges Bryson and Lorie, as "kitschy".

In the now-issued decision, the Court found that all claims related to isolated DNA were patentable, while the claims related to diagnostic methods which merely consist of "comparing" or "analyzing" DNA sequences were found non-patentable.

Under these assumptions, the Court found that claims reciting isolated DNA relate to molecules that have a distinctive chemical identity from molecules that exist in nature, because claimed isolated DNA molecules do not exist as in nature within a physical mixture to be purified, as they have to be chemically cleaved from their chemical combination with other genetic materials to which they are covalently bonded. The Court illustrated this by stating that forms of isolated DNA exist which require no purification at all, because DNAs can be chemically synthesized directly.

Further, the "magic microscope test" was also rejected, which, according to the Court, misunderstands the difference between science and invention and fails to take into account the existence of molecules as separate chemical entities.

In this context, the Court emphasized that the ability to visualize a DNA molecule through a microscope is worlds apart from possessing an isolated DNA molecule that is in hand and usable, as visualization does not cleave and isolate the particular DNA; the latter being the act of human invention.

The rejected method claims related, for example, to methods for detecting a gene mutation which comprised the step of analyzing a sequence of a gene, or to methods of screening the germline of a subject comprising the step of comparing germline sequence of a particular gene from a tissue sample.

The court found these claims unpatentable because they related to abstract mental processes only. This means that the Court did not exclude diagnostic method claims *per se* from patent protection. However, it seems that claims related to such diagnostic methods will need explicit wording with respect to the actual method steps, and sufficient enablement.

When still pending, this case had fueled fears that also therapeutic proteins isolated from nature would no longer be patentable, should the CAFC

+ from our firm +

MH patent attorneys act as editors for "SpringerBriefs in Biotech Patents"

MH patent attorneys have now signed an editor contract with Springer International Publishers for a new textbook series called "SpringerBriefs in Biotech Patents". The series will issue both as print version and eBook, The first issue is scheduled to be published in autumn 2011 and will deal with General aspects of Biopatent law. Find more information about the book series here. Further information will follow in the next issue of the Rhineland Biopatent Gazette.

MH partner Dr. **Ulrich Storz** has published the fourth of a series of four article authored by MH attorneys related to the protection of innovations in the pharma industry. The series is being published in "pharmind". Dr Storz's contribution now appeared in pharmind 7/2011, 1272, and has the title "Ergänzender Schutz für pharmazeutische Produkte" Please ask for a reprint here. Please feel free to ask for the full series of four articles also.

As regards claims related to isolated DNA, the CAFC reversed the district court decision because it found that the molecules as claimed do not exist in nature. The CAFC referred to the Supreme Court's decisions in Chakrabarty and Funk Brothers, which define the framework for deciding the patent eligibility of isolated DNA molecules.

The court went on by stating that the distinction between a product of nature and a human-made invention turns on a change in the claimed composition's identity compared with what exists in nature.

confirm the first instance decision. This related, particularly, to therapeutic antibodies isolated from man. The rationale applied by the first instance court, as well as the arguments set forth by the DOJ in an amicus curiae brief submitted to the CAFC, could have been considered to apply to other naturally-occurring substances, including, e.g., antibodies, too.

The recent decision has dispelled these concerns, although it might be expected that the plaintiffs may want to file a request for a rehearing *en banc* at the CAFC, or even appeal this decision before the U.S. Supreme Court.

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Archive

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Michalski Huettermann & Partner are getting personal... Today: Dr. Sonja Althausen

Sonja Althausen, born in 1971, studied Chemistry at the University of Cologne, obtaining her Diploma in 1997 and her Doctorate in 2001 with a thesis in the field of biochemistry.

She is co-author of several scientific publications in the field of molecular biology of neuronal cell damage. After her doctorate she worked in the field of neurological research.

Sonja Althausen passed the German Patent Bar Examination in 2005. Since 2005, she has been admitted to practice as European Trademark Attorney at the European Trademark Office (OHIM). Since 2006 she is admitted to practice as European Patent Attorney before the EPO.

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