

## Monsanto Soy Bean Patent Cases— A Paradigm Shift Gathering In Case The ECJ Takes Over Patent Jurisdiction

By Ulrich Storz and Aloys Huettermann

Recently, two patent disputes have attracted public interest not only due to the fact that Monsanto, one of the favourite evildoers of the anti-patent movement, was involved, but also because different jurisdictions in Europe, namely the Advocate General of the European Court of Justice (ECJ) and the UK High Court, have appraised the cases differently, although with similar outcome. The following article gives a short overview of the dilemma, and the paradigm shift which could arise should the opinion of the Advocate General prevail.

### 1. The Opinion of the Advocate General of the European Court of Justice (ECJ) (*Monsanto vs. Cefetra C 428/08*)

The respective case is related to the import of soy bean meal from Argentina to the Netherlands. The meal has been produced from genetically modified soy beans originally provided by Monsanto, and grown in Argentina. Interestingly, the said soy beans carry a DNA sequence which provides a resistance against Monsanto's Roundup herbicide.<sup>1</sup> While Monsanto has no patents protecting the said soy beans in Argentina, a respective patent is in force in Europe.<sup>2</sup>

For this reason, Monsanto had tried to sue the importer, Cefetra BV, for patent infringement in the Netherlands,<sup>3</sup> among others, on the basis of the following claim:

6. An isolated DNA sequence encoding a Class II EPSPS enzyme selected from the group consisting of SEQ ID NO: 3 and SEQ ID NO:5.

Monsanto held that this claim is infringed by the imported soy bean meal as the respective DNA sequences can be found in the meal, at least in traces.

The Dutch court (Rechtbank's-Gravenhage) has referred the case to the ECJ, as it found that the respective legal issues require an interpretation of the Biopatent Directive.<sup>4</sup> The ECJ's Advocate Gen-

eral, Paolo Mengozzi, has delivered his non-binding pleading on 9 March 2010, in which he opined, among others, that the protection for a patent relating to a DNA sequences is limited to situations in which the genetic information is currently performing the functions described in the patent.

This opinion, and the argumentation provided, are in fact noteworthy, as they challenge some general principles related to the protection of biological sequences, and to compound matter as such.

#### 1.1. Some General Aspects

The Advocate General has rightfully stated that the fact that Monsanto is unable to obtain patent protection for their inventions in Argentina cannot be remedied by extending the patent protection in the European Union.

Furthermore, it is reasonable to argue that when, as it is the case here, a DNA sequence is a mere impurity in a given product, the patent protection related to said DNA sequence comes to an end. Otherwise, one could argue that products made from said soy bean meal, or livestock being fed with said soy bean meal, would still infringe the said patent in case the DNA sequence could still be detected in the latter.

The Advocate General has moreover correctly stated that there is no *de minimis* provision in the Directive which limits or exclude protection relating to DNA sequences which are present only in variable quantities. The problem of patent protection for cases in which the claimed matter is comprised in another matter as a mere impurity can thus not be solved on the basis of the provisions set forth by the Biopatent Directive.

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1. DNA encodes for an enzyme called "5-enolpyruvylshikimate-3-phosphate synthase."

2. EP0546090B1.

3. Parallel cases were, or are, pending in the UK, Denmark and Spain.

4. Directive 98/44/EG.

## 1.2. The Function Requirement of Art. 9 of the Biopatent Directive

For this reason, the Advocate General has tried to address this issue by referring to the function requirement, as it is recited in Art. 9 of the Directive, according to which

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

It is to be mentioned that the term “function” is recited six times in the text of the Directive. Three times the term relates to the function of the internal market, or to the function of a patent as such, while three times the term is mentioned in connection with a claimed DNA sequence. However, the Directive fails to properly specify, or define, the term “function,” like the Advocate General, who, in his opinion, does not define said term either.

Biologically speaking, the function of an encoding DNA sequence can be performed in different ways:

- One function is to merely provide a *blueprint for the construction of a physiologically or structurally functional protein*. This means that, by its mere existence, an encoding DNA sequence fulfils this function already, even if it is comprised in a physiologically inactive environment, like processed soybean meal, or when the soy bean is stored, for example in a silo.
- Another function is to *actually perform such blueprint function*, i.e., when the protein is being produced. For such purpose, a functional protein expression apparatus is required, which can for example be provided by a viable soy bean.
- Yet another function is to simply store a genetic information for future generations, when the latter could become relevant (e.g., for a period of drought).

