

The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys

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Duesseldorf/Munich, 15 October 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, MH partner Andreas Hübel draws your attention to a recent decision of the Technical Board of Appeals at the EPO (T 1729/06) providing a distinguished analysis of what was deemed to be an essentially biological process for the production of plants with respect to seedless watermelons – right ahead of the oral proceedings to be held on October 27, 2014 in cases G 1/12 (Tomato II) and G 2/13 (Broccoli II). MH partner Ulrich Storz discusses lessons learned in the afterplay of the Myriad decision.



A fruit is not a plant

Fruitful considerations on essentially biological processes

European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application ([Article 52 \(1\) EPC](#)). One of the exceptions to patentability are essentially biological processes for the production of plants or animals ([Article 53 \(b\) EPC](#)). A better understanding of the fuzzy term “essentially” has been provided by the Enlarged Board of Appeals in their decisions [G 2/07](#) and [G 1/08](#), better known as the “Broccoli case” and the “Tomato case”. The Enlarged Board of Appeals ruled that:

1. A 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 is in principle excluded from patentability as being „essentially biological“ within the meaning of Article 53(b) EPC.
2. Such a process does not escape the exclusion of Article 53(b) EPC only because it contains, as a further step or as a part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.
3. If, however, such a process 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.

The Myriad afterplay

New USPTO Guidance, and what do Australia and Europe say ?

The ones of you who attended the 7th Rhineland Biopatent Forum in June 2014 have had the opportunity to listen to Andreas Hübel's brilliant talk about the experiences we made with the new USPTO examination policy after the US Supreme Court decision [Association for Molecular Pathology v. Myriad Genetics](#) 569 U.S. 12-398 (herein called “Myriad”), plus the subsequent discussion with Hans Sauer, who is BIO's chief intellectual property counsel.

For those who haven't: In Myriad, Justice Clarence Thomas found that “a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring.”

Justice Thomas went on by stating “that genes and the information they encode are not patent eligible (...) simply because they have been isolated from the surrounding genetic material”

You may have heard that this decision sent shockwaves through the entire Biopatent community. While we still tried to anticipate the consequences of this decision, and how far they go (in particular, we wanted to know in how far this decision affects the patent eligibility of therapeutic proteins, like antibodies, or antibiotics etc., that have been isolated from nature, e.g., from a human donor, or from a tropical fungus), the Commissioner for Patents of the USPTO issued, on March 04, 2014 the so-called “Guidance for determining subject matter eligibility of claims reciting or involving laws of nature, natural phenomena, & natural products”, which can be found [here](#).

Said guidance suggests that subject matter claimed must be “substantially different” from the Judicial Exceptions, the latter being laws of nature/natural principles, natural phenomena; and/or natural products“, in order to be patent-

+ from our firm +

First MH Patent Seminar takes place Nov 6, 2014

Next to the Rhineland Biopatent Forum, which has become a well-established event in the last years, Michalski Huettermann & Partner Patent Attorneys will establish a second series of seminars devoted to general topics of IP.

We are proud to announce that the first edition of this series will take place Nov 6, 2014, in our office in Düsseldorf.

We have been able to recruit external speakers, among them Michael Gollwitzer, Head of Corporate IP Support at Siemens AG, and David Kappos, former director of the USPTO, now with Cravath, Swaine & Moore LLP.

Michael Gollwitzer speaks about the challenges Inhouse IP divisions face

Briefly summarized, a process for producing plants is an essentially biological process – and thus excluded from patentability under Art. 53 (b) EPC – if the hereditary information of a plant is not (purposely) altered by human intervention in the period between fertilisation and the end of a subsequent selection of offsprings.

The dispute said decisions of the Enlarged Board of Appeals should have settled went on, because product-by-process claims reciting essentially biological processes were maintained. For resolving the discrepancy between non-patentability of essentially biological processes for the production of plants (and - due to the scope of product claims - thereby the products directly obtained from said process, i.e. a plant) on one hand and patentability of plants produced by means of an essentially biological process (which by itself is not patentable), the broccoli case and the tomato case were brought before the Enlarged Board of Appeals a second time.

