The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 5/2016

Duesseldorf/Munich, **11 July 2016** 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 recent developments and decisions affecting the Biopatent community, and provide expert insight into what's going on behind the scenes. In this issue, MH partner Dr. Andreas Hübel reports that the US Supreme Court is not yet ready to reconsider the undue breath and scope of their previous ruling on patent eligibility, and Dr. Ulrich Storz, summarizes unprecedented consequences of the UK brexit vote.

Sequenom will not be reviewed

US Supreme Court missed chance to reconsider consequences of their prior ruling on patent eligibility

On June 27. 2016, the US Supreme Court denied certiorari in the in *Ariosa Diagnostics, Inc. v. Sequenom, Inc. case* (U.S., No. 15-1182, 6/27/2016) despite the urgings of more than 20 amicus briefs, and therefore let stand the decision of the CAFC which held a truly revolutionary diagnositc test patent ineligible, and keeps the biotech industry suffering the consequences of the Supreme Court's ignorance on the issue of patent eligibility.

Sequenom, Inc. owns a patent for a process of detecting paternally-inherited fetal DNA in maternal blood samples and diagnosing possible birth defects without highly intrusive measures. Sequenom, Inc. The patent (US 6,258,540) teaches to use the non-cellular portion of a maternal blood sample, to amplify the genetic material that only they had discovered was present, and identify paternally inherited sequences as a means of distinguishing fetal and maternal DNA.

A panel of the Federal Circuit affirmed a district court decision that the claimed method is patent-ineligible even though the invention revolutionized prenatal care. Applying the rule in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012), the Court explained that the method acts on natural phenomenon with well-understood, routine, and conventional steps.

While the Federal Circuit denied en banc review, particular judges expressed concerns for medical diagnostics under the current state of patent eligibility law. For example, Judge Dyk noted that the *Mayo* principles are important to a healthy patent system, but acknowledged that a too restrictive test reflected in some of the *Mayo*

Brexit and its consequences on the IP landscape

UK vote will delay the UPC, but have other implications on the IP landscape as well

The outcome of the UK brexit vote has caught the entire IP community on the wrong foot.

First off, the vote will NOT directly affect UK's membership in the European Patent Convention (which is not a body of the European Union), nor in the London Agreement, meaning that, pending further notice:

a) European Patents can in the future still be validated in the UK, and
b) the validation can be carried out without any further translations, and most probably without the need of a national UK representative.

Personally, we do not believe that Britain will have any ambitions to exit the EPC, or the London Agreement.

UK's role in the upcoming Unitary Patent System will however be highly affected should the Brexit become reality. The Unitary patent will then not have any effect in the UK, meaning European Patents will always have to be validated individually in the UK. The Unitary Patent Court will hence have no say on questions of infringement and validity of a European Patent validated in the UK.

Further, the designated seat of the biotech/chemistry satellite of the Court's central division will unlikely remain to be London (probably moving to Milan or the Hague), and UK lawyers or UK patent attorneys (even if European representatives) will unlikely be allowed to represent before the Court.

Because currently, only 10 % of patent infringement suits in Europe are held in the UK, the Brexit will not seriously affect the role of the future Unitary Patent Court.

+ from our firm +

MH partner Ulrich Storz spoke at antibody congress in Montpellier

MH partner Ulrich Storz spoke at the 4th Antibody Industrial Symposium in Montpellier (July 4-5, 2016). His talk focused on possibilities and limitations of antibody patent protection in Europe. See the conference homepage here.

MH associate Dr. Christoph Volpers spoke at two international congresses.

MH associate Dr. Christoph Volpers spoke at the C5 International Forum on Pharmaceutical Patent Term Extensions in Munich (21-22 June 2016) about SPCs and FTO work flow processes.

He also was an invited speaker at the 5th European Biosimilars Congress in Valencia, Spain (27-29 June 2016). His talk focused on IP issues of complex global biosimilar programs.

Article on antibody dosage patents published

MH partner Dr. Ulrich Storz has published an

language may discourage development and disclosure of new diagnostic and therapeutic methods. "In my view, *Mayo* did not fully take into account the fact that an inventive concept can come not just from creative, unconventional application of a natural law, but also from the creativity.

