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EUROPEAN COURT OF JUSTICE RESTRICTS SCOPE OF BIOTECH PATENTS IN EUROPE: MONSANTO LOSES DISPUTE ON SOY MEAL

BRIEF SUMMARY OF THE COURT DECISION

The European Court of Justice delivered a judgment on July 6, 2010 that certainly may be seen as a breakthrough decision for European biotechnology patent law. Exactly 12 years after the European Parliament and the Council adopted European Directive 98/44/EC ("Biotech Directive"), the European Court of Justice (ECJ) in its Case C-428/08 ("*Monsanto v. Cefetra*") interpreted Article 9 of the Directive regarding the scope of protection for a patent on a product containing or consisting of genetic information ("gene patents").

The judgment limits patent protection of gene patents to the living biologic material, ruling out protection for processed, derivative products thereof. According to the judgment, European law does not confer patent protection if a patented DNA sequence (*e.g.*, effecting herbicide resistance in soy plants) is merely present in a derivative (*i.e.*, downstream) product (*e.g.*, soybean meal) where it can no longer perform the specific function for which this DNA sequence was patented (*i.e.*, provide herbicide resistance). This effectively establishes a purpose-bound protection for gene sequences rather than "absolute" protection.

Remarkably, the judgment not only limits the scope for future patents, but it applies retroactively, even if patents had already been applied for and granted prior to the adoption of the European Biotech Directive. The ECJ specifically investigated and confirmed that this finding is in compliance with the World Trade Organization's international "Agreement on Trade-Related Aspects of Intellectual Property Rights," Articles 27 and 30 ("TRIPS").

Judgments of the European Court of Justice are binding for all Member States of the European Union ("EU"). From now on, any national laws in the EU have

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to be interpreted in accordance with this ECJ judgment, effectively limiting the scope of gene patents throughout the European Union.

Obviously, the judgment has a major impact on assessing existing patent portfolios but also will affect future biotech patent practice and strategy.

BACKGROUND

The ECJ decision is the culmination of a series of patent litigation actions brought by Monsanto against several EU importers of soybean meal originating in Argentina. The soybean meal in dispute was obtained from genetically modified soybean plants tolerant to the herbicide glyphosate due to the presence of a gene encoding a specific enzyme—EPSPS. Although the DNA sequence of the EPSPS gene is validly patented in several EU Member States, no patent protection existed in Argentina, and the genetically engineered soybean plants were thus cultivated and processed in Argentina without needing a license. Monsanto then tried to enforce its European patent claim on the DNA sequence against the downstream products resulting from these soy plants, *i.e.*, the soybean meal, once it was imported into the EU. Indeed, the soybean meal still contained the patented DNA sequence and did originate from the genetically modified plants, but it now was dead biologic material.

If "absolute" patent protection applied to a patent for a DNA sequence, the mere presence of the DNA sequence in a material might arguably infringe the patent. If "purpose-bound" protection applied, the functionality of the DNA sequence would also have to be taken into account.

While European patents are granted in a single prosecution process, the resulting patent is not a single right, but rather is viewed as a bundle of national patents. With each national state applying its own tests for claim construction, different scopes of protection might exist for different territories even if the description and claims are identical. It was thus the aim of the Biotech Directive to harmonize the laws of the Member States by requiring them to adopt the standards laid out in the Biotech Directive.

Uncertainties in the applicability and scope of the Biotech Directive, in particular regarding Article 9 of the Directive, led one of the European courts where the Monsanto infringement litigations were pending (a Dutch court) to refer several questions to the ECJ for a preliminary ruling. Briefly, the questions upon which the court sought clarification were: (1) whether a DNA sequence must perform its function at the time of the alleged infringement to invoke protection under Article 9 of the Biotech Directive, or whether performance before or potential later performance is sufficient for Article 9 to apply, and (2) the relationship between the Biotech Directive and national patent law. That is, does the Biotech Directive only provide for a minimum standard of protection in addition to the general provisions of national patent law (*i.e.*, absolute product protection as such), or is it exhaustive in that the DNA sequence is further required to "perform its function" to establish infringement?

In addition, the Dutch court sought clarification from the ECJ regarding the relevance of the patent filing or grant date in relation to adoption of the Biotech Directive, and the impact of international treaties, specifically the TRIPS Agreement, for any interpretation of the Biotech Directive.

JUDGMENT OF THE COURT

While the Dutch case settled following the Advocate-General's opinion, the ECJ nonetheless proceeded to deliver a judgment. In its ruling, the ECJ determined that the protection conferred by Article 9 of the Biotech Directive is not available when the genetic information has ceased to perform the specific function it performed and for which patent protection was granted. The fact that the patented product (the DNA sequence) had performed the claimed function in the past or would possibly be able to perform that function in the future (*e.g.*, after extraction of the DNA sequence from the soybean meal and insertion into a cell of a living organism) is irrelevant for the purposes of Article 9. The ECJ clarified that patent protection is thus not available if a patented DNA sequence is contained in soybean meal, *i.e.*, dead material, where the DNA sequence no longer performs its specific function.

