Court of Justice of the European Union
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Press and Information

Advocate General's Opinion in Case C-428/08
Monsanto Technology LLC v Cefetra BV and Others

For the first time the Court of justice is asked to interpret the scope of EU legislation on the protection of biotechnological inventions

Advocate General Mengozzi suggests that the Court should rule that protection for patents relating to genetic sequences is limited to situations where the genetic information is currently performing the functions described in the patents

Since1996 Monsanto has held the European patent for a DNA sequence which, when introduced into the DNA of a soya plant, makes that plant resistant to Glyphosate, a herbicide produced by the same company and marketed under the name 'Roundup'. Growers can use the herbicide to destroy invading weeds without fear of damaging the soya crop. The genetically modified soya plants ('RR soya', meaning 'Roundup-ready soya') are cultivated in various countries over the world but not in the European Union.

In 2005 and 2006, the defendant companies in the case before the referring court imported soy meal, for the production of animal feed, from Argentina, where RR soya is cultivated on a vast scale, but where Monsanto does not hold a patent for the DNA sequence. An analysis requested by Monsanto revealed the presence of traces of the DNA characteristic of RR soya and it was thus established that the imported soy meal had been produced from the genetically modified soya for which Monsanto holds the European patent.

The Dutch Court before which Monsanto brought proceedings has asked the Court to clarify the extent to which biotechnological inventions – and, in particular, patents relating to genetic information – are protected in the European Union.

It has to be determined whether genetic information is protected as such – as a chemical compound – even when it is located as a kind of 'residue' within a product (such as soy meal) resulting from the processing of the biological product (the soya plants) in which the sequence performed its function (making the plants resistant to Glyphosate).

After examining the wording and aims of the directive on the legal protection of biotechnological inventions[1], Advocate General Mengozzi maintains that the patented DNA is protected as such – that is, as a chemical substance – only where it performs the function for which it was patented. In his view, those are the only circumstances in which the protection also covers the 'material' in which the DNA sequence is contained.

By reference to the function performed by the DNA sequence, Directive 98/44/EC enables a distinction to be drawn between a 'discovery' (isolation of a DNA sequence without any indication of a function) – which, as such, is not patentable – and an 'invention' (the discovery together with an indication of the function that it performs) which, by contrast, is patentable.

Accordingly, to protect the DNA sequence with regard to all its possible functions, even those not identified at the time when the patent was applied for, would mean recognising patents as covering functions as yet unknown at the time of the patent application or, in other words, making mere discoveries patentable, in breach of the basic principles on patents.

[1] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 (OJ 1998 L 213, p. 13).

What is more, since it is not possible to say for how long, or up to which stage of the food and derived product chain, traces of the original DNA of the genetically modified plant are still identifiable, their very presence – even though they would no longer be performing any function – would mean that an unspecified number of derivative products would come under the control of whoever had patented the DNA sequence of a plant.

The Advocate General concludes, therefore, that **the protection for a patent relating to a DNA sequence is limited to the situations in which the genetic information is currently performing the functions described in the patent. That holds true both as regards the protection of the genetic information as such and as regards the protection of the materials in which the genetic information is contained**.

In his view also, **Directive 98/44/EC constitutes an exhaustive body of rules governing the protection to be recognised in the European Union as accruing to a biotechnological invention and precludes national legislation from conferring protection which is wider**. The aim of the directive is to promote the market and competition and to prevent existing legislative differences in that area from having a negative effect on trade within the European Union.

The fact that a patent has been awarded before the entry into force of Directive 98/44/EC (30/07/1998) **is irrelevant.** First, the directive does not contain any transitional provisions and, secondly, the obligation to interpret national law in conformity with EU law applies, according to established case-law, also to provisions of national law which pre-date the relevant EU provisions. Furthermore, the protection of the functions for which the genetic sequence has been patented is assured by the directive and is unquestioned.

NOTE: The Advocate General's Opinion is not binding on the Court of Justice. It is the role of the Advocates General to propose to the Court, in complete independence, a legal solution to the cases for which they are responsible. The Judges of the Court are now beginning their deliberations in this case. Judgment will be given at a later date.

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

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