Despite the fact that the meaning of the term “function,” as used in the Directive, is far from clear, the Advocate General seems to feel able to conclude that, in the soy bean meal which is the subject of the present case, the DNA sequence comprised in the meal does not perform any function at all, thus denying, to said meal, the protection conferred by Art. 9 of the Directive.

In some kind of *obiter dictum*, the Advocate General tries to pour oil on the troubled water, by stating that the requirement of Art. 9 does not mean that the respective gene must always be active, or “switched on,”

in order to enjoy the protection under Art. 9. If the latter applied this would mean, e.g., that in a transgenic soy bean which is stored in a silo, and where the resistance gene is not needed and thus “switched off,” the genetic information would not perform its function, and would thus not be protected by Art. 9.

Such interpretation, the Advocate General admits, would go too far, and he bases this statement on the thesis that, under the Directive, a DNA sequence performs its function in the meaning of Art. 9 when: (i) it is within live matter of which it forms part; (ii) it is transmitted when the live matter reproduces itself; and (iii) it performs the function for which it was patented, either continuously or on the occurrence of specified circumstances.

Unfortunately, the respective clarification of the function requirement is not part of the Directive or its recitals, nor can it be found elsewhere. The said statement has therefore some brisance, as it can be understood as a fit occasion for the ECJ, or other courts, to interpret Art. 9 in a stricter sense. This, of course, would in some way open Pandora’s box.

A drug, for example, which comprises a nucleic acid (i.e., a product as such, but a carrier of genetic information in the meaning of Art. 9 as well) performs its function (if function is defined physiologically) when administered. When still in the shelf of a pharmacy it does not perform such function, and would, in case Art. 9 is interpreted in a stricter sense, not be protected by the patent which was meant to protect it.

## 1.3. Absolute Compound Protection

What is even more striking is that the Advocate General concludes from recitals 22, 23 and 24 as well as from Article 5(3) of the Directive, which define the requirements of patentability (i.e., not the scope of protection the granted patent provides), that, in the European Union, a claimed “DNA sequence has no importance in the context of patents if the function performed by that sequence is not indicated.”

Despite the fact that this wording is somewhat vague, this is a remarkable statement, particularly without defining what a sequence’s “function” actually is.

In his opinion, the Advocate General reveals a strong attitude against the concept of compound protection, not only in the field of biosequences, but for compounds as such, e.g., by stating that “to maintain that a DNA sequence enjoys traditional patent protection [...] would mean that patents would be recognised as covering functions as yet unknown at the time of the patent application,” which [...] “would ultimately, in practice, make a mere discovery patentable, in breach of the basic principles on patents.”

What the Advocate General bewails here is, however, a well established principle not only in European caselaw, according to which a new compound can enjoy absolute protection in case the applicant has provided evidence that the compound has a technical effect (see, e.g., decision T939/92).<sup>5</sup> This principle applies both for synthesized new chemical entities as well as for compounds isolated from nature. Although the Directive requires, in Art. 5 (3), that an industrial application of a claimed gene sequence must be disclosed in the patent application in order to make the sequence patentable, this requirement does not mean that, as stipulated by the Advocate General, the scope of protection of the respective sequence claim is restricted to the said application only.<sup>6</sup>

Luckily, the ECJ and the EU administration have, so far, only restricted access on European patent law, namely for fields in which a respective Directive exists. Currently, this applies only for Biotech inventions.<sup>7</sup> Should the Advocate General succeed with his opinion, this would have drastic effects on the patenting of Biotech inventions. However, such ruling would have no general effect on the protection of chemical compounds as such, or even on inventions from other disciplines, as, so far, ECJ can only decide on Biotech inventions, where the Biopatent Directive exists.

## 2. The UK High Court Decision (*Monsanto vs. Cargill*, [2007] EWHC 2257 (Pat))

In this parallel case, Justice Pumfrey decided that the importation of the said soybean meal to the UK does not infringe any claims of the respective patent.

Interestingly, his argumentation is completely different from that of the Advocate General, as it is mainly based on the fact that Monsanto had failed to properly define the term “isolated” in “an isolated DNA sequence.” This gave Justice Pumfrey full freedom to generate a *de novo* interpretation of this term,

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5. The concept of compound protection has further been developed for cases in which a known substance has, for the first time, been described for a medical indication. According to established caselaw, the applicant will receive protection for all medical indications, even for those which he has not described or did not know.

