The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 3/2016

Duesseldorf/Munich, **11 April 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, we discuss two decisions that make a reference to the US Supreme Court decision Mayo v Prometheus (566 US (2012)).

BMS's anti PD-1 patent stands Merck's validity attack

"product of nature" is not a universal killer argument

As we have discussed earlier (see Issue 3/2015 of this Gazette), Bristol Myers Squibb (BMS) and Merck & Co have engaged in a patent dispute with several battlefields. Merck has now suffered a further setback.

In an infringement action filed in July 2015 at the Delaware District Court, BMS alleged that Merck would infringe their US Patent No. 9,073,994, claiming, *inter alia:*

> 1. A method of treating a metastatic melanoma comprising intravenously administering (...) a human or humanized anti-PD-1 monoclonal antibody and a solubilizer in a solution to a human with the metastatic melanoma (...)

Merck had received approval to sell its anti PD-1 antibody pembrolizumab (Keytruda ®) in the U.S. in September 2015.

In the course of the proceedings, Merck demanded dismissal of the demand due to lack of patent eligibility. The court denied this demand on March 17, 2016. Merck had argued that the patent would claim "the natural operation of the body's immune system via the PD-1 pathway". Hence, Merck demanded that the patent be dismissed as covering non patent eligible subject matter under 35 USC § 101. Merck suggested that the claimed subject matter was similar to that claimed in the patent that was eventually found to be ineligible in the Supreme Court decision Mayo vs Prometheus (566 US (2012)).

BMS ackowledged that every method of therapeutic treatment relies, basically, on the biological activity of the patient's immune system, and thus referred to the ultimately weak point in the rationale of the Mayo decision (see also the BGH decision discussed in the right hand column). Hence, BMS added, that administration of the drug would

> „result in an immune response that would otherwise not occur in the patient's natural state."

Federal Supreme Court (BGH) takes aim at Mayo

decision "Rezeptortyrosinkinase" has multiple implications

In a decision that issued Jan 19, 2016. The German Federal Supreme Court declared its explicit dissent with the rationale of the Mayo vs Prometheus decision of the US Supreme Court (BGH X ZR 141/13 „Rezeptortyrosinkinase").

Here are the facts: The European Patent Office (EPO) had granted patent EP959132B1 assigned to Takara Bio (US counterparts are US6846630 and US8178292). The German part of this patent was partly revoked (i.e., maintained in restricted form) in a nullity action before the Federal Patent Court (BPatG).

The corresponding infringement action is Invivoscribe Tech vs Münchner Leukämielabor, which was negotiated at the Munich District Court, and in which an infringement of claim 7 was confirmed.

Claim 7 of patentee's main request in 1st instance of the nullity action was as follows

> 7. A method for detecting the nucleic acid molecule of claim 1, or the nucleic acid molecule of claim 2, comprising the steps of:
>
> (a) subjecting a nucleic acid sample from a human to a gene amplification reaction, wherein a nucleic acid fragment comprising exon 11 or exons 11 to 12 of the FMS-like tyrosine kinase 3 (FLT3) gene and having a tandem duplication mutation in the juxtamembrane is amplified, which can be found in FLT3 gene;
>
> (b) detecting the presence of the tandem duplication mutation in the nucleic acid fragment of step (a).

Claimant alleged that claim 7 would relate to a non-patentable method of diagnosis on the human body. The BPatG revoked said claim. However, In the 2nd instance at the Federal Supreme Court (BGH), the claim was reestablished. The BGH gave the following keynote:

> "A technical teaching, which teaches the use of a mere discovery to achieve a particular technical object, is patent eligible regardless of whether the teaching comprises an "inventive surplus" that goes beyond the purposeful use of the discovered law of nature or not. This also applies to the provision of a nucleic acid sequence coding for a human protein. It is not necessary to designate the sequence as isolated or obtained by a technical process."

+ from our firm +

MHP at the 8th International Congress of Antibodies

MH partner Dr. Ulrich Storz will organize an IP panel at the 8th International Congress of Antibodies (ICA) in Dalian, China, April 26, 2016.

The panel will assemble Antibody IP experts from China (Luke Zuo, NTD), Japan (Makoto Aihara, SIKS & Co), India (Gandhi Tarun, Chada & Chada) and the United States (Colin Sandercock, Perkins Coie).

The contributors will provide a comparative view on antibody IP on a global perspective. This panel is the first of its class worldwide and will become extremely interesting.

