The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 7/2011

Duesseldorf/Munich, **05 December 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 provide 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, William E. Bird, Principal of Bird Goen Co in Leuven, Belgium, with whom we are connected by our pan-european legal association (see "from our firm"), throws a second eye on the Monsanto decision by the EPC. MH associate Julia Wind-Falk reports on the recently issued decision G2/10, which clarifies so far enigmatic issues of disclaimers before the EPO..

The Monsanto decision of the ECJ – a postscriptum

About a year has passed since the European Court of Justice (ECJ) has issued his decision in the notorious Monsanto Case ("Monsanto vs. Cefetra" C 428/08). The discussion triggered controversial discussions in the Biopatent community. Now that the gunsmoke has disappeared, it seems that the time for a second sight has come.

In the respective decision, the ECJ has defined the limitations of compound protection in patents relating to gene sequences.

Claim 6 of Monsanto's EP 0 546 090 related to a DNA-Sequence coding for a class II EPSPS enzyme, selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO: 5.

The DNA in question was found in trace amounts in soy meal, imported into the Netherlands from Argentina. The soy meal had been derived from soy bean harvested from Monsanto's RoundUp Ready variety of soybean plant. The DNA sequence at issue encoded for a glyphosate tolerant synthase, which conferred resistance upon soybean plants to certain herbicides, including RoundUp. This sequence is patented in Europe, including The Netherlands, but not patented in Argentina. As imported, the DNA was in essentially dead material (the soy meal) where the DNA was no longer being expressed. The presence of traces of DNA appears to have been an artefact of the harvesting and processing methods employed.

The ECJ had to interpret Art. 9 of the Biotech Directive with respect to the question of the import of the soy meal into Holland:

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material in which the product in incorporated and in which the genetic information is contained and performs its function.

The ECJ argued that if absolute product protection existed (i.e. DNA treated as if it were a chemical

EBA takes biotech case to clarify pending disclaimer issues

In the decision G2/10, which issued Aug 30, 2011, the Enlarged Board of Appeal (EBA) of the European Patent Office (EPO) has published another ruling regarding the allowability of disclaimers for original disclosed subject-matter.

The underlying question referred to the EBA was: "Does a disclaimer infringe Article 123(2) EPC (added subject-matter) if its subject-matter was disclosed as an embodiment of the invention in the application as filed?"

The technical background of this case is located in the field of biotechnology. The patent application in suit was EP 0981646 A1 assigned to Scripps Research institution.

The subject-matter of claim 1 discloses endonucleases with substrate binding regions of a generic formula disclaiming specific sequences for the binding region.

The application was refused in February 2007 due to non-compliance with Art 123 (2), as comprising subject matter not originally disclosed.

Scripps appealed this decision, and in the oral proceedings, which took place in June 2010 the Technical Board of Appeal (TBA) decided to refer a question of law to the EBA, namely, whether or not a disclaimer infringes Art 123 (2) EPC if its subject matter was disclosed as an embodiment of the invention in the application as filed.

In its ruling, the EBA defined the word "embodiment of the invention" as everything being subject-matter of the

+ from our firm +

MH Patent announces successful foundation of European patent law firm.

MH Patent in Duesseldorf, Germany, and Bird Goen Co in Leuven, Belgium, are delighted to announce that they have successfully founded a new European Corporation devoted to IP counselling.

The new Corporation runs under statutes set forth be the European Council for a new type of European Corporation called European Economic Interest Group ("EEIG").

We are now in a process of name finding and acquiring members from other EU countries.

Under this corporation, we are now in position to offer improved and optimized services in all aspects related to European Patent law, and Patent law of the different member states. Further, all members of the EEIG have access to increased manpower and a higher degree of specialized expertise, in order to address the higher demands which

product) then there would be no need for this provision as the EPC effectively granted this right to the patent owner anyway. In fact the ECJ erred in this assessment.

The ECJ held that with respect to the "dead" non-expressing DNA in the soymeal:

"such a sequence does not…enjoy patent right protection …neither Article 9 or any other provision thereof accords protection to a patented DNA sequence which is not able to perform its function."

The ECJ also held that "It follows that the harmonisation effected by Article 9 must be exhaustive."

The analysis of the ECJ would appear to be clearly erroneous. If we examine the wording of Art. 64(2) EPC and Art. 9 of the Biotech Directive there is a clear similarity:

Art. 64(2) EPC:

If the subject matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process.

Art. 9 Biotech Directive:

The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material., in which the product in incorporated and in which the genetic information is contained and performs its function.

One would assume that the phrase shall be interpreted in the same way for both provisions. Applying the ECJ opinion to Art. 64(2) EPC, namely that this language is indicative of an exhaustive provision, then Art. 64(2) EPC would grant patent infringement only and exclusively to the direct product of the process and not to the method itself. This is clearly erroneous – and hence so is the ECJ when it applies such an exhaustive interpretation to Art. 9 of the Biotech Directive.

Instead one must assume that both Art. 64(2) EPC and Art. 9 Biotech directive extend or add to the protection already provided by Art. 69 EPC. If this were not so, then the EPC would have had to be amended (especially Art. 69 EPC would have needed clarification) when the rules derived from the Directive were added to the EPC.

