



NEWSLETTER

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| The scope of DNA patents - European Court of Justice Judgement in Case C-428/08 (Monsanto Technology LLC v Cefetra BV et al.)



Since 1996 Monsanto holds a European patent (EP 0 546 090 B2) relating to a DNA sequence which, once introduced into the DNA of a soybean plant, makes it resistant to the herbicide glyphosate. Glyphosate is commonly used in agriculture and is a popular, non-selective herbicide. Farmers can thus eliminate weeds without harming soybean plant cultivation.

Claim 1 reads as follows:

1. An isolated DNA sequence encoding a Class II EPSPS enzyme, said enzyme being an EPSPS enzyme having a K_m for phosphoenolpyruvate (PEP) between 1-150 μM and a K_i (glyphosate)/ K_m (PEP) ratio between 3-500, which enzyme is capable of reacting with antibodies raised against a Class II EPSPS enzyme selected from the group consisting of the enzymes of SEQ ID NO:3 and SEQ ID NO:5.

The genetically-modified soybean plant is cultivated on a large scale in Argentina, where there is no patent protection for Monsanto's invention. In 2005 and 2006, European companies imported soy meal from Argentina into the Netherlands. Soy meal is the solid residue after hot pressing or extracting ground soybeans. Following the extraction, soy meal is heated to destroy harming proteins.

Tests carried out at Monsanto's request revealed the presence of traces of the DNA claimed, which indicated that the imported soy meal had been produced using that type of genetically-modified soybean plant.

The national infringement court in the Netherlands (Rechtbank's-Gravenhage), before which Monsanto brought proceedings, referred questions to the European Court of Justice (ECJ) concerning the issue whether the mere presence of the DNA sequence protected by a European patent is sufficient to constitute infringement of Monsanto's patent when the soy meal is marketed in the European Union.

The ECJ observed that the Biotechnology Directive 98/44/EC of July 06, 1998 makes the protection conferred by a European patent subject to the condition that the genetic information contained in the patented product or constituting that product performs its function in the material in which that information is contained.

Article 8 of the Directive states that

"The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

However, Article 9 clearly defines that

"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."

The national infringement court has referred several questions to the ECJ. The main question can be summarized as follows:

Should Article 9 of the Directive be understood in such a way that it confers protection when the genetic information present in the material does not perform any function but has performed a function in the past or when it is theoretically capable of performing a function in the future (i.e. when the gene sequence is isolated and again introduced in plant cells)?

In that regard, the ECJ notes that the function of Monsanto's invention is being performed when the genetic information protects the soybean plant against the effect of the herbicide glyphosate. However, that function of the protected DNA sequence can no longer be performed when it is in a residual state in the soy meal, which is a dead material obtained after the soy has undergone several treatment processes.

As a result, the ECJ held that protection conferred on European patents is not available when the genetic information has ceased to perform the function it performed in the initial material from which the material in question is derived.

Such protection cannot be granted on the ground that the genetic information contained in the soy meal could possibly perform its function once again in another plant. For that to be so, it would be necessary that the DNA sequence actually be introduced in that other plant for protection under a European patent to be conferred in relation to that plant.

In those circumstances, Monsanto cannot rely on the Directive to prohibit the marketing of soy meal originating from Argentina which contains its protected DNA sequence in a residual state.

Conclusion:



The decision is of great importance for patents on genetically modified plants and the nucleic acids they contain, but also generally for biotechnological inventions.

The ECJ makes the attributed function of the "genetic information" (the DNA sequence) in exactly this product an essential prerequisite for the protection of the genetic information described in the patent. For European patent applications, applicants should ensure that this attributed function is properly reflected in the application text since it will directly limit the scope of protection of a future European Patent. Extreme caution should be exercised not to formulate this function in a too narrow manner.



The judgement of the ECJ will strongly influence (national) infringement proceedings in the EPC member states since it states that Article 9 of the Directive effects an exhaustive harmonisation of the protection it confers, with the result that it precludes the national patent legislation from offering absolute protection to the patented product as such, regardless of whether it performs its function in the material containing it.



However, the ECJ judgement leaves questions open as regards the definition of the term "function" of the DNA. It did not make any comments on the question what extent of activity a DNA must have in order to fulfil its function. Where is the justified borderline of the function of genetic material as described in a patent application? To which extent will a function determine the scope of protection if no or only minor supporting evidence is contained in the patent application? These and other questions have to be answered in future Court decisions.

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