6. Note that Germany (and France) have overfulfilled the requirements of the Directive when implementing the latter into the national law, by requiring that the industrial application is recited in a claim related to human sequences. This provision implements a real purpose-bound protection for such sequences, but can easily be bypassed by prosecuting the patent before the EPO rather than before the GPTO.

7. A proposal for a software patent directive has been rejected by the European parliament in 2005.

which he did as follows:

“72. *This is a surprising word to use when the ultimate destiny of the gene is to be incorporated in the genome of a plant to be inherited by future generations upon which it will confer Round Up resistance. It is quite inappropriate to refer to a sequence present in a genome, even if that sequence is exogenous.*

77. *I conclude that in the claims the word “isolated” has precisely the meaning [...] “separated from other molecular species in the form of a purified DNA fragment”.*”

From these considerations, Justice Pumfrey concluded that in a soy bean meal comprising a DNA sequence, said sequence is not present in an isolated form. Monsanto had probably used the term “isolated” to anticipate objections against the patentability of the claim (see Art. 5 (2) of the Directive, which states that an element isolated from the human body, including the sequence of a gene, may constitute a patentable invention).

Despite Justice Pumfrey’s understanding, the said term is commonly used in patent language to designate a DNA sequence which has been isolated from an organism and transferred into another organism (see, e.g. US20090176254, US6225045, or WO2004039943).

In a quite sophisticated approach, however, Justice Pumfrey deduced that all claims reciting an isolated sequence were not infringed by the imported soybean meal, which was the *corpus delicti*. Other claims related to a Class II EPSPS enzyme were not considered to be infringed for other reasons not important in this context.

Unlike the Advocate General, Justice Pumfrey did not address questions of compound protection. However, he addressed the *de minimis* issue as well, and came to a similar solution as the Advocate General, namely that there is no legal provision to solve such issue. However, he sees, in this dilemma, no question of patent infringement (which, provided other requirements are met, must be confirmed even when the sequence is present only in residual traces), but only a question of causative damage.

Furthermore, Justice Pumfrey did not mention the Directive 98/44 even once. This may probably be due to the fact that the said Directive came into force in June 1998, i.e., after the priority date of the patent in suit, so that the court found it is not applicable. This opinion is, however, in stark contrast to that of the Advocate General, who opined, in his pleading,

that the Directive should as well be applicable on a patent that was granted before the Directive came into force.

As an aside, the problem which arises from Justice Pumfrey's interpretation of the term isolated is that each additional matter in a DNA sample, be it a contamination, an additive or even mere water, could be interpreted as destroying the isolated state of the DNA. This would mean that claims reciting an isolated DNA could no longer be enforced, as the respective samples always contain some kind of additional matter.

### 3. Conclusion

While the UK high court decision has some sophisticated aspects, it is still within the boundaries of current caselaw. The opinion of the Advocate General, however, is fully contrary to the current granting practice of the EPO, and to the established understanding of compound protection.

That author can't help but think that, in a motion to dampen the increasing importance of patents related to Biosequences, and particularly to address Monsanto and their controversial patent enforcement strategy, the Advocate General has gone too far. Should his opinion be confirmed by the ECJ this would be a model case for the motto "Bad Cases Make Bad Law."

The author hopes that the ECJ will take this opportunity to clarify the meaning of the term "function," particularly as set forth in Art. 9 of the Directive, and make sure that the concept of compound protection will prevail, not only for biosequences, but also as such. However, history tells us that in most cases the ECJ subscribes to the opinion of the Advocate General.

The present case shows the consequences which arise once the European Union gets their hands on patent matters—a sector which has, in Europe, so far been under the exclusive competence of the European Patent Office, which is not a body of the European Union. With the issuance of the Biopatent Directive, however, the European Union has obtained a legal tool to exert its influence into the patent field, too. ■

### 4. Acknowledgements

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**Note:** *Shortly after the end of the editorial deadline of this issue of les Nouvelles, Monsanto has withdrawn its lawsuit against Cefetra, probably in order to anticipate a negative decision by the ECJ, which was scheduled for July 6, 2010. On the said date, however, the court issued its decision which largely follows the opinion of the Advocate General.*