The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 1/2011

Duesseldorf/Munich, **07 August 2013** 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 actual decisions issued by European Patent authorities for the Biopatent community, and provide expert insight into what's going on behind the scenes. In this issue, Dr. Andreas Hübel reports on the recent joint decisions (G 2/07 and G 1/08) which concern the exclusion of essentially biological processes from patent protection. Dr. Claudia Meinken und Dr. Ulrich Storz give insights into recent decisions related to Supplementary Protection Certificates.

„essentially biological processes" clarified ?

EPO decsions G 2/07 and G 1/08 issued

On December 09, 2010 the Enlarged Board of Appeals (EBA) of the European Patent Office (EPO) released their joint decisions with respect to „essentially biological processes for the production of plants". In its joint decisions G 2/07 (Broccoli case) and G 1/08 (Tomato case), the EBA elucidates what kind of processes for producing plants are excluded from patentability under Article 53(b) EPC as being essentially biological processes, and attempts to clarify the expression „essentially biologically". See the respective decision here.

Upon interlocutory decision T 85/05 the Technical Board of Appeal (TBA) referred the following questions to the EBA: does a non-microbiological process for the production of plants which contains the stages of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as further step or as part of any of the steps of crossing and selection, an additional feature of a technical nature? In case this question is answered in the negative, the TBA wanted to know what the relevant criteria for distinguishing non-microbiological plant production processes that are excluded from patent protection under Article 53(b) EPC from those processes not-excluded. In particular, the TBA wanted to know whether it is relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level.

Very similar question were referred to the EBA by interlocutory decision T 1242/06, namely does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants fall under the exclusion of Article 53(b) EPC only if these steps reflect and correspond to phenomena which could occur in nature without human intervention? If not, does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as part of any of the steps of crossing and selection, an additional feature of a technical nature? When the latter question is answered to the negative, the TBA asked for the relevant criteria for distinguishing non-microbiological plant production processes that are excluded from patent protection under Article 53(b) EPC from non-excluded ones.

SPCs under increased scrutiny

Iodosulfuron and Erbitux cases

Two recent decisions have again made clear how important a correct match between patent, marketing authorization and the respective product is to successfully obtain SPC protection.

On Nov 11, 2010, the European Court of Justice (ECJ) ruled in Case C 229/09 ("Iodosulfuron") that a provisional authorization is sufficient under Art 3(1)(b) of EU Regulation 1610/96 for the issuance of an SPC.

Lovells Rechtsanwälte had filed an action before the Federal Patent Court (BGH) for revocation of SPC DE10075026, protecting Bayer's herbicide iodosulfuron and some of its salts and esters, which is still protected under EP Patent 0574418, filed Feb 12, 1992.

Said SPC has been granted July 17, 2003, for the period between patent expiry and March 9, 2015. For the calculation of the SPC lifetime, a market authorization of March 9, 2000 was considered as the first authorization. However, this was a provisional authorization under Art 8(1) of EU Directive 91/414, which provides a transitional solution for the temporary authorization of new active substances being in a state of Evaluation, and which have not been on the EU market by July 27, 1993. Said provisional authorization was only later followed by a definitive market authorization (Jan 13, 2005).

+ from our firm +

4th Rhineland Biopatent Forum will take place May 16, 2011

Michalski · Huettermann & Partner Patent Attorneys are delighted to announce that they will again host the "4th Rhineland Biopatent Forum" on May 16, 2011.

Guest speakers will include William E Bird from Bird Goen & Co in Leuven, Belgium, Colin Sandercock from Perkins Coie in Washington and Markus Ambriosius from Sträter Rechtsanwälte, Bonn.

Colin Sandercock, who is listed as one of the "Best Lawyers in America in the field of biotechnology law" will discuss KSR, Bilsky, BRCA, Ariad, J&J vs. Abbott, and Therasense, and tell us what we can learn from the most influential US decision of the past two years.

Markus Ambrosius will give an introduction to data exclusivity and market exclusivity, and their interplay with patent protection. Markus will take the

The EBA answered the referrals to the end that a non-microbiological process for the production of plants are in principle excluded from patentability under Article 53(b) EPC as being "essentially biological" within the meaning of this legal provision as long as said process either consists of or comprises the steps of sexually crossing the whole genomes of plants and of subsequently selecting progenitors. No additional step of technical nature which serves to enable or assist the performance of sexually crossing the whole genomes of plants of the subsequent selection of progenitor plants can overcome the processes exclusion of patentability under Article 53(b) EPC, regardless of whether said additional step of technical nature is known or new, trivial or a fundamental alteration of a known process. The EBA provides that claims shall not, explicitly or implicitly, include the sexual crossing and selection process when concerning an additional technical step which is performed either before the crossing or after the selection. However, if a process non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of said trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC.

