

## Court of Justice Decision in Monsanto v Cefetra (C-428/08)

The scope of protection of DNA claims insofar as they protect materials incorporating a DNA that is not able to perform the function for which it was patented has been decided in a recent ECJ Judgment.

### Summary

The Judgment of the Court of Justice of the European Union in [Monsanto Technology LLC v Cefetra BV and others](#), was handed down on 6th July 2010 and confirms that it will not be possible to rely on DNA claims to protect materials incorporating the DNA where the DNA is not able to perform the specific function for which it was patented. Significantly, the decision abolishes absolute protection for DNA as such. On the face of it this is good news for licencees but bad news for patentees. However, depending on how the requirement for performance of a specific function is interpreted, the decision may not have many practical consequences. The Judgment applies to patents in all EU Member States including patents granted before the date of the Judgment.

### The invention

Monsanto's invention was a gene which confers herbicide (specifically glyphosate) resistance on plants. Monsanto's patent has DNA claims, as

well as claims to plants transformed with the glyphosate resistance gene and methods of producing such plants. Monsanto tried to use the DNA claims to prevent importation of soy meal made from soybeans transformed with the glyphosate resistance gene, on the basis that the gene was detectable in the soy meal. The importer, Cefetra, argued that the soy meal is dead material and so the gene is not expressed to provide any herbicide resistance and consequently, the DNA claims are not infringed.

The issue before the Court was one of scope of protection and concerned the interpretation of Article 9 of the Biotechnology Directive, which reads as follows:

**“The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1),**

**in which the product is incorporated and in which the genetic information is contained *and performs its function*”** (emphasis added).

In particular, the Court was asked to consider whether Article 9 can be interpreted as meaning that protection is invoked even in a situation in which the product (the DNA sequence) forms part of a material (soy meal) and does not perform its function at the time of the alleged infringement, but has indeed performed its function (in the soy plant) or would possibly again be able to perform its function after it has been isolated from that material and inserted into the cell of an organism. In view of the wording of Article 9, the Court found that the protection conferred by the DNA claims did not extend to the soy meal material in the present case because the patented DNA sequence encoding the glyphosate resistance gene could not perform its function in the dead soy meal material.

Of more interest is the Court's finding that Article 9 of the Directive effects an exhaustive harmonisation of the protection it confers, with the result that it precludes 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.

The Court's reasoning for this is that an interpretation that, under the Directive, a patented DNA sequence could enjoy absolute protection as such, irrespective of whether or not the sequence was performing its function, would deprive Article 9 of its effectiveness. The Court did not explain what is meant by "absolute protection". However, the outcome may be that isolated DNA is not protectable by DNA claims. This would prevent a DNA claim being enforced against a third party in possession of an isolated DNA.

The requirement for performance of the function for which the DNA sequence was patented is open to interpretation. The Court's comments are given in the negative in that they indicate that no protection is accorded to a DNA sequence which is not able to perform the specific function for which it was patented. The Judgment does not clarify exactly what may be protected, for example, whether the function must actually be performed, and if so, whether performance must be continuous or only under certain circumstances, or whether the DNA need only be in a state in which it is capable of performing the function. The latter interpretation would have the consequence that the use of a DNA sequence for a function for which the DNA was not patented may still be found to infringe the original DNA claim because the DNA sequence would be in a state in which it is capable of

performing the function for which the DNA was patented. If this is the case, DNA claims may still protect DNA for any use provided that the DNA is in a state in which it is able to perform the function for which it was patented. Thus the lack of protection for isolated DNA sequences may not have significant commercial implications. Further, exactly which functions a DNA sequence has been patented for may also be open to interpretation. It will be interesting to see how the national courts interpret the requirement for performance of a function in cases which are not as clear cut as the Monsanto case.

In the meantime, biotechnology and pharmaceutical companies might take comfort in the fact that it will still be possible to obtain protection for materials that incorporate a DNA sequence of interest which no longer performs the function for which it was patented by incorporating claims in patent specifications specifically directed to such materials, for example, claims directed to seeds, to harvested materials or to other derived products. Unfortunately for Monsanto, such claims were not present in its patent.

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