On October 27, 2014 oral proceedings will be held in Tomato II and Broccoli II, such that we will have – hopefully- more clarity with respect to the patentability of plants that are obtained/obtainable by means of essentially biological processes.

In view of the forthcoming oral proceedings in G 2/12 and G 2/13, it was interesting to recognize that the Technical Board of Appeal 3.3.04 issued its decision in case [T 1729/06](#) wherein the applicant appealed against the refusal of its European patent application 03 744 126.8 by the Examining Division for being directed to essentially biological processes for the production of plants. However, the author appreciates the differentiated and distinguishing view of the Technical Board of Appeals.

European patent application 03 744 126.8, entitled “Enhanced pollinizer and method for increasing seedless watermelon yield”, included four independent claims which were submitted on April 07, 2006. Said four independent claims were directed to i) the use of a diploid water melon plant ... in a process of producing triploid seedless watermelon fruit ...; ii) a method for producing triploid, seedless watermelon fruit ...; iii) a method of increasing the yield of triploid, seedless watermelon plants ...; and iv) another method of increasing the yield of triploid, seedless watermelon plants.

The independent claim directed to a method for producing triploid, seedless watermelon fruit reads:

- A method for producing triploid, seedless watermelon fruit comprising the steps of:
- planting a field with rows of triploid watermelon plants;
 - planting said field with rows of diploid watermelon plants comprising a gene e and small fruits in a size range of between [sic] 0.9 to 3.2 kg with a brittle rind breaking under pressure in the range of 90 to 150 g/mm²; and
 - allowing pollination of said triploid

eligible, and has a couple of examples of patent eligible subject matter and non-patent eligible subject matter after Myriad.

However, it is our experience, that, in pending US applications related to Biotech inventions, the frequency of objections for non-patent eligible subject matter (also called objections under 35 U.S.C. § 101, or “101 objections”) has increased, with quite a few of them relating to inventions that formerly would have been considered patent eligible (because they are far from being related to plain products of nature).

But there is light at the end of the tunnel: It appears that the USPTO has listened to user’s concerns, because a new Guidance has been announced recently that will replace the current version, and is envisaged for the end of this year.

In its announcement, the USPTO claims they agree that § 101 should be a “low hurdle” and both structural and functional differences should be considered when analyzing claims to so-called natural products.

On this background, it may be wise that the ones of you struggling with unjustified 101 objections postpone responding to the respective office action until the new Guidance is public.

Interestingly, European Patent Law holds material isolated from nature patent eligible. Rule 27 (a) EPC sets forth that Biotechnological inventions shall also be patentable if they concern biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature; while Rule 29 (2) EPC states that an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

Ahhh, that’s Europe as we like it. But still, you may want to avoid the term “an isolated nucleic acid” in your claims, because it appears that some judges may take this term too literal, by referring rather to the actual status of the nucleic acid and not to the process of isolating the DNA from nature.

In case [Monsanto vs. Cargill, \[2007\] EWHC 2257 \(Pat\)](#), the UK High Court denied that an “isolated nucleic acid” claim was infringed, because the *corpus delicti* was a soybean meal that comprised said nucleic acid, which initially had been isolated from *Agrobacterium tumefaciens*.

In the decision, Justice Pumfrey stated that the “isolated nucleic acid”, as claimed, was only present in the laboratory, but not in the transformed plants, and even less in the meal derived from them.

It is thus probably a good idea not to use the term “isolated” in your sequence claims, even if such sequence has initially been isolated from nature.

Let me add one further thing: On September 5, 2014, the Full Federal Court of Australia upheld the validity of Myriad Genetics’ Australian patent directed to isolated DNA sequences covering BRCA1 gene in decision [D’Arcy v Myriad Genetics Inc.](#)

when major changes of the IP portfolio are to be effected.

