The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 6/2016

Duesseldorf/Munich, **22 September 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. Ulrich reports about the 2nd ever compulsory license decision issued by the Federal Patent Court, and MH partner Torsten Exner discusses Tomato III – yet another BoA decision dealing with patent eligibility of plant-directed product-by-process claims.

Tomatoes III: The Question of Enablement

BoA dismisses further attacks on claims on Tomato obtainable by non-patent eligible method

At the EPO another decision on product claims directed to plant material such as fruits has been taken (T 1242/06), which further strengthens the value of a product claim for circumventing the exclusion of essentially biological processes from patentability under the EPC.

In March 2015, the Enlarged Board of Appeal at the EPO held in decision G 2/12 that the mere fact that Article 53(b) EPC excludes essentially biological processes for the production of plants from patent eligibility, does not negatively affect product claims. Even if the only method available at the filing date for obtaining the claimed product is an essentially biological process, it is only a method claim that falls under the patentability exclusion. Patent protection is nevertheless available for the obtained plant or plant material in the form of a product claim, as long as no plant variety is being claimed.

Proceedings then continued before the Board of Appeal, which had to decide on further objections raised by the opponent.

One question that remained to be answered was: is a product that has been obtained by an essentially biological process

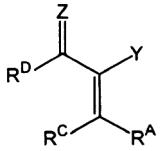
Compulsory license awarded to Merck

Federal Patent Court entered unchartered waters

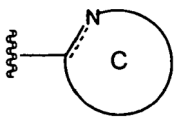
On August 31, 2016, the Federal Patent Court of Germany (BPatG) entered unchartered waters: For the first time in its 55-year history the court issued a compulsory license with respect to the use of a patent protected invention by way of a preliminary order.

In the respective case (3 LiQ 1/16), the Japanese pharma company Shionogi was ordered to grant a license to US company Merck with respect to Shionogi's European patent EP1422218B1, which covers, *inter alia*, Merck's HIV drug raltegravir.

Claim 1 as granted recites a markush formula with, inter alia, the following structure:



with R^A being a group shown by



The patent claims a priority of Aug 8, 2001, was granted March 21, 2012 and withstood subsequent opposition by Merck, while an appeal is now pending.

Raltegravir is a so-called integrase inhibitor. It does not cure infected humans, but prevents propagation of the HIV virus in a patient by

+ from our firm +

MH partner Ulrich Storz spoke at Boston Patent Law Association

MH partner Dr. Ulrich Storz was an invited speaker at a seminar of the Boston Patent Law Association (BPLA) organized by Boston Law Firm Nutter McClennan Fish LLP, on August 8, 2016. His talk was titled „Navigating EPO Case Law on Antibody Patents", and he spoke about a new database he has established in which all antibody-related decisions of the EPO Board of Appeal 3.3.04 are analyzed in great detail. Inquire here if you are interested in a copy of the slides.

Duesseldorf IP allstars rocked the scene

On August 26, a rock event took place on the terrace next to our office building which we called Duesseldorf IP allstars. We managed to assemble different bands and performers from the Duesseldorf IP community, and had a wonderful night with

after all enabled?

In this regard the opponent had in particular objected on the basis of the unpredictability of the process of meiosis. It stated that the patentee had only shown the crossing of two parent tomatoes, resulting in two hybrid plants, which in turn lead to a single plant with fruit falling under the product claim. Meiosis, the principle underlying the cross, would randomly determine the genetic make-up. Therefore, obtaining the product could not be repeated without undue burden. In addition, one of the parental lines used was proprietary, kept by the patentee as a trade secret, and had not been deposited according to the Budapest Treaty.

The opponent referred to the German landmark decision "Red Dove" (Federal Court of Justice of Germany, case X ZB 15/67), which had held that a necessary prerequisite for the patentability of an animal breeding method is its repeatability. The situation for the opposed patent would be the same as in the case "Red Dove", where the patentee had merely informed the public that it had developed a breading method, but did not reveal how to breed a new variety.

The Board of Appeal agreed with the opponent to the extent that meiosis is a random process, so that an exact repetition of the crosses described in the Working Examples of the patent was not possible for the skilled artisan.