As regards the other questions, the ECJ established that the Biotech Directive does not merely provide a minimum standard of protection (which might allow a state to pass legislation for its territory granting "absolute" protection in addition to the mere "purpose-bound" protection conferred by the Biotech Directive). In the ECJ's view, only a uniform level of protection throughout the EU will avoid barriers to trade. Consequently, it ruled that the Directive intends to effect complete harmonization, precluding national patent legislation from offering absolute protection.

The ECJ further clarifies that the provisions of the Biotech Directive apply to relevant patents already granted before the Directive was adopted. On first sight, this retroactive effect is surprising, as it seems to limit an asset that might have been rightfully obtained under the previous laws. However, the ECJ clarifies that according to settled case law, new rules apply, as a matter of principle, immediately to the future effects of a situation that arose under the old rule. The Biotech Directive does not provide for any derogation from that principle, and thus the limitation of patent scope will affect patents that might previously have had a broader scope of protection. Of course, the Biotech Directive also applies to all patents granted after the Directive was adopted irrespective of the day of filing.

The ECJ also investigated and decided that this decision complies with the TRIPS Agreement. Limiting the scope of gene patents, even retroactively, is not discriminatory, and TRIPS signatories are free to provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties (Article 30 TRIPS).

COMMENTS ON THE JUDGMENT AND PRACTICAL ASPECTS

This is the first judgment of the ECJ on a matter concerning and requiring the interpretation of the provisions of the EC Biotech Directive concerning the scope of protection conferred by biotech patents. The relevance and implications of the judgment are far-reaching. Indeed, the circumstances of the situation that led to the questions being referred to the ECJ are not unique. In particular, in the pharmaceutical, diagnostic, and agricultural sectors, patented gene sequences encoding for proteins or enzymes of commercial interest are more and more utilized in the production of goods (*e.g.*, foodstuff and pharmaceuticals) with specific characteristics. While the locations where those products are grown/produced (and where the patented gene sequences are utilized) are often located outside the EU, the final destination of the processed products derived from them (*i.e.*, goods made from these products) is often the EU.

In a situation like the one underlying the present ECJ judgment, the capability of the owner of a patent on a gene sequence to enforce her/his right based on Article 9 of the Biotech Directive will depend on a thoughtful patent strategy.

Of course, for the patent proprietor, a straightforward approach would be to pursue and obtain patents relating to gene sequences and live material (such as plants and animals) on a broader geographical basis, *i.e.*, in all countries where the patented genes and live material would be expected to be grown or processed to provide downstream products such as oil or meal—which is worldwide. However, such a costly strategy is unlikely to be feasible for many biotech companies.

Another, certainly more reasonable, approach is proper and thoughtful patent drafting. As a DNA patent will not automatically cover the commercial processed products obtained from, for example, using the genetically modified organism, the wording of the claims should to the extent possible also be directed to harvested goods and products derived from them. On the other hand, in many cases it might be difficult to argue the inventiveness of downstream products (such as soy meal produced from genetically engineered soy), which as such would have no superior properties as compared to the same products obtained from ordinary origin (such as soy not containing the patented DNA). However, as under European practice and case law, the protection conferred by a patent extends to the products directly obtained by a patentee. The patent proprietor could, for example, seek to indirectly protect a downstream product by way of claiming its production processes that include the use of the genetically engineered organisms.

Furthermore, additional IP right protection systems like Plant Variety Protection ("PVP") should be also taken into consideration. For instance, the UPOV Convention for plant variety protection provides in its Article 14(3) for a discretionary extension to downstream products. Although in the specific situation of Monsanto, the downstream products would not necessarily be protected by PVP in all EU Member States, the PVP system is an alternative that offers protection over an extended region for lower costs and probably also covering downstream products.

The judgment certainly is a breakthrough decision. However, while it brings greater clarity across the EU on this issue, it still leaves a series of open questions with respect to the Directive that might have to be answered by further referrals to the ECJ. For instance, does the interpretation of the expression "genetic information […] performs its function" in Article 9 given by the ECJ in the present judgment generally leave out harvested (not processed) agricultural products? Even if this were not the case, how should agricultural products that, for example, contain a gene conferring resistance to environmental factors during storage of the harvested product or improving the nutritional content or the quality of the harvested product (*e.g.*, fruits, vegetables, cut-flowers), be treated? Are such genes still "performing their function" in the harvested product?

What becomes clear is that biotech patenting and enforcement is one of the most challenging legal areas and requires thoughtful and thorough planning. Preferably, the patent practitioner should work in an integrated team of experts from the very beginning, *i.e.*, before filing the patent application covering the invention. Specifically, he/she should seek the advice of an experienced patent litigator after having consulted with the businesspeople within the company and have the full picture of what different aspects are (or might be) of future commercial value.

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