David Kappos will present a perspective on Changes to the US Patent System Brought on by Recent Supreme Court Decisions, Federal Circuit Decisions, and USPTO Post-Grant Review Decisions.

Further Panelists are Shenping Yang und Guangjie Li, Beyond Attorneys at Law, China, who speak about Effective Patent Enforcement in China.

The panel is completed by speakers from our firm who will give an update on recent developments in case law and the unitary patent.

If you would like to attend the seminar, or want to learn more, contact us [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](#).

watermelon plants by pollen of said diploid watermelon plants to obtain triploid, seedless watermelon fruits.

Although the method steps in the other method claims are not identical, I refrain from repeating the entire claims for the reason of conciseness. The full wording of the other method claims can be found [here](#).

The Examining Division refused all claims - as well as the claims of an auxiliary request filed during oral proceedings - as unpatentable under the provisions of Article 53 (b) EPC since their subject matter were essentially biological processes for the production of plants.

In its decision, the Technical Board of Appeals set the refusal of the application aside and remitted the case to the Examining Division for further prosecution on the merits.

In its thorough analysis, the Technical Board of Appeals recognized that triploid watermelon plants are male and female sterile, and that a pollinizer plant - in the instant case the specific diploid watermelon plant - is required for pollination. The pollination, i.e. the transfer of pollen from an anther (male part) to a stigma (female part) of a plant, thereby enabling fertilization, is essential for the triploid watermelon plant to produce its fruit, whereas the fertilization of the triploid watermelon plant is not necessary for the triploid watermelon plant to produce its fruits.

Thus, the Technical Board of Appeals emphasized that the claims are directed to those steps in the production process of seedless watermelons which involve the planting/growing of the triploid and diploid plants, the pollination of the triploid female flowers by the diploid pollen and the development of the seedless watermelon fruit on the triploid plant. Briefly, the method aims at the production of triploid seedless watermelon fruits on existing triploid watermelon plants, but not at the creation of any genetic make-up of any plant produced as a result of meiosis (according to G 2/07, essentially biological processes are characterized by the fact that the traits of the plants resulting from the crossing are determined by the natural phenomenon of meiosis). The Technical Board of Appeals concluded that the use and the methods of above-identified claims are not such methods which the Enlarged Board of Appeal considered as falling under the exclusion of "essentially biological processes for the production of plants" pursuant to Article 53 (b) EPC in their decisions G 2/07 and G 1/08.

The Technical Board of Appeal then provides its further considerations on the exclusion of essentially biological processes according to Article 53 (b) EPC in the light of G 2/07 and G 1/08.

First, the Technical Board of Appeals emphasized that the Enlarged Board of Appeal did not provide a comprehensive and exhaustive definition of the subject matter to which the process exclusion in Article 53 (b) EPC applies in relation to plant inventions.

Second, the seedless, triploid watermelon fruit

In their decision, the judges held that isolating a DNA sequence involves more than just taking it out of a cell. Rather, the judges continued, these sequence products were different compared to the gene comprising the sequence as it exists in nature, involving structural and functional changes, and thus constitute patentable subject matter.

The following citation makes clear that the Court expressly rejected the conclusion of the U.S. Supreme Court,

"What is being claimed is not the nucleic acid as it exists in the human body[...]. The claimed product is not the same as the naturally occurring product. There are structural [...] and functional differences because of isolation."

You see, there is hope. And, there is a P.S. In fact, there is two:

P.S.: Consider an antibody isolated from a human donor. Assume said antibody is useful for the treatment of, say, a neurodegenerative disease, and has the potential to become a real blockbuster.

In light of the above, you may run into problems when trying to obtain a patent on such antibody in the United States, which means you would have to claim a method of treatment in which such antibody is used, or claim a structurally modified version thereof. Not first choice if you ask me.

But, have you ever considered to claim it's cDNA ? remember that Myriad held cDNA patent eligible.....