Judge Linn, who concluded that "Sequenom's invention is truly meritorious.", wrote a separate concurring opinion, explaining that given the unnecessarily sweeping language of the Supreme Court's decision in *Mayo* he was constrained to agree that the patent claims at issue were ineligible. Judge Linn explained that the Supreme Court lumped all post-solution conventional activity together as if it necessarily had to be qualitatively the same.

Sequenom filed a Petition for Writ of Certiorari in the Supreme Court of the United States, challenging the decision of the United States Court of Appeals for the Federal Circuit. In the petition, the single question presented by Sequenom was whether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery?

However, the Supreme Court denied review of the Federal Circuit panel decision that an important medical diagnostic method is ineligible for patent protection under 35 U.S.C. 101.

If the Supreme Court would have taken the case they would have been required to reconsider the overwhelming breadth and scope of their prior ruling in *Mayo Collaborative Servs. v. Prometheus Labs*.

And would have had the chance of providing a basis for a more reasonable approach in assessing patent eligibility of inventions in biotechnology, diagnostics and medicine.

It can furthermore be expected that, after a transitional period, even infringement actions which today still go to a UK court will then go to the Unitary Patent Court, because of the bigger market that can be covered by a respective decision.

The Brexit will also affect the role UK patent firms have in the European market. Clients who seek for a one-stop solution for European IP matters will in the future consider to have their cases represented by a continental law firm, e.g., from Germany, in particular to make sure that the cases are prosecuted in a way that is favorable for later litigation before the Unitary Patent Court.

The envisaged entering into force date of the Unitary Patent (was spring 2017) will have to be postponed. However, it appears that the legal provisions can easily be adopted to account for the leave of the UK. We therefore anticipate that the delay will not exceed two years.

Further implications involve the loss of effect of several EU directives, including (i) the Biopatent Directive (which is probably good news for the UK) (ii) the regulation for Supplementary Protection Certificates and (iii) the different biosimilar guidelines. As regards the latter, UK will have to establish national laws instead.

Further, Community Designs and Trademarks will lose their effect in the UK (with probably the possibility to convert them, as regards their effect for the UK, into corresponding UK rights).

Depending on whether the UK will become member of the European Economic Area or not, the exhaustion of IP rights may change, which would have an effect on reimportation of drugs.

Other side effects are, e.g., that the EMA will likely move to the continent, too.

In a time of harmonization of IP affairs and regulatory affairs, the Brexit hence represents a full throttle reverse.

article about the extension of therapeutic antibody market exclusivity through dosage patents (Storz U mAbs. 2016 Jul;8(5):841-7). Ask for a reprint here.

Feedback please !

What do you think about this newsletter? Let us have your comments here.

Archive

To obtain a neat overview of the quickly changing world of Biopatents, find prior issues of the Rhineland Biopatent Gazette here.

EURIPTA® EEIG is getting personal... Today: Pjotr Kaminski (Kamniski & Partners)

Dr. Piotr Kaminski manages patent practice at Kaminski & Partners, which is the Polish member of EURIPTA®. Polish Patent Attorney and European Patent Attorney, an engineer and biotechnologist, Dr. Kaminski holds a Master's degree in biochemistry from the Faculty of Biotechnology and Food Chemistry of the University of Technology of Lodz.

In year 2000 he was awarded a PhD degree from the University of Westminster, Great Britain, in recognition of programme of work in fungal biotechnology. He also studied Intellectual Property Law at School of Laws at the University of Birmingham, Great Britain. Before entering postgraduate studies of Law on Industrial Property at the Cracow Jagiellonian University, he gathered extensive experience in the field of Research & Development both in academic and pharmaceutical industry sectors.

Registered in Polish Chamber of Patent Attorneys, Dr. Kaminski is also registered to practice before the European Patent Office and before Office on Harmonization of Internal Market. Focuses on litigation and prosecution work in patents, utility models and industrial designs. Since 2009, national trainer certified by EPI (European Patent Institute). Dr. Kaminski also teaches patent law at the Medical University of Lodz. Contact Pjotr under: piotr@kaminskipatent.com

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