The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 2/2014

Duesseldorf/Munich, **25 July 2014** 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, Dr. Torsten Exner discusses the Advocate Generals's opinion in the Parthenote stem cell case, while our partner Dr. Andreas Hübel reports on the recent decision "*Limelight Networks v. Akamail Technologies"* of the US Supreme Court and it impact on personalized medicine claims.

No inducement of infringement without direct infringement

The impact of Limelight vs. Akamai for personalized medicine claims in the US

In early June, the US Supreme Court issued its unanimous decision *in Limelight Networks vs. Akamai Technologies* and held that a defendant is not liable for inducing infringement under 35 U.S.C. § 271 (b) when no one has directly infringed under 35 U.S.C. § 271 (a) or any other statutory provision. Liability for direct infringement under § 271 (a) requires performance of all steps of a method claim to be attributable to a single party. Where no direct infringement has occurred, there can be no inducement of infringement under § 271 (b) – and thus no liability.

Well, what is this all about and what does that mean to us in biotech?

Just a brief history of the case: Akamai Technologies, Inc. is an internet content delivery company that owns and maintains thousands of servers in the USA and contracts with internet service providers. Akamai Technology can deliver stable, fast internet to far-reaching customers with less risk of slowdown or failure. Akamai Technologies, Inc. was founded by two professors at the MIT to capitalize their research results with respect to providing stable internet services. On July 12, 1998, said professors filed a patent application through MIT which issued as US Patent 6,108,703, assigned to Akamai as exclusive licensee.

In 2004, Akamai entered into negotiations to purchase Limelight Networks. However, when Limelight Networks announced in 2006, that they no longer want to be purchased, Akamai Technologies sued Limelight Networks in district court for violating §271 (a) and §271 (b) prohibiting patent infringement and inducing patent infringement.

The case proceeded to trial and a jury awarded Akamai a $41.5 million verdict based on lost profit, lost royalties, interest, and price erosion damages as the jury found Limelight liable for direct infringement. After a series of post-trial motions, the district court ultimately ruled in favor of Limelight and held that, although Akamai's patent was violated, much of the violation occurred when Limelight's customers took the key steps to violate the patent. Although Limelight allowed these steps to occur, it did not control its customers' actions and therefore was not liable.

Parthenotes Advocated no "Human Embryos"

Advocate General provides his opinion

On 17 July 2014 Advocate General Cruz Villalón has delivered his opinion to the CJEU in Case C-364/13, *International Stem Cell Corporation (ISCC) v Comptroller General of Patents*. He recommends that the CJEU should hold parthenogenesis patentable, but exclude cells from patentability that have been genetically manipulated to acquire the capacity of developing into a human being.

As a legal background, Article 6(2)(c) of the European biotechnology directive (Directive 98/44/EC) prohibits uses of human embryos for industrial or commercial purposes as non-patentable subject matter.

The underlying case concerns two patent applications by ISCC, claiming methods of producing and isolating pluripotent human embryonic stem cell lines from parthenogenetically activated oocytes. Parthenogenetic activation is a method of artificially inducing cell division in unfertilized ova without fertilization.

On 16 August 2012 the Hearing Officer of the UK Intellectual Property Office had rejected these applications as relating to inventions excluded from patentability according to *Brüstle* (C-34/10, EU:C:2011:669), even though he found: *"The parthenotes produced by the methods of the invention are incapable of continued normal development i.e. they cannot develop into a viable human being".*

On appeal, Judge Carr at the

+ from our firm +

Article on Rituximab approval/patent history authored by MH partner has just issued

MH partner Dr. Ulrich Storz has just authored an article in which the relationship between the approval strategy and the patent strategy of an antibody is discussed on the example of Rituximab.

The article titled "Rituximab: How approval history is reflected by a corresponding patent filing strategy" has issued in mAbs 2014; 6:820 - 837; PMID: 24866199.

Find the article link here, or ask for a reprint here.

One of MH patent's clients has published an article in nature

We are excited to announce that one of our clients has just published an article in nature.

Our Congratulations go to Alban Bessede of ImmuSmol, Pessac/Bordeaux, who is the leading author of the article "Aryl hydrocarbon receptor control of a disease tolerance defence pathway", which issued in Nature 511, 184–190 (10 July 2014).

The district court granted Limelight's motion for judgment as a matter of law (JMOL) of non-infringement. The case proceeded to the CAFC which found Limelight liable for induced infringement.

In particular, the CAFC held: *If a party has knowingly induced others to commit the acts necessary to infringe the plaintiff's patent and those others commit those acts, there is no reason to immunize the inducer from liability for indirect infringement simply because the parties have structured their conduct so that no single defendant has committed all the acts necessary to give rise to liability for direct infringement.*

Thus, the CAFC found*: Limelight would be liable for inducing infringement if the patentee could show that (1) Limelight knew of Akamai's patent, (2) it performed all but one of the steps of the method claimed in the patent, (3) it induced the content providers to perform the final step of the claimed method, and (4) the content providers in fact performed that final step.*

After the jury verdict but before the district court granted JMOL, the CAFC issued its decision in *Muniauction, Inc. vs. Thomson Corp*., where it held that direct infringement of a method claim under 35 USC § 271(a) arises only when a single party performs every step or exercises "control or direction" over another's performance, "such that every step is attributable to the controlling party." Under *Muniauction*, Limelight could not be liable for direct infringement, because it did not exercise "control or direction" over its customers' performance of the step at issue.

The US Supreme Court declined to rule on the merits of the Federal Circuit's rule for direct patent infringement, which states that a single party must perform or exercise "control or direction" over each step of the patented process, but expands the position to induction of patent infringement. The US Supreme Court holds that liability for inducement can only be found when there is direct patent infringement. Because patent rights extend only to the claimed combination of steps, there is no direct patent infringement unless all the steps are performed by one (legal) person.