What was decisive for the question of enablement, however, was whether there were substantiated and serious doubts that the skilled artisan was not put in a position to carry out the invention. Putting the skilled artisan in a position where he/she can carry out the invention did not require an exact reproduction of a tomato disclosed in the patent at issue. The relevant question in the context of sufficiency of disclosure was rather whether or not the patent in suit provided the skilled person with sufficient guidance and knowledge to produce tomatoes like those that are the subject-matter of the claims.

Starting from appropriate parental lines, the patent clearly disclosed how on the basis of appropriate crossing and

blocking the integration of viral DNA into cells.

In 2007, Merck was the first to obtain regulatory approval in the USA for raltegravir, which is marketed under the trademark Isentress®, and achieved in 2015 global sales of about 1.5 bn USD.

Isentress is said to have advantages in the treatment of pregnant women, new born children and newly infected patients.

Shionogi has developed dolutegravir (Ticay®), which was outlicensed to ViiV healthcare, which is a joint venture of GSK and Pfizer. In Germany, Ticay is approved for the treatment of adult and adolescent HIV patients aged 12 or over, but nor for children or infants.

Opposite thereto, Isentress is also approved for the treatment of children of 2 years or older and at least 12 kg body weight.

In 2015 Shionogi sued Merck at the Duesseldorf District Court for patent infringement, and demanded an injunction (case No 4c O 48/15).

As a response, Merck filed an action at the Federal Patent Court under § 24 and § 81 of the German Patent Act, to order a compulsory license under reasonable royalties. Further, Merck demanded a preliminary decision under § 85.

§ 24 sets forth that a compulsory licensee may be awarded to a petitioner if the latter has unsuccessfully tried to obtain a license from a patent proprietor, while the public interest demands such license.

§ 85 provides that compulsory licenses can be awarded by means of a preliminary order, provided that such license serves public interest.

Merck argued that an injunction would lead to severe consequences for those patients that have an Isentress prescription, because there would not be any suitable alternative medications on the German market. Merck emphasized, in particular, that there would not be any other approved integrase inhibitor suitable for the treatment of infants and children,

The court followed Merck's arguments not only with respect to the grounds for a compulsory license, but also with respect to the urgency Merck suggested.

The judges justified their decision with an urgent public interest. They further acknowledged that Merck had earlier offered 10 mn USD for a global license. Shionogi had denied that offer, and argued, in the proceedings, that, with Shionogi's dolutegravir and Gilead's adult drug elivitegravir (Vitekta®), two alternative treatments were already available.

The written decision is still pending, so the scope of the compulsory license is not yet public. One would assume that the scope only covers those patient groups which cannot be treated with dolutegravir. However, in a press release, the BPatG announced that Merck can

barbecue and drinks. Performers were "DJ D" aka MH partner Dirk Schulz, who was responsible for the warm up/chill out music. Then we had „Die Mychalskys" - a band consisting of members of our firm, plus district court judge Tilmann Büttner on the drums and Christof Augenstein from Kather Augenstein on the trumpet.

Martin Quodbach from CBH lawyers gave a comedy performance, and the trio "Prior Art" feat. Julia Wind-Falk from Sartorius performed a short singer/songwriter session

The night's top act were the "Swamp ‚n' Roll Ambassadors" feat. Olaf Giebe from Klaka Lawyers, who performed a Blues-Rock session.

We truly believe this was an unforgettable night, and hope for a revival next year.

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.

selection steps tomatoes in accordance with the claims could be obtained. When referring to the reasons of decision "Red Dove", it was emanating that in this aspect the facts of the present case differed from the situation of "Red Dove". A deposit in line with the Budapest Treaty was therefore not required.

After acknowledging novelty and inventive step, the patent was maintained on the basis of an auxiliary request. The main request had already been rejected as extending the protection relative to the granted claims in the Board's previous interlocutory decision, which referred questions to the Enlarged Board of Appeal. The Board, which had changed in composition, was thus bound by its previous decision.

