The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 1/2015

Duesseldorf/Munich, **31 March 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, we discuss the recent decisions issued by the enlarged Board of Appeal, G 2/12 and G 2/13 (MH Partner Dr. Andreas Hübel), and G3/14 (MH Associate Dr. Torsten Exner)

Patentability of plants obtained by essentially biological processes

Decisions G 2/12 and G 2/13 of the Enlarged Board of Appeal

On March 26, 2015 the Enlarged Board of Appeal (EBA) at the EPO published its eagerly awaited decision on the patentability of plants and plant product obtained by an essentially biological process.

Pursuant to Article 53 (b) EPC, essentially biological process for the production of plants are excluded from patentability. In their interluctory decisions G 2/07 (Broccoli) and G 1/08 (Tomato) the EBA clarified that any non-microbiological process for the production of plants which consists or contains the steps of sexually crossing the whole genomes of plants and subsequently selecting plants is excluded from patentability as being "essentially biological" within the meaning of Article 53 (b) EPC unless such a process includes a step within the sexual crossing and selection which introduces a new trait into the genome or modifies a trait in the genome of the offspring.

In the absence of any guidance as to whether products of essentially biological processes remain patentable, the proprietors pursued product-by-process claims seeking protection for plants or parts of plants, wherein the process said plants are obtainable from is an "essentially biological" process within the meaning of Article 53 (b) EPC.

Briefly, numerous amicus curiae briefs were submitted, and also the President of the EPO commented in writing and at the oral proceeding which were held on October 27, 2014. The President concluded that Article 53 (b) EPC does not have a

Enlarged Board of Appeal calls Appeal Board off on Clarity

Decision G 3/14 lays down return to customary practice

On March 26, 2015 the Enlarged Board of Appeal (EBA) at the EPO published its eagerly awaited decision on the admissibility of clarity attacks in *inter partes* proceedings. It held that after grant an examination of the requirements of Article 84 EPC, i.e. clarity and support by the description, can only commence if an amendment introduces this issue, i.e. when it did not previously exist. The examination of the requirements of Article 84 EPC is then limited to the extent that a lack of clarity or support has been introduced by the amendment. According to its own explanations, the EBA thereby takes a position at the extreme end of the spectrum.

Under the EPC a lack of clarity is not a ground for opposition. After grant, improving clarity is also not a valid reason for amending the claims. Nevertheless Article 101(3) EPC stipulates that the Opposition Division needs to assess whether the patent meets all the requirements of the EPC. Unsurprisingly, there have been continued attempts by opponents to use this Article for bringing in clarity attacks against vague features in granted claims through the back-door, and in a few proceedings they were successful.

Already in decision G 9/91 the EBA confirmed that in opposition or appeal proceedings amendments (but only amendments) have to be "fully examined as to their compatibility with the requirements of the EPC". In other words, assessment on Article 84 EPC is not being closed for good once a patent is granted, if amendments are filed, these amendments have to be examined in this regard.

This approach reflects what can be regarded as the established line of case law; it has been applied by an overwhelming number of decisions at the EPO. It is therefore not surprising that this

+ from our firm +

8th Rhineland Biopatent Forum – still vacancies available !

As already reported, the 8th Rhineland Biopatent forum has been scheduled for May 21, 2015.

We have again gathered an excellent panel of speakers, including 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), and Randall A. Rader, (former Chief Judge of the CAFC).

The topics will include a review of antibody patent jurisdiction in the US, a personal retrospective to 25 years of antibody protection in Europe, criticism on the new EU Regulation on Biodiversity and the Nagoya protocol, IP strategies in the biobased economy, and a critical review on recent decisions

negative effect on the allowability of product claims to plants or plant material.

In both cases, the EBA found that Article 53 (b) explicitly refers to processes and does not permit an exception of patentability of a product claim, not even as a result of a broad reading of the process exclusion. Moreover, it would introduce an inconsistency into the EPC system if the scope of process exclusion would be broadened to the extent that the exclusion would include also the products obtained by essentially biological processes.

In addition, the EBA realized that a distinction needs to be made between aspects of patentability and scope of protection conferred by European patents.

Despite the various ethical, social, and economic aspects in the general debate associated with the instant cased, the EBA did not see any need or legal justification to alter the understanding of Article 53 (b) EPC achieved by applying the traditional means of interpretation.

Finally, the EBA concluded that the exclusion of essentially biological processes for the production of plants in Article 53 (b) EPC does not affect allowability of product claims directed to plants or plant material such as plant parts or fruits. Even if the plant or plant material is claimed by means of a product-by-process claim, wherein the process steps define an essentially biological process for the production of plants, the claim is not rendered unallowable under Article 53 (b). This does not change even though an essentially biological process was the only process for the production of plants available at the filing date of the patent.

