

The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys

Issue 6/2011

Duesseldorf/Munich, 18 November 2011 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 we give an interim report on the status quo of the Resumed Tomato and Broccoli cases after the EBA decision, and we report on the HGS vs Eli Lilly decision issued recently by the UK Supreme Court.



Resumed Tomato and Broccoli cases remain enigmatic

TBA proceedings are continued in writing, one case re-referred to EBA

In Issue 1/2011 of the Rhineland Biopatent Gazette we reported about the outcome of cases G 2/07 ("Broccoli case") and G 1/08 ("Tomato case"), according to which the Enlarged Board of Appeal ("EBA") decided on Dec 9, 2010 that non-microbiological processes for the production of plants are in principle excluded from patentability under Article 53(b) EPC as being "essentially biological", as long as said processes either consist of or comprise the steps of sexually crossing the whole genomes of plants and of subsequently selecting progenitors.

However, both patents not only comprised method claims, but also claims directed to a broccoli or tomato plant as such. The Technical Board of Appeal ("TBA") therefore resumed both proceedings and had to decide about the patentability of the latter.

In the Broccoli case, the patentee had filed a main request on May 3, 2011, in which all breeding method claims were excluded, while product claims and product-by-process claims ("pbp") were maintained in amended form, plus an auxiliary request, in which all product-by-process claims were deleted, merely leaving two product claims behind.

Claim 1 of the main request reads as follows:

1. An edible Brassica plant produced according to a method for the production of *Brassica oleracea* with elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, which comprises:
 - (a) crossing wild *Brassica oleracea* species selected from the group consisting of *Brassica villosa* and *Brassica drepanensis* with broccoli double haploid breeding lines;
 - (b) selecting hybrids with levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, elevated above that initially found in broccoli double haploid breeding lines;
 - (c) backcrossing and selecting plants with the genetic combination encoding the expression of elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates,

HGS gets Court nods for industrial application

But argumentation may corrode inventive step

The UK Supreme Court has, on Nov 2, 2011, revoked the High Court's decision according to which Human Genome Science's patent EP939804 was invalid in the UK.

The patent has claims related to nucleic acids encoding for Neutrokin- α , and an antibody that binds specifically to the latter. Neutrokin- α is a member of TNF- α superfamily, and was novel at the time of filing, but no experimental data were given in the specification which supported a potential therapeutic use. The only data related to the cloning and expression of the cytokine in established expression systems (examples 1 – 3) and to the tissue distribution of Neutrokin- α mRNA (example 4).

In August 2008, the UK High Court referred to Directive 98/44/EC and found the UK part of the patent invalid for lack of industrial applicability, insufficiency and obviousness ([2008] EWHC 1903 (Pat)).

A few months later, an opposition division of the European Patent Office (EPO) found the European Patent as a whole invalid for lack of inventive step. This decision was revoked in appeal proceedings in September 2009, when the Technical Board of Appeal (TBA) judged that the tissue distribution data suffice to provide a valid basis for an industrial application and may be used to develop appropriate means and methods for diagnosis and treatment. Further, the board found that the available prior art (i.e.: known EST sequences plus pipeline screening technologies) was not sufficient to render the claimed subject matter obvious, in terms of enabling the skilled person to recognize the claimed sequence immediately and successfully retrieve it (decision T0018/09).

+ from our firm +

MH Patent's one stop validation of EP patents now available for 14 EPC member states

Finland has joined the London Agreement on Nov 1, 2011. From now on, European Patents which are in English can be validated in Finland by filing a translation of just the claims into Finnish. If the patent is in German or French, it is sufficient to file an English translation of the specification together with the Finnish claims.

Hence, Finland is the 14th EPC member state which applies for MH Patent's unique one stop validation service.

This service, which our firm offers to our clients for about two years now, takes advantage of the fact that many EPC member states do not require a national representative for EP Patent validation.

MH Patent's one stop validation service provides the validation of European Patents in Germany, United Kingdom, France, Switzerland, Denmark, the Netherlands, Sweden, Ireland, Austria, Hungary, Finland, Monaco,

or both; and
(d) selecting a broccoli line with elevated levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, capable of causing a strong induction of phase II enzymes.

and is therefore a true product-by-process claim. Claim 1 of the auxiliary request, which corresponds to claim 4 of the main request, reads as follows:

1. A broccoli plant having elevated levels of 3-methylsulfinylpropyl glucosinolates, or 4-methylsulfinylbutyl glucosinolates, or both, wherein the broccoli plant is a hybrid plant following crossing of broccoli double haploid breeding lines with wild *Brassica oleracea* species selected from the group consisting of *Brassica villosa* and *Brassica drepanensis*, and the levels of 4-methylsulfinylbutyl glucosinolates, or 3-methylsulfinylpropyl glucosinolates, or both, are between 10 and 100 µmoles per gram of dry weight of said plant.

The two opponents declared their consent with both requests made by the patentee by Oct 2011, and requested oral proceedings only in case the board decides not to admit either the main request or the auxiliary request.

The TBA thus cancelled the oral hearing scheduled for Oct 26, 2011 and announced that the decision will be issued in writing – a step which anticipates that the Board will either allow the main request or the auxiliary request. Bets can still be placed, but it is our feeling that the auxiliary request could make the race because it has no PbP features.

Oral proceedings in the Tomato case took actually place on Nov 8, 2011. The patentee had filed different requests most of which comprised only product claims, with the exception of auxiliary request 6, which comprised product-by-process claims.

The main request was as follows:

1. A tomato fruit of the species *Lycopersicon esculentum* which is naturally dehydrated wherein natural dehydration is defined as wrinkling of skin of the tomato fruit when the fruit is allowed to remain on the plant after a normal ripe harvest stage, said natural dehydration being generally unaccompanied by microbial spoilage.
2. A tomato fruit of the species *Lycopersicon esculentum* characterized by an untreated skin dehydration of the fruit and wrinkling of the skin, said dehydration being generally unaccompanied by microbial spoilage.