In summary, it appears that no particular risk emerges for product claims circumventing the patent eligibility exception of method claims in terms of enablement. At least in the present case the fact that a biological process involves some degree of unpredictability could not shift the burden of proof to the patentee.

The burden of proof, which is upon an opponent, appears to be as high as for any other product claim. Pointing to a particular Working Example may be an expression of doubts, but according to case law, challenging enablement requires more substantiation than simply expressing doubts.

continue to offer Isentress in the scope of the dosage forms that have been on the market so far – whatever that means.

Shionogi can still appeal this case to the Federal Supreme Court (BGH), or demand a decision in non-preliminary proceedings.

In the corresponding infringement case, the oral hearing took place Sept 13, 2016. A decision is not yet published. We will keep you updated about it's outcome.

As said, this is the first compulsory license the BPatG has ever issued by way of a preliminary order under § 85, and it is only the 2nd decision in its history in which a compulsory license was granted at all.

It is important insofar as Shionogi, or its licensees, cannot be blamed to not have used the patent protected subject matter on the German market. It is only that said use did not cover all potential patients, with patients under 12 years of age not covered.

Shionogi emphasized that Ticay was actually on the market and hence denied a public interest. However, it appears that the judges did not find that potential use which can only be accomplished by off-label prescription would satisfy the requirements set forth under § 21 of the German Patent Act.

It is somewhat difficult to predict the consequences of this decision. Consider, e.g., originator A has a broad API patent, and has his drug candidate X only approved for a few indications, while originator B has a drug candidate Y which falls under the API patent of orgininator A, but is approved for different indications. Would, in such a situation, the BPatG grant a compulsory license to originator B, at least for those indications which are not drug candidate X is not approved for, because treating this indication would serve oublic interest ? This would largely undermine the concept of absolute compound protection.

Unfortunately, because this is only the second decision by the BPatG so far, it is difficult to see where the court's red line is.

Interestingly, drug originators have a split relationship to compulsory licenses, in particular after Bayer's kinase inhibitor sorafenib (Nexavar®) became subject of a compulsory license in India.

In a press release of 2008, Merck announced that they would „respect that compulsory licenses may be issued, under limited and specified circumstances, to meet a health crisis or emergency", while such authority „should be used only in the most extraordinary and limited circumstances". Merck further said that they would „work vigorously in the interests of meeting health needs to discourage the compulsory licensing of Merck medicines."

EURIPTA® EEIG is getting personal... Today: William Bird (IPLodge)

William Bird was educated at Queen's College, University of Cambridge, UK. He has an MA in Natural Sciences, majoring in Physics. He has worked in the major industrial activities of development, marketing, product and project management, from which he has obtained a wide experience of the requirements and functioning of an industrial company. He also has exceptional experience in a wide range of technologies.

William is a Chartered Electrical and Electronic engineer. He is experienced in the design of underground high voltage power cable and cable accessories (1 kV to 500kV AC or DC cable and accessory design) and in energy distribution systems. He had responsibilities, for example, in the manufacture of the aluminum sheathed high pressure oil filled 500kV cable for the 690 MW Grand Coulee Dam Third Power Plant. He has been involved in many energy distribution cable projects in the Middle East, Africa and the UK.

William Bird has nearly three decades' experience in the IP field. He started his career as a patent attorney at Hoffmann & Eitle (München) and temporarily switched over to industry (3M Europe) before founding the successful patent firm Bird Goën & Co. in Belgium, where he remained active until the acquisition of the firm by the Gevers Group. From May 2012 unitl Septemper 2015, William worked in law office Patentive in Düsseldorf, Germany. William joined IPLodge in September 2015.

He is a member of the Board of the Licensing Executives Society (LES) Benelux Chapter, where he is an accredited tutor and participates in the organization of the annual Advanced Licensing Course. He is an approved instructor in Intangible Asset Management and is a Certified Patent Valuation analyst.

William is a qualified British, German and European patent attorney and hence has a unique expertise in both common law and civil law systems. He is also a British trademark agent and a registered professional representative before OHIM, the European trademark and design and office. William's native language is English, and his secondary working language is German. He also has a passive knowledge of Dutch.

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