P.P.S. On Oct 6, 2014, the CAFC held an oral hearing in *University of Utah v. Ambray Genetics Corp.*, [Fed. Cir., No. 2014-1361](#). In the underlying case, Ambray Genetics had announced to sell discount versions of a BRCA test. Not surprisingly, University of Utah and Myriad Genetics were not amused, and filed suit at the District Court of Utah.

The court rejected the request for a preliminary injunction, because it found that claims to primers (or synthetic DNA) and method claims were patent ineligible according to the Supreme Court's guidance in *Myriad*, as they were not markedly different from naturally occurring DNA, thus extrapolating the supreme Court's benchmark to even synthetic non-cDNA.

Myriad and the University of Utah appealed to the CAFC. In brief, the appellant argued that the district court improperly dissected the discovery out of the method claims, stressing that the claim must be examined as a whole as an ordered combination of all elements, eligible and ineligible.

Ambray argued that primers and probes are merely segments of DNA which according to the Supreme Court are not patentable subject matter, as the latter decided that cDNA that is indistinguishable from the genomic DNA is not patent eligible.

The judges raised different issues: Judge Prost said the Supreme Court's decision requires to set

resulting from the claimed use and methods constitutes biological material pursuant to Rule 26 (2) EPC, and are - in principle – patentable in view of Article 52 (1) and Rules 26 (3) and 27 EPC. As such the resulting seedless, triploid watermelon fruit is not explicitly and a priori excluded from being a patentable invention under the EPC.

Third, due to the legislative history, the legislator did not have the intention to exclude a whole class of inventions, i.e. horticultural or agricultural processes, from patentability, but only wished to exclude those process aspects from patentability which are applied by plant breeders and for the result of which a special property right is available (the plant variety protection).

So what is next? Definitely the decisions of the Enlarged Board of Appeal in in cases G 1/12 (Tomato II) and G 2/13 (Broccoli II). It will be interesting to see whether the Enlarged Board of Appeal shares the view of the Technical Board of Appeal as set forth in T 1729/06 or not. We will keep you posted.

aside the abstract idea or law of nature in a claim to determine if what remains, examined as a whole, adds anything of significance.

Judge Cleverger emphasized that the claims were to a laboratory-made cDNA, and that the BRCA1 probe used in the method was new.

The main question seems however: If, in the light of Myriad, products of nature are not patent eligible, are at least methods of using them (like, e.g., medical indications), patent eligible? If not, drugs isolated from nature to use as, e.g., antibiotics, will likely become history, because no patent equals no exclusivity equals no incentive to go through cost-intensive approval.

We expect a decision in this case with bated breath. An audio recording of the oral argument can be found [here](#).

Michalski · Huettermann & Partner are getting personal... Today: Guido Quiram

Dipl.-Ing. Dipl.-Wirt. Ing. Guido Quiram, born in 1972, graduated in Electrical Engineering, Information Technology, Business and Eco-nomics from RWTH Aachen University in 1997.

Before starting his IP career with Michalski · Hüttermann & Partner in 2007, Guido Quiram worked almost a decade as a development engineer, technical expert and project manager for American, Swiss and German technology corporations in both Switzerland and Germa-ny. In 2010 he was admitted as German patent attorney as well as European trade mark and design attorney and in 2011 as European patent attorney. Guido Quiram is listed as a frequently recommended patent attorney in German JUVE-Handbuch issues 2011/2012, 2012/2013 und 2013/2014.

Guido Quiram´s activities cover all aspects of industrial property rights in the fields of electronic and information technology, especially telecommunications, software related inventions, electrical and mechanical engineering, process engineering, optics and laser, as well as in the fields of trademarks and designs. Since his prosecution and litigation portfolio includes major international corporations, he is excellently equipped and experienced to provide the requisite global perspective for all prosecution, enforcing and nullification matters of the respective IPRs. He speaks German, English and Spanish.. You can reach him by email under gq@mhpatent.de.



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