According to auxiliary request 1, claim 1 was identical to the main request and claim 2 read as follows:

2. A dehydrated tomato fruit of the species *Lycopersicon esculentum* characterized by an untreated skin which permits said dehydration of the fruit so as to obtain wrinkling of the skin, said dehydration being generally unaccompanied by microbial spoilage.

In contrast to the Broccoli case, PbP claims were no longer pursued. The opponent requested revocation of the patent, or, alternatively, that the following questions of law be referred to the EBA:

- a) Is a claim which is not directed to an essentially

In response to a motion of the UK Court who requested an acceleration of the EPO appeal proceedings in January 2009 to have that appeal decided prior to the UK appeal hearing, the TBA further expressed its consent with the Court's request that in parallel proceedings before a national court and a TBA, parties should inform both tribunals of the position as early as possible and ask the appropriate tribunal for acceleration in order to avoid duplication of proceedings. However, the TBA announced that such acceleration requires a certain degree of discipline by all parties, and can have no effect on the equal treatment of all Parties, nor can it confer any advantage on any party.

Turning back now to the UK Supreme Court decision, the Court overturned the High Court's verdict and thus brought UK's jurisprudence related to allegedly speculative nucleic acid applications back in line with EPO's case law.

A great deal of the decision is devoted to policy issues, particularly with respect to the specific interests of the biotech industry, namely in a clear, consistent and certain law in general, and the possibility to file patent applications at an early stage in particular.

Further, the judges philosophize on the purpose of the patent system as such, and state that even people who are sceptical about the value of intellectual property rights accept that there is a public interest in patent protection in the pharmaceutical field – quite an optimistic conclusion in view of the anti-patent movements emerging everywhere nowadays.

Last, but not least, the decision focuses almost exclusively on the requirement of industrial application (Art 57 EPC), and addresses inventive step issues only shortly. In this context, the judges' argument that "experiments are not needed if sufficient information is provided in the description, when common general knowledge is taken into account, to show that [...] a profitable use can readily be identified", which is meant to support the conclusion that the patent meets the requirement of industrial application, can be a dangerous one, as the very same reasoning can be used to develop an argumentation against sufficiency of inventive step.

Before this background, it would be interesting to learn how the German Patent Courts would consider this case if the patent was subject of an invalidity action. It is generally considered that the inventive step bar set by the German Courts is higher than that set by their UK counterparts (see, e.g. the Inventive Step Consultation survey of 2007 published by the UKIPO, which can be found [here](#)) – while court proceedings in Germany come at a significantly lower price tag than in the UK.

Luxemburg and Iceland without involving a national representative.

This results in considerable cost reductions, which, combined with the waiver of translations under the London Agreement, kills at least part of the cost-related pain involved with the validation of European Patents.

In case you are interested in our unique one stop validation service, or would like to have a quote, please contact us [here](#).

MH partner **Dr. Ulrich Storz** has published an article on international patent strategies in the journal "mAbs". The article titled "International intellectual property strategies for therapeutic antibodies" appears in mAbs 3 (6), 2011. Please ask for a reprint [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](#).

biological process per se as defined in Art 53 (b) EPC and G1/08 patentable, if such claim would render inoperative the exclusion from patentability as defined in G01/08 ?

- b) Is a claim patentable if such claim is directed to a plant, fruit, seed or any other part of an essentially biological process as defined in Art 53 (b) and G01/08 if such claim would render inoperative the exclusion from patentability as defined in G01/08 ?
- c) If such claim is patentable which other requirements are there to be met ?
- d) If such claim is patentable which other requirements are there to be met to escape the exclusion from patentability as defined in G01/08 ?

According to the minutes of the oral proceedings, which come without any statement of grounds and can be found [here](#), the Board rejected the main request, and decided to continue the proceedings in writing with auxiliary request 1. In a press release issued later that day the EPO announced that the Board intends to again refer questions of law to the EBA.

The two cases remain enigmatic. We will keep you updated about the further developments.

Michalski Huettermann & Partner are getting personal... Today: Dr. Cersten Bethke

Cersten Bethke, born 1969, studied physics at the University of Duesseldorf. He achieved his Diploma degree as well as his Doctorate at the Institute for Applied Physics at the University of Duesseldorf, both in the field of electron spectroscopy. Afterwards he worked as a scientific member of an interdisciplinary group in a Life Science project in Duesseldorf for three years.

Cersten Bethke started his IP career in a patent and law firm in Stuttgart in 2005. In 2008 he was admitted as a German Patent Attorney and joined Michalski Huettermann & Partner. In 2011, he has been registered in the list of representatives before the European Patent Office.

His main fields of expertise are in the fields of telecommunication, power engineering, automation, automotive engineering, as well as optics and lasers. He works as well in the field of Trademarks and Design. He works on prosecution, nullification and enforcing of the respective intellectual property rights.

He speaks English and German fluently and has basic knowledge of French. You can contact him under cb@mhpatent.de



M I C H A L S K I · H Ü T T E R M A N N & P A R T N E R

Imprint: Michalski · Huettermann & Partner Patent Attorneys, c/o: Dr. Ulrich Storz
Neuer Zollhof 2 - 40221 Düsseldorf - Tel.: +49 (0)211 159 249 0 - Fax: +49 (0)211 159 249 20 – email: st@mhpatent.de

The information provided herein reflect the personal views and considerations of the authors. They do not represent legal counsel and should not be attributed to Michalski · Huettermann & Partner Patent Attorneys or to any of its clients.