The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 2/2015

Duesseldorf/Munich, **19 June 2015** 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 will report about the recent dismissal of a lawsuit filed by German Plant Breeders against the implementation of the Nagoya protocol. MH Partner Dr. Ulrich Storz and Dr. Christoph Volpers, Senior Patent Manager in our, firm discuss the Sequenom decision by the CAFC.

CAFC confirms Sequenom's prenatal diagnosis patent to be invalid

Decision demonstrates increasing impact of *Mayo* and *Myriad*

On June 12, 2015, the US Court of Appeals for the Federal Circuit (CAFC) confirmed a 1st instance decision issued by the District Court for the Northern District of California, according to which the claims of Sequenom's prenatal diagnosis patent U.S. Patent 6,258,540 are not directed to patent eligible subject matter, and are thus invalid under 35 USC § 101. See the decision's full text here. Claim 1 of the patent relates to

> "A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises amplifying a paternally inherited nucleic acid from the serum or plasma sample and detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample."

In 2011, US company Ariosa Diagnostics, which develops prenatal blood tests for maternal and fetal health, filed declaratory judgement action alleging non-infringement of the '540 patent. Sequenom sued for infringement in response and filed motion for prelimimary injunction. Because the court denied the preliminary injunction, Sequenom appealed the case to the CAFC, which applied a different claim construction than the District Court and remanded the case in 2013.
The latter, upon direction of the CAFC, then examined patent eligibility issues under 35 USC §101 in view of the Supreme Court's *Myriad* decision (see Rhineland Biopatent Gazette, Issue 4/2014), and concluded that the patent is invalid. Sequenom again appealed this decision to the CAFC, which this time confirmed the District Court's finding.

In its review, the CAFC employed a framework set forth in the Supreme Court's *Mayo* decision for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. In this test, it is first determined whether the claims at issue are directed to a patent ineligible concept. If the answer is yes, the elements of each claim are considered both individually and as an ordered combination to determine whether additional elements "transform the nature of the claim" into a patent-

Nagoya Protocol: Plant breeders' action dismissed

no "personal affection", says Court

On May 18, 2015, the General Court of the European Union (EGC) dismissed the actions of German and Dutch plant breeding companies against the EU regulation on the implementation of the Nagoya Protocol (Regulation (EU) No 511/2014) as inadmissible (T-559/14 and T560/14).

A total of 17 German plant breeding companies and 15 Dutch plant breeding companies had filed actions, because they are concerned that the implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization will collide with established Plant breeders' rights, and that the prescribed diligence measures provide an undue burden.

According to the German Association of Plant Breeders (GDP), the court dismissed the action of the German Plant Breeders on formal grounds only and did not consider the factual arguments raised by the plaintiffs.

The court objected that the individual plaintiffs were not personally affected by the regulation – which is a prerequisite for the admissibility of an action for annulment before the courts of the EU.

+ from our firm +

8th Rhineland Biopatent Forum has been a great success

30 attendees joined the 8th Rhineland Biopatent forum, which took place on May 21, 2015 in our office in Dusseldorf.

We were able to assemble a high-profile panel of speakers, including Randall A. Rader, (former Chief Judge of the CAFC), Paul A. Calvo (Sterne, Kessler, Goldstein & Fox), Dieter Wächter (European and Swiss Patent Attorney and former Head of Special Tasks at F. Hoffmann-La Roche Ltd), Claudia Hallebach, (Head of R&D Legal Affairs and Intellectual Property, KWS SAAT AG), Sander Arendsen (DSM Expert Center Intellectual Property), as well as partners from our firm.

Attendees came from, among others, from SPC GmbH, DSM, Sartorius Stedim Biotech GmbH , ZBM Patents, Molecular Partners, Bavarian Nordic, Homburger AG RAe, DSM, Boehringer Ingelheim, Biontech AG, Novo Nordisk A/S, Ganymed AG, Bio.NRW, Bavarian Nordic, Rospatt Osten Pross RAe, Wildanger,

eligible application. This second step is also defined as a search for an inventive concept, i.e., an element or combination of elements that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the ineligible concept itself".

The CAFC found that the claimed method begins and ends with a natural phenomenon as the claims are directed to cell-free fetal DNA (cffDNA), matter that is naturally occurring. Insofar, the court found that the first step set forth in the Supreme Court's *Mayo* decision was met.

As a result of turning to the second step, the court concluded that the claimed method

> "amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA. Because the method steps were well-understood, conventional and routine, the method of detecting paternally inherited cffDNA is not new and useful. The only subject matter new and useful as of the date of the application was the discovery of the presence of cffDNA in maternal plasma or serum."

Thus, the court quite obviously did not consider the combination of process steps as a whole. In spite of the fact that amplifying a paternally inherited fetal nucleic acid from a coming mother's serum sample was *new*, and that detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample was *new and useful,* the court commented:.

> "Where claims of a method patent are directed to an application that starts and ends with a naturally occurring phenomenon, the patent fails to disclose patent eligible subject matter if the methods themselves are conventional, routine and well understood applications in the art."

Interestingly, the court was well aware of the impact Sequenom's technology had, and still has, in the scientific community, and the groundbreaking new options provided by it for prenatal diagnosis. However, the court found that this real world effect could not heal the alleged deficiencies under 35 USC §101.

The court also shared the concerns the first instance had raised with regard to possible preemption. The claims were construed to relate not only to particular applications of cffDNA, but also to methods for detecting this natural phenomenon. As the latter was regarded as a prerequisite for any application of cffDNA, present claims were considered to carry a substantial risk of preempting all practical uses of it.