Despite that the EBA did not provide a clear and direct definition of "essentially biological processes" it clarified that purposeful alteration of a plant's genome, for example by inserting a gene into the genome of said plant or by modifying one or more genes of said plant as such is no essentially biological process, and that a process comprising sexual crossing the whole genomes of plants, then introducing a trait into or modifying a trait of the genome of the progenitor plant, and subsequently selecting the resulting progenitor plants does not fall under the exclusion of patentability according to Article 53(b) EPC. Whenever no purposeful human intervention in the plants genomes is performed between pollination and selection of the progenitor plants, the process is an "essentially biological process" in the meaning of Article 53(b) EPC, and is thus excluded from patentability.

Notably, the EBA introduced the expression "sexually crossing the whole genomes of plants" into their decisions. This expression was not present in the referrals. As no definition is provided by the EBA, in particular no definition of "whole genome", one may guess whether "the whole genome" is restricted to the nuclear hereditary information of the plants or whether it also comprises non-nuclear hereditary information such as the mitochondrial DNA. One may also consider that the genome of a given progenitor plant is not the mixture of the whole genomes of the parental plants as the gametes are obtained after meiosis where the nuclear hereditary information is bisected. Anyhow, processes for sexually crossing and selecting plants wherein definitely not the whole genomes of both plants are involved are not covered by the EBA's decisions and appear to be patentable under Article 53(b) EPC, although it is doubted that this was the intention of the EBA.

The decisions G 2/07 and G 1/08 on essentially biological processes for the production of plant was appreciated by the biotechnology industry as wall as by breeders. For example BIO Deutschland, the German biotechnology association, stated that the decision of the EBA provides biotechnology companies with planning certainty when filing patent applications and seeking for patent protection as patent allocation remains possible for inserting a feature into the genome of a plant or altering a plant's genome by methods of genetic engineering. The German Plant Breeders'

Lovells argued that the SPC was invalid under EU Regulation 1610/96, Art. 3(1)(b), according to which an SPC may be issued only after a definitive market authorization has been issued under the conditions set forth in Art. 4 of EU Directive 91/414. The market authorization of March 9, 2000 for iodosulfuron was a provisional one according to Art 8(1) of said directive, Lovells went on, and thus not a sufficient basis for grant of the said SPC. Bayer objected this view as being contrary to the practice of the national authorities.

The BGH referred this case to the ECJ and asked for a preliminary ruling with respect to the problem whether (i) the marked authorization required for the issuance of an SPC under Art 3(1)(b) of Regulation No 1610/96 has to be a definitive one under Art 4 of Directive 91/414, or (ii) if a provisional authorization under Art 8(1) of said directive is sufficient. On Nov 11, 2010, the ECJ ruled in Case C 229/09 that Art 3(1)(b) must be interpreted in such way that said provisional authorization suffices. The text of the decision can be found here.

Another case leads us to the UK, where the High Court of Justice declared two SPCs invalid (case [2010] EWHC 1733 (Pat)). The decision, which dates from June 2010 already, is related to a combination therapy. Israel company Yeda had a patent (EP0667165) for Cetuximab ("Erbitux") and uses thereof, claim 1 of which recited a therapeutic composition comprising a monoclonal antibody and an anti-neoplastic agent, while claim 2 covered separate administration of said components, and claim 6 related to a swiss type use of the monoclonal antibody and the anti-neoplastic agent.

The responsible EU agency granted market authorization in June 2004, for use of Erbitux. The clinical details described the authorized product as 'Erbitux in combination with Irinotecan ... for the treatment of patients with... (EGFR) expressing metastatic colorectal cancer".

Yeda filed two SPC applications in the UK ('037 and '038). The '037 application related to Cetuximab in combination with

escitalopram case as an example, as all of us are well aqcuainted with the parallel patent decisions

William E. Bird will discuss the recent Monsanto decision by the ECJ, which is highly controversial due to the new interpretation of the compound protection concept.

Speakers from our firm will contribute, too, and discuss recent decisions in European Patent Law.

Inquire for a full program here.

Forum-Seminar "Basiswissen Patente für F&E-Mitarbeiter" on March 31, 2011

Dr. Ulrich Storz, Senior Partner of the firm, will contribute to the seminar "Basiswissen Patente für F&E-Mitarbeiter" organized by Forum Management GmbH on March 31, 2011.