The US Supreme Court explains that it can reach no other conclusion than that "there has simply been no infringement of the method in which respondents have staked out an interest, because the performance of all the patent's steps is not attributable to any one person."

So far, so good. But why should the pharma and biotech industry care?

While the claims at issue in this case related to computer systems, the decision is important to patents in the personalized medicine space.

Well, due to the Supreme Court's ruling, the scope of method claims is severely restricted, and it will be much harder in the US to enforce patent protection for personalized medicine, companion diagnostics or dosage regimens.

In those categories, typical claim languages are – for example – "A method for treating disease X, said method comprising (i) testing for disease X, and (ii) prescribing/administering drug Y". Another typical claim language is: "A method for treating disease X, said method comprising (a) determining the level of metabolite Z, and (b) adjusting the dosage of drug Y".

Usually the different method steps are performed by

Patents Court (High Court of Justice) of England and Wales concluded that there was insufficient clarity as to what the CJEU meant in *Brüstle*. He was faced with the facts that "*there are no totipotent cells present in a parthenote*" and "*parthenotes and fertilised ova are not identical at any stage*". In his preliminary view the process used by ISCC should not be excluded from patentability as a 'human embryo'. From his understanding of the intention of the legislation, only totipotent cells, but not pluripotent cells, should be excluded from patentability.

With a decision of 17 April 2013 the Patents Court referred the following question to the CJEU:

"*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?*"

At the beginning of his opinion, the Advocate General somewhat dry-wittedly remarks that Judge Carr struggled with the CJEU's answer in *Brüstle* that parthenotes would fall under the term "human embryos" in the sense of Article 6(2)(c) of the Directive. Nevertheless, he then essentially concurs in Judge Carr's reasoning.

According to the Advocate General, the key criterion in *Brüstle* is the question whether an organism is "*capable of commencing the process of development of a human being*". In other words it needs to be decided whether a parthenote constitutes the functional equivalent of a fertilised ovum. The facts at hand, in particular parthenotes not being totipotent cells, would indicate that this was not the case. Therefore he concludes that parthenotes are not excluded from patentability. He adds that in his view in *Brüstle* the Court had not been made aware of the fundamental difference between parthenotes and non-fertilised ova.

However, he continues that it may one day be possible to genetically manipulate a parthenote in such a way that it obtains the capacity to develop into a human being. Once such a cell exists, it can in his view not be patented.

While the Advocate General's recommendation in the Opinion is not

Find the article link here, or contact ImmuSmol if you would like to have a reprint.

German-Dutch Business Forum Chemistry and Life Sciences.

MH Partner Andreas Hübel attended the German-Dutch Business Forum Chemistry & Life Sciences which was organized by the German-Dutch Chamber of Commerce and held on June 18, 2014 at the Bayer Conference Center.

About 150 participants discussed how academic success can be transformed into products and business such that Germany and the Netherlands can stay capable of competing in the global economy.

Briefly, cooperation of politics and R&D should be improved for establishing an R&D friendly environment such that young talents can be attracted in the region, such that increasing venture capital becomes available, and such that innovations can be brought to market much faster.

Science4Life Venture Cup

Our firm contributed to this year's Science4Life Venture Cup in that our partner Andreas Hübel examined several business concepts and business plans. The awards were given to the best teams on July 07, 2014 in a ceremony at the Frankfurt am Main branch of the Deutsche Bundesbank.

Due to his ongoing pro bono activity for the Science4Life VentureCup throughout the past years, Andreas Hübel became a designated "Science4Life"-expert.

Feedback please !

different entities. The testing for disease X or the determination of metabolite levels are performed in a laboratory, whereas prescribing, administering and/or adjusting the dosage of the drug to be administered is performed by an MD. Moreover, the MD is not a person in privity of the laboratory and vice versa.

Thus, it appears that neither the laboratory nor the MD can be held liable for infringing typical claims directed companion diagnostics and personalized medicines.

At least with respect to currently ongoing prosecution, Applicants who are facing rejections under the USPTO's new Subject Matter Eligibility Guidance should be cautious about adding additional method steps to their claims in order to overcome the new § 101 rejections, especially if it is likely that such steps would be carried out by different actors.

binding on the Court, it carries considerable weight, and the Court has often followed the Advocate General's advice. The present opinion thus increases the chances that the CJEU will adjust its statement made in *Brüstle*.

As a final note, rule 28(c) EPC stipulates that "…*European patents shall not be granted in respect of biotechnological inventions which, in particular, concern uses of human embryos for industrial or commercial purposes*." Should the CJEU follow the Advocate General's opinion, it can be expected that the EPO will take a similar approach as the CJEU.

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.

Michalski · Huettermann & Partner are getting personal... Today: Beiyi Xu

Mr. Beiyi Xu was born in Beijing, the capital city of China, in 1979. He came to Hannover, Germany in 2000 and studied Electrical Engineering and Automation. In 2007 he wrote his master thesis in the Volkswagen Corporation in Wolfsburg. In the same year he obtained his Master of Science degree from the University of Hannover.

Beiyi Xu obtained his training in intellectual property law in an internationally active law firm in Cologne, Germany, where he was responsible for a project of acquiring Chinese clients. After that he worked as an intern at the German Patent and Trademark Office and the German Federal Patent Court.

In 2013 he passed the German patent bar examination examination, and was admitted, in 2014, to practice as a German Patent Attorney as well as a European Trademark and Design Attorney at the Office for the Harmonization in the Internal Market in Alicante (OHIM). Beiyi Xu joined Michalski · Hüttermann & Partner in 2014. He speaks Chinese, German and English.

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