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ECJ to interpret Biotechnology Directive (Phase 2)

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According to the Advocate General Article 9 of the Biotechnology Directive does not limit the scope of protection of patents for biotechnology inventions. Nonetheless protection for DNA sequences as such is excluded.

In its decision rendered on 19 March 2008 the District Court of The Hague referred questions to the European Court of Justice on the interpretation of article 9 of Directive 98/44/EC 0f the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions ("Biotechnology Directive"). In particular the Dutch court wished to know whether article 9 of the Biotechnology Directive should be interpreted as extending the rights conferred by a patent covering a biotechnological invention, or, on the contrary, whether it should be interpreted to limit the proprietor's right to prevent the exploitation of material containing the patented product (DNA sequence), on the condition that such product still performs its function. The Advocate General in his opinion comes to the conclusion that it is irrefutable that article 9 of the Biotechnology Directive is a rule for the extension of patent protection. However, in his opinion the system put in place by the Biotechnology Directive excludes protection for DNA sequences as such. Such protection is limited "to the situations in which the genetic information is currently performing the func-tions described in the patent." But how does this relate to the obligations under the European Patent Convention (EPC)?

Monsanto v. Cefetra, District Court The Hague 19 March 2008

Monsanto is the proprietor of a European patent in force in the Netherlands covering a DNA molecule comprising DNA encoding a kinetically efficient, glyphosate tolerant EPSP synthase. The invention makes it possible to create transgenic plants containing the patented EPSP synthase. These plants are tolerant to Monsanto's herbicide Round-Up.

Monsanto commenced patent infringement proceedings in among othrers the Neth-erlands against companies importing soy meal from Argentina (where no patent is in force) still containing the DNA molecules falling under the scope of Monsanto's patent.

The defendants raised a rather surprising defence. They argued that the scope of protection of the patent at hand is determined exclusively by article 53a of the Dutch Patent Act which implements articles 8 and 9 of the Biotechnology Directive in Dutch patent law. According to the defendants article 53a limits the scope of protection granted to patents on biological material to material that contains the patented DNA, provided it still performs its function.

The Dutch court was of the opinion that because the article does not specify that it derogates from the general protection provided by article 53(1) of the Dutch Patent Act it cannot be considered to limit the protection granted by that article.

The court looked at the intention of the Biotechnology Directive. It referred to the preamble sub 8 that states:

> "Whereas legal protection of biotechnological inventions does not neces-sitate the creation of a separate body of law in place of the rules of na-tional patent law; whereas the rules of national patent law remain the essential basis for the legal protection of biotechnological inventions given that they must be adapted or added to in certain specific respects in order to take adequate account of technological developments involving biological material which also fulfil the requirements for patentability;"

The court came to the conclusion that the Biotechnology Directive does not derogate from the protection granted by article 53 (1) of the Dutch patent Act. On the contrary, it intends to create a minimum protection. This also seems to follow from the word-ing of articles 8 and 9 of the Biotechnology Directive which use the words "shall extend to" instead of "shall be limited to". Nonetheless, the Dutch court was of the opinion that the situation is sufficiently unclear to refer questions the European Court of Justice.

Opinion Advocate General 9 March 2010

The Advocate General agrees with the Dutch court that it is correct in its opinion that article 9 cannot be interpreted as limiting the scope of national patents. However, surprisingly he comes to the conclusion that it follows from the aim of the Directive that in EU territory the protection conferred on DNA sequences is a 'purpose-bound' protection. He finds that allowing protection to the DNA sequence as such would – contrary to principles of patent law – make a discovery patentable: "… lodging an application for a patent for a single function of a DNA sequence is all it would take to obtain protection for all the other possible functions of the same sequence." That would make it possible for the owner of such patent to prevent the importation of cattle that was fed with genetically modified plants and still having traces of the patented sequences in their stomach. He concludes that protection is limited "to the situations in which the genetic information is currently performing the functions described in the patent."

Although the AG's conclusion seems reasonable, some questions can be asked about the underlying reasoning.

Monsanto's patent is a European patent. The extent of protection of a European patent is determined by article 69 (1) EPC only. This article should be interpreted the same in all contracting states. Not all contracting states are subject to the Biotechnology Directive. When the Biotechnology Directive came into force, the EPC was also amended. The changes that were made to the EPC as a result of the Biotechnology Directive are limited to rules regarding patentability. This seems to demonstrate that the Biotechnology Directive has not changed the extent of protection and that a European patent covering a DNA sequence as such can, in the states covered by the EPC, be invoked against the use of any material wherein the DNA sequence is present, in the same manner as this is possible for chemical substances.

Chemical substances (pharmaceuticals) are patentable as such. Also for chemical substances it is necessary to specify the technical problem that is solved. Also for chemical substances the result is that the patent owner can act against the use of such substances for solving a different problem (notwithstanding the possibility to obtain a patent for such new use). Also in that case the question may come up whether the owner of such patent may block the importation of cattle having been treated with a patented pharmaceutical of which traces can be found in its stomach or blood.

In the opinion of the Advocate General, however, nothing can be found about the EPC.

It is a valid question for chemical substances, pharmaceuticals, and DNA sequences, whether it would not be better to limit their patentability to a specific use or function. This is not a question of scope of protection (69 (1) EPC) but a matter of patentability (52 and 53 EPC).

The opinion of the AG can be found here.

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