While the decision was authored by Circuit Judge Reyna and joined by Circuit Judges Linn and Wallach, Judge Linn also filed a concurring opinion, according to which the *Mayo* framework should be reconsidered, and at least permit the consideration of "post-solution activity" when that activity is novel:

> "Sequenom 'effectuate[d] a practical result and benefit not previously attained,' so its patent would traditionally have been valid. …. But for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible."

The case might well make it to the Supreme Court. Sequenon commented in a public statement that the ruling has little business impact, and there did not appear to be a significant effect on its stock price. However, the decision will unsettle the diagnostic community, as it demonstrates the increasing impact of the *Mayo* decision on the patent eligibility of diagnostic methods. It appears that the mere

This formalistic approach has been criticised as ignoring the tremendous impact the new Regulation will have on the plant breeding industry.

Unlike other sectors, plant breeders cannot draw a direct benefit from a genetic resource. Such benefit crops up only after lengthy breeding work. The development of new plant varieties requires thousands of crossing steps, and different breeders to contribute. A comprehensive documentation about the use of genetic resources, their "origin" and given consent of use as required by the EU Regulation, is therefore considered virtually impossible.

But above all, the new regulation is said to undermine the European system of plant variety protection, which is de-facto an open-source system.

Plant breeders thus fear that the use of newly bred and protected plat varieties as a genetic resource for further breeding and research, which is currently not subject to any restrictions whatsoever, will hardly be possible in the future, due to extensive documentation requirements.

A further concern among the plant breeding companies is, that the regulation requires that the information on the origin and use of the genetic resource has to be provided to subsequent users as well. Despite being an open-source system due to the breeders exemption, which allows a breeder to use a plant variety that is protected by plant variety protection rights for further breeding, the regulation prescribes that the originator of the plant variety further has to provide comprehensive information on its variety to any competitor. This will for sure not encourage plant breeding efforts.

The parallel action of the Dutch plant breeding companies was dismissed by the court the same as the action of the German plant breeding companies was dismissed day for virtually the same reasons. The decision can be appealed to the Court of Justice of the European Union (CJEU). So far we have no information whether the consortium, or individual members, will make use of this option.

Kehrwald Graf v. Schwerin RAe, AiCuris GmbH & Co KG, UCB Pharma GmbH, Qiagen, , Bayer IP GmbH, Syngenta, BASF, Taylor Wessing RAe, Pharmed Artis GmbH, CBH RAe, and BSN medical,

We have received overwhelming feedback by the attendees, and are looking forward to next year's Rhineland Biopatent forum already.

For those who could not attend we have made the slides available for download here.

MH partner **Dr. Andreas Hübel** will attend the Annual Meeting of the IPO on September 27 to 29 in Chicago. He will give a presentation on the implementation of the Nagoya protocol by the EU in a session entitled "The Nagoya protocol: Conserving Bioderversity or Withering the Frueits of Innovation?" Contact Andreas here if you would like to schedule a meeting.

Dr. Christoph Volpers, senior patent manager in our firm, has been panelist speaker at the World Pharma Licensing Congress in the London Stock Exchange on February 10. Find a respective congress entry here. Dr. Volpers further attended the German Biotech Days in Cologne on April 22 and 23.

MH partner **Dr. Ulrich Storz** has attended the International Congress of Antibodies (ICA) in Nanjing, China, from April 25 – 29. Ulrich gave a lecture entitled "Intellectual Property in the Antibody Space: Strategies for Startups, Pharma and Biosimilar Manufacturers". Find a respective congress entry here.

Feedback please !

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

existence of subject matter that qualifies as natural phenomenon may contaminate the entire claim, even if further features exist which do not suffer from this deficiency – at least if such further features could be deemed conventional, routine or well understood.

Prenatal blood tests for fetal health have raised ethical issues in the past. However, before praising said decision, ethical activists and religious conservatives should consider that, once the decision is final, the method which was once exclusive to Sequenom can also be practiced by competitors.

On the other hand, it becomes ever more clear that a too broad interpretation of 35 USC §101 may affect the development of new diagnostic methods and pharmaceutics. The perspective to obtain exclusivity by patent protection is undoubtedly a key driver for R&D investments. It appears questionable whether or not the Sequenoms of this industry will be investing resources into the development of such assay systems without any prospects of exclusivity.

Therefore, the Supreme Court's justification of the judicial exception that renders products of nature and natural phenomenon patent ineligible on the basis that "manifestations of laws of nature" should be "free to all men and reserved exclusively to none," may eventually lead to the contrary, or at least runs the risk that new diagnostic methods are no longer developed, and would thus never become available to the public.

Archive

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

Michalski · Huettermann & Partner are getting personal... Today: Tobias Kleinohl

Tobias Kleinohl studied physics at the Rheinische Friedrich-Wilhelms-Universität Bonn with emphasis on nuclear and particle physics, nuclear medicine and medical technology. After graduating in 2012, he began to work as a research assistant at the Physics Institute of the University of Bonn. During this time, Tobias Kleinohl was involved in international research projects in the field of experimental particle physics. He collected experiences within the "Belle II" collaboration at the High Energy Accelerator Research Organization in Japan (KEK), particularly in the areas of silicon pixel detectors and radiation hardness of semiconductor particle detectors. His research led him among other things, to the European Laboratory for Particle Physics, CERN, near Geneva.

He gained first insights into industrial property rights by a distance learning course in "Intellectual Property Rights" at the University of Hagen and during the "Summer School on Intellectual Property" in July 2014 at the University of Bonn. In the same year Tobias Kleinohl began working as a patent attorney candidate at the patent law firm Michalski · Hüttermann & Partner. Tobias Kleinohl is member of the German Physical Society and speaks German and English.

MICHALSKI · HÜTTERMANN & PARTNER

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