It is perfectly possible to interpret Article 9 in a way that is consistent with an extension of the protection conferred while maintaining all rights previously derived from Art. 69 EPC. Article 9 covers the case where DNA is incorporated into a foreign host. Biotech inventions differ from chemical cases because the addition of DNA to a host cell does not automatically result in expression. The new combination is not necessarily enabled by the patent if the elements required for expression, e.g. a promoter, are not disclosed. One can argue that no protection is conferred on such a non-enabled combination. Article 9 does not refer to sufficiency or enablement - meaning that it is a provision which overrules any sufficiency requirement and grants protection to combinations of host cells and DNA that are not enabled by the patent.

Accordingly, Article 9 of the Biotech Directive can be interpreted to give a patent owner a significant extension or addition to scope of protection when one takes sufficiency and novelty into account as it provides an extension to hosts for which the expression is not enabled by the patent. This extension leaves Art. 69 EPC unchanged.

application as filed.

This definition goes along with the term "subject-matter" as used in Art. 123 (2) EPC.

Former decisions of the Board (G 1/03 and G 2/03) found that a previously 'undisclosed' disclaimer may be allowable in order to:

- restore novelty by delimiting a claim against state of the art under Article 54(3) and (4) EPC;
- restore novelty by delimiting a claim against an accidental anticipation under Article 54(2) EPC - an anticipation is accidental if it is so unrelated to and remote from the claimed invention that the person skilled in the art would never have taken it into consideration when making the invention; or
- disclaim subject-matter which, under Articles 52 to 57 EPC, is excluded from patentability for non-technical reasons.

However, G 1/03 and G 2/03 are silent on disclaimers on disclosed subject-matter.

Let´s give two examples:

1. The application discloses subject-matter ABC with embodiments for ABCD, ABCE and ABCF. Due to prior art, applicant included a disclaimer on ABCE which is correct due to the fact, that ABCE is explicitly present in the application.
2. The application discloses subject-matter A with B as embodiment, which means A minus B might be also implicitly disclosed.

With respect to example 2 the EBA speaks well of a "logical complement" approach. In consequence a claim on A disclaiming B might be sufficiently disclosed.

The jurisdiction of the TBAs however varies, e.g. T1050/99 defines B as part of the invention and as such not excludable, whereas T1068/07 sees A minus B as logical complement implicitly disclosed and a disclaimer on B allowable.

The Board summarized that the allowability of such disclaimers should be assessed under normal added subject-matter procedure. Thus, such disclaimers may be allowed at the EPO. In establishing the allowability of such a disclaimer. One will have to assess particular projects make.

We will keep you updated about all further progresses.

MH associate has published an article about the ECJ judgement in stem cell case

MH associate Dr. Andreas Hübel has published an article in the "Mitteilungen der deutschen Patentanwälte" about the recent decision of the ECJ in the Brüstle stem cell case. Andreas comments that the ECJ has interpreted the term "human embryo" as encompassing totipotent cells. Although embryonic stem cells do not qualify as totipotent, the ECJ excludes them from patentability because for the production embryoes have been destroyed, even if this took place years ago and the claimed cells have only been derived from . said stem cells. The ECJ leaves it to the national courts whether they want to expand the term "embryo" also to pluripotent cells – which could render induced pluripotent stem cells (iPS) unpatentable in EU member states. Please ask for a reprint of this article here.

5th Rhineland Biopatent Forum to take place on May 31, 2012

MH Patent announce that the 5th Rhineland Biopatent Forum, will take place on May 31, 2012. Issues on the agenda are, among others, inventive step requirements set forth by the EPA for new therapeutic antibodies, and the changing legal framework with respect to the patentability of plants.

Again, we have invited highly expertised speakers which will make this Forum a true worthwhile event for IP professionals from small and large Biotech enterprises.

The finalized program will be available soon. In case you would like to

The ECJ appears to have interpreted Article 9 of the Directive without due care and has not avoided consequences which plainly conflict with fundamental concepts of national patent legislation such as prior user rights, novelty and sufficiency, as had been warned by Kamstra et al (2002) previously.

whether the skilled person would, using common general knowledge, regard the remaining claimed subject-matter as being directly and unambiguously disclosed in the application as originally filed, either explicitly or implicitly.

The full text of the decision can be found here.

attend, or contribute, please inquire 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: Philip Gehrig, B. Eng.

Born and raised in Melbourne, Australia, Philip Gehrig studied mechanical engineering at the University of Melbourne and was admitted to the degree of Bachelor of Engineering with Honours in 1991. In that same year he joined one of Australia's largest and most-respected patent attorney firms, where he qualified as an Australian Patent Attorney in 1997 and was later elevated to Associate of that firm. After an initial stay with a German patent attorney firm in 2000, he returned to Germany in 2003 and qualified as a European Patent Attorney in 2007.

His practice in Europe is primarily focused on patent rights, with particular emphasis on patent drafting and prosecution, as well as on opposition and appeal proceedings before the European Patent Office. The main technical areas of his practice include medical technology, such as surgical instruments, diagnostic systems, medicament delivery devices, prostheses and implants, as well as automotive technology, such as vehicle clutch and braking systems, and solar technology, such as solar panel mounting systems.

Philip Gehrig is a registered European Patent Attorney, a registered Australian Patent Attorney, a registered Australian Trade Marks Attorney and a registered New Zealand Patent Attorney. He is a member of the Institute of Professional Representatives before the European Patent Office (epi), a member of the Association Internationale pour la Protection de la Propriété Intellectuelle (AIPPI), a Fellow of the Institute of Patent and Trade Mark Attorneys of Australia (IPTA) and has been active in the field of intellectual property since 1991.

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