Find further information on this seminar here.

Humira decision revoked

In Issue 2/2010 we reported about the Humira decision under which Abbott had been sentenced, to pay about $1.67bn in damages to centocor. This decision has been revoked on Feb 23, 2011, by the US Court of Appeals for the Federal Circuit, based on considerations that Abbott's humira, which is a fully human antibody, does not make use of Centocor's patented technology, which was for a chimerized antibody.

The decision will be discussed later this year in an issue of "mAbs" edited by Janice Reichert.

Inquire here for a reprint.

Association also welcomed the decisions of the EBA as confirming that conventional breeding processes are not patentable, but that the results of conventional breeding processes remain solely subject to plant variety protection.

However, the decisions of the EBA on exclusion of essentially biological processes for producing plants raise serious concerns with respect to obtain protection for plants and plant varieties that are not the direct result of genetic engineering but that based on sexual crossing and selection, and which only differ in physiological features rather than in morphological features from other varieties of the same species. Note that the broccoli case (G 2/07) concerns a process for producing broccoli containing elevated levels of particular glucosinolates. Glycosinolates are compounds proposed to be beneficial in protecting against cancer. The claimed method is not patentable according to the instant decision of the EBA as being essentially biological within the meaning of Article 53(b) EPC. The claimed process comprises crossing wild *Brassica oleracea* species selected from the group consisting of *Brassica villosa* and *Brassica drepanensis* with broccoli double haploid breeding lines, and backcrossing selected plants having elevated glycosinolate levels compared to those of the broccoli double haploid breeding lines. It may or may not be that the resulting *Brassica oleracea* is morphologically distinguishable form other broccoli varieties and that plant variety protection can be obtained for these varieties. But the morphology of the resulting *Brassica oleracea* is not the gist of the invention. The gist is the elevated glycosinolate level. Given that the resulting *Brassica oleracea* does not meet the criteria for obtaining plant variety protection, i.e. being among others distinguishable, no plant variety protection can be obtained. This is an unacceptable legal gap as there is no doubt that the originator of said resulting *Brassica oleracea* should be eligible to some economic exclusivity for his intellectual property.

Mainly for historical reasons, plant variety protection is provided for morphologically unique plant varieties as examination of new varieties is base on descriptive variety lists. Those lists almost exclusively consist of morphological features, and it is upon the examining Office's discretion to consider physiological features in the examination of new varieties. It is apparently necessary to amend the legal provisions for plant variety protection in that physiological features can equally well be used to distinguish a new plant variety from already existing ones. Thereby, the legal provisions for plant variety protection will be adapted to current and future developments in plant production. For practical reasons, the applicant has to define the physiological feature of relevance, and may also be requested to provide a method of determining said physiological feature such that no undue obstacles remain for the examining Offices.

Irinotecan. This application was refused because the market authorization was for Cetuximab only. The SPC application did thus not comply with Article 3(b) of Regulation 1768/92, since the SPC was not for the product for which authorization was granted.

The '038 application, which related to Cetuximab only, was also rejected because Cetuximab alone was not the invention protected by the patent according to Art 3(a) of the Regulation, which requires that the product be protected by the patent.

Yeda appealed both decisions. With respect to the '038 application, Yeda argued that the therapeutic composition as claimed in Claim 6, would in fact take place inside the patient's bloodstream, putting everybody who supplies Erbitux without Yeda's consent into secondary infringement.

Both appeals were eventually dismissed, because, in the view of the High Court, "what constitutes a product must be strictly construed, looking at what it is, rather than what it does, and taking into account only its active ingredients." Further, the authorization identified only Erbitux as its subject-matter. The additional discussion in which Irinotecan was mentioned served only to explain how Erbitux was used. This alone, however, could not be considered a marketing authorization of a combined product.

See the full text of the decision here.

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. Claudia Meinken

Claudia Meinken was born in 1965 in Bremen, Germany. She studied Chemistry and Biochemistry and received a degree in Chemistry at Münster University in 1991. After several years of research in biotechnology she received her PhD at University of Hohenheim in Stuttgart in 1996. Since 1996 Claudia Meinken is working in the field of intellectual property. Since 2002 she is European Patent Attorney. In 2010 she was accredited as German Patent Attorney. During her professional career Claudia Meinken worked for different multinational companies in Germany and abroad. She has gathered in-depth experience in pharmaceutical sector as well as in the food and steel industries. She joined Michalski Hüttermann in 2010.

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