Find a respective congress entry here.

Rhineland Biopatent Forum – few places left !

We have a few places left for the 9th Rhineland Biopatent Forum on June 2, 2016, in Duesseldorf. Make sure to not miss this event, and apply here !

The court, in turn, acknowledged that the patent did indeed relate to a natural phenomenon:

> "The inventors relied on the fact that inhibiting 'signals of PD-1, PD-L 1 or PD-L2 inhibit cancer proliferation through the mechanism of the recovery and activation of immune function.' This interaction is a natural phenomenon."

However, the Court reminded that, in infringement actions, the presumption of valdity applies, plus found that the question at stake, namely whether the claims add enough subject matter to overcome the „natural phenomenon bar" could not be resolved on a motion to dismiss:

> "Whether the claims amount to an implementation step is a complicated factual determination that the court could better resolve after discovery. Additionally, the'999 patent is entitled to a presumption of validity under 35 U.S.C. § 282. Rarely can a patent infringement suit be dismissed at the pleading stage for lack of patentable subject matter."

Accordingly, BMS's motion was dismissed, and the infringement proceedings will now continue.

Merck's attempt appears slighty suicidal at first sight, because the claim category in dispute is one of the most frequently used categories in the industry, and undoubtedly Merck's portfolio has claims with similar language.

This would not have been Merck's first own goal. In the infringement action, BMS further stated that Merck's representative in the opposition against BMS's corresponding EP patent EP1537878 had admitted that Merck were aware of the corresponding US patent, and thus knew that pembrolizumab would fall under said patent. BMS has used this argument to establish that Merck willfully infringed their US patent, which, under certain circumstances, may qualify them to demand tripled damages.

Back to the case: Experience shows that in prosecution, an objection on the basis of 35 USC 101 is sometimes extremely difficult to overcome, once the examiner has made up his mind in this regard. For this reason, it is satisfying to see that, at least in infringement proceedings, a "product of nature" attack is not always a killer argument, although the court's argument is astonishingly weak, in view of such clear teaching of the claim.

The following passage from the decision is noteworthy, as it directly addresses the Mayo vs Prometheus of the US Supreme Court (emphasis added):

> "Under Art. 52 (2) (a), (3) EPC, a discovery as such is not patent eligible, just like a scientific theory or a mathematical method isn't either. Contrary to the decision of the US Supreme Court (566 US (2012) - Mayo vs Prometheus), however, a technical teaching which teaches the use of a discovery to achieve a certain object, is patent eligible under European - and German - law, regardless of whether the teaching comprises an "inventive surplus" that goes beyond the purposeful use of the discovered law of nature. This is because **all technical activities rely on a purposeful use of laws of nature**. It is therefore inappropriate, when considering whether the technical teaching relies on an inventive step, to ignore the question whether the finding of the physical, chemical or biological relationship which forms the basis of the teaching of the invention was obvious for the skilled person."

While this decision merely confirms the well-established granting practice of the EPO, the BGH's direct reference to the US Supreme Court is somewhat outstanding.

It is also noteworthy that, in the eyes of the BGH, it is not necessary to designate a naturally occurring sequence as isolated. In the UK Patent Court's decision Monsanto v. Cargill, such restriction (which Monsanto had obviously used to render a sequence claim patent eligible), was construed to necessarily mean that the claimed DNA is separated from other molecular species and so being available for further manipulation.

Hence, because in that case, the *corpus delicti* DNA was mixed with soybean meal (hence not isolated), infringement was denied (see Issue 7/2011 of this Gazette). We can only speculate what had happened in case the term "isolated" had not been in the claims.

It should be addressed in this context that diagnostic methods as such are not patent eligible under the EPC. Unlike in the US, and in particular in the Mayo case, the rationale of this exclusion does not rely on a doctrine devoted to laws of nature or natural products, but merely to make sure that medical practitioners are free in the choice of their diagnostic approach.

The respective exclusion under Art 53 (c) EPC can be bypassed by leaving away, in the claim language at least one of the steps I – IV defined in Enlarged Board of Appeal (EBA) decision G1/04.

Euripta Website online

The website of our Pan-European IP alliance "Euripta" is now online !

Euripta is an alliance of four major law firms in different European countries, IPLodge, (Belgium) Kaminski (Poland), Corradini (Italy) and MHP (Germany). Find the website here.

Feedback please !

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

Archive

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Michalski · Huettermann & Partner are getting personal... Today: Euripta

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