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European Court of Justice “Monsanto” decision diminishes the scope of European patent rights for biological inventions involving genetic material.

On 6th July 2010 the European Court of Justice (ECJ) issued its much anticipated judgement in connection with the Monsanto “Soya Bean” case that was referred to it by the Dutch courts.

As expected, and feared by biotechnology patent holders, the ECJ has come to the sweeping decision that the European Biotechnology Directive (Directive 98/44/EC) should be interpreted such that patent protection in which genetic material is claimed in Europe does not extend to protecting biological materials in which such genetic material is functionally inactive.

Monsanto had initiated an action for patent infringement (in the District Court of The Hague) based on the presence of patented genetic material (a DNA sequence encoding a class II EPSPS enzyme) in processed soybean meal imported from Argentina. Though there were no claims in Monsanto’s patent (EP 0 546 090 B2) protecting the soya meal itself, the Dutch court was satisfied that the imported soybean meal contained genetic material that fell within the scope of the granted patent claims covering genetic material. However, given the lack of functionality of the genetic material in the meal, there were questions about the scope of protection given by the claims. The Court asked the ECJ to rule on the applicability of the Directive insofar as it excludes biological materials from patent protection in Europe.

The ECJ has considered whether or not Article 9 of the Directive (as implemented by Article 53a of the Dutch law) defines an exception to patentability for genetic material. One construction of Article 9 of the Directive was argued to stipulate that any product containing a biological material (i.e. the gene in suit) would not infringe patent rights if that material was not functional. The ECJ has followed this construction and ruled that the biological material was not functional in the soybean meal (which was biologically inert) and as such there was no patent infringement.

What is troubling about the ECJ Decision is its retroactive effect with regard to existing patents, whether they are granted before or after the Directive came into force. Litigators will wish to consider carefully the enforceability of existing patent claims directed to biological molecules or materials, where the alleged act of infringement involves arguably non-living and/or non-functional material.

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Patent Attorneys will be keen to explore drafting and prosecution strategies for avoiding what appears to be a wide reaching decision that could seriously limit the scope of protection offered by patent claims to biological material, particularly genetic material in Europe. The Monsanto patent claims isolated DNA sequences, recombinant DNA molecules, methods of producing transgenic plants, transformed plants *per se* and methods of selectively controlling weeds utilising transgenic plants. However their patent did not include claims directed to a product derived from transgenic plants (i.e. the soybean meal *per se* - whether defined specifically or encompassed by a generic claim). Attorneys will need to consider the range of non-living and/or non-functional biological materials associated with an invention and develop claims directed to products *per se*, not ostensibly being biological materials.

On the one hand the ECJ could be slamming the door on any form of protection for inactive/non-functional genetic material – whether covered by Monsanto’s claim categories or otherwise. On the other hand, there may still be opportunity to develop straightforward product category claims, with suitable support in the description, in addition to the usual types of biological material claims secured by Patentees. So as well as claiming functional genetic material by employing the usual DNA molecule claims, vector claims and transformed cell/organism claims, basic “chemical” type product claims could be drafted to focus on industrially processed, dead or other commercially useful material lacking specific biological function. Such product claims could be argued to be unaffected by the Directive because they plainly do not include material that falls within the definition of biological/genetic material in Article 9 of the Directive as construed by the ECJ. Hopefully this will provide a clear route for Patent Offices and Courts to recognise a limitation to the extent of the ECJ decision.

There could still be pitfalls, e.g. wherein a particular nucleic acid sequence has to be used as an essential defining feature for distinguishing a novel substance over known substances. If there is inherent or explicit absence of biological functionality for such genetic material, i.e. it only acts as a marker for the origin and/or the process to which the material is subjected, this might require developing a different justification for inventive step from that used for the main “biological” invention. As well as potential uncertainty over being able to show inventive step, lack of unity of invention could arise leading to a need to have a divisional filing strategy.

It remains to be seen if the strategy of securing grant of normal biological material claims in conjunction with composition/product claims (containing the inactive biological material) will afford the Biotechnology Industry with the necessary extent of protection it needs.

This judgement could have serious and wide ranging implications for Biotechnology companies and, if you hold patents or are seeking protection for genetic materials, we urge you to contact one of the Attorneys in the HGF Life Science team to discuss how this may affect you. Given the short time bar on divisional filings now before the EPO, applicants are urged to give earliest consideration to the effect of the ECJ Decision.

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