It is not relevant for these claim's allowability that the protection conferred by such product claims encompass the generation of the claimed product by means of an essentially biological process for the production of plants excluded as such under Article 53 (b) EPC.

It is interesting in this regard, that revision of the German patent law with legal effect of January 01, 2014 explicitly excludes plants from patentability that are exclusively produced by essentially biological processes (§ 2a (1) 1). Although the German legislation wanted to have plants and plant material that is exclusively produced by an essentially biological process excluded from patentability, they were not able to do so in view of the recent EBA decisions, because European patents may be granted for such subject matter. These European patents may be validated in Germany, but the legal provisions (IntPatÜG) do not permit revocation of the German part of a European patent for violating § 2a (1) 1. Thus, using the European way rather than a national German application may secure the inventor's interests in Germany despite the national legal provisions.

approach has now officially received the "approved" stamp from the EBA.
The approach traces back to decisions as old as T 308/87, where it was held that clarity attacks cannot be raised if they do not arise out of amendments made.

The established approach was fundamentally put into question in the year 2013 by a Board of Appeal (BoA) in decision T 459/09. The Board *de facto* held that any amendment would in principle justify a complete examination for the compatibility of a claim with regard to the requirements of the EPC. Subsequent decision T 409/10 even made this view "*established jurisprudence*". Parties in appeal proceedings then repeatedly tried to have this issue brought before the EBA, which finally resulted in the present decision. Decision T 459/09 has now de facto been dismissed as incorrect by the EBA.

The EBA notes, marking with the "disapproved" stamp, that there have been (very few) deviating decisions were amendments that "bring into notice" an already existing ambiguity were taken to permit an assessment on Article 84 EPC. Disapproved are also rare deviating decisions were a claim was rejected as unclear, because an added ambiguous feature was the only feature that might distinguish the claim from the prior art.

It is also established case law at the EPO that only claim amendments based on disclosure in the description are open to clarity attacks. In contrast, including an entire dependent claim - or only a feature of a dependent claim - into an independent claim does not open examination on clarity. Let alone can any of the other claims be examined for clarity/support. This approach has now not only received the "approved" stamp. According to the EBA anything else would mean "opening Pandora's Box", making Article 84 EPC a ground for opposition.

The EBA also accepts that "it is not optimal" that claims can remain in granted patents although they are unclear. However, it notes that the legislator deliberately excluded clarity and support from the grounds for opposition. In an attempt to shed some light on the reasons the EBA looks at the historic background. It comes to the conclusion that at least one of the reasons was that enablement was considered largely adequate to deal with the problem, a comprehension apparently shared by the EBA. As a side note, the same can be said of the BoAs. For example in decision T 430/10 of last year it was held that an ambiguous feature has to be construed in its broadest reasonable meaning, and that enablement was required over the entire resulting scope of the claim. The submission by the president of the EPO that the reason for omitting Article 84 from the grounds for opposition was "to streamline opposition proceedings" is regarded probably correct by the EBA.

In summary, the EBA has put the kibosh on attempts to water down the established approach of restricting clarity attacks after grant to amendments that introduce something new into the claims. Anything else would have had large-scale consequences, reaching not only into the examiner's approach during prosecution, but also into drafting applications and filing/prosecution strategy.

by the CAFC and the Supreme Court in the last three years.

Further, MH partners Dr. Hübel and Dr. Storz will speak about actual issues of Biotech IP.

Like always, participation is free of charge. We have still vacancies available ! Please apply directly by email here.

MH partners on tour

MH partner **Dr. Andreas Hübel** will attend the annual German Biotechnology Days on April 22 and 23 in Cologne. Contact Andreas here if you would like to schedule a meeting.

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

MH associate **Dr. Torsten Exner** will meet with his co-markers of a Marking Committee at the EPO in Munich on April 13 and 14 to fix the final marking scheme for this year's EPO bar exam. Thereafter he will attend the events "Guidelines2day and Article 123(2) EPC" and "Examination Matters" at the EPO in The Hague on April 15-17.

Feedback please !

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: Dr. Christoph Volpers

Christoph Volpers holds a PhD in Molecular Biology from the University of Mainz and an MBA from Bradford University, UK. He is (co-)author of about 20 scientific publications in the areas of molecular virology, gene therapy, antibodies and signal transduction.

After holding various research positions in academia and industry, also in USA, Christoph Volpers has been working in patent and licensing management in the biopharmaceutical industry for more than ten years. For the last six years, he was Director IP Biologics of the Teva ratiopharm group with global responsibility for managing and coordinating all patent and licensing activities in the areas of biosimilars and innovative biopharmaceutical products; this included portfolio management, freedom-to-operate activities, project evaluation and IP support for all ongoing development projects.

Christoph Volpers has joined Michalski & Hüttermann in early 2015. He speaks German and English. You can contact him under cv@mhpatent.de.

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