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Litigating Biotech Patents

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Introduction

Biotech patents have faced the courts with a series of new policy issues on the permissible width of claims, on how far developed a product or process must be in order that it should count as a patentable invention rather than a claim to a research programme, and on how, the courts have struggled with a series of new policy issues. This is a broad survey of how the courts have tackled these key issues.

The permissible width of claims

Genentech Inc's Patent [1989] RPC 147, CA.

> "It is undesirable to allow claims the object of which is to cover a wide and unexplored field or where there is no disclosure in the specification which is in any way coterminous with the monopoly claimed" per Dillon LJ at 237 1-3.

Biogen Inc v Medeva PLC [1997] RPC 1, HL.

> "the specification must enable the invention to be performed to the full extent of the monopoly claimed. If the invention discloses a principle of general application, the claims may be in correspondingly general terms. The patentee need not show that he has proved its application in every individual instance. On the other hand, if the claims include a number of discrete methods or products, the patentee must enable

> the invention to be informed in respect of each of them." per Lord Hoffmann at 48 4-48, distinguishing *Genentech I/Polypeptide Expression* (T 292/85) [1989] OJEPO 275.

The House of Lords judgment makes an interesting contrast with the EPO Board of Appeal decision on the same patent, *Hepatitis B virus/Biogen Inc* Case T886/91.

Chiron Corp v Murex Diagnostics [1996] RPC 535, CA. Sufficient support for general technique across width of claims.

Industrial application or mere discovery or interesting research result?

Chiron v Murex (cited above): not an invention "to make or use that which is useless for any known purpose".

Evans Medical Ltd's Patent [1998] RPC 517, Laddie J. Pertussis antigen: requirement of enabling disclosure.

Eli Lilly & Co v. Human Genome Sciences Inc [2008] RPC 733, Kitchin J, 31 July 2008. Mere disclosure of gene sequence with unknown function not enough.

Impact of Directive 98/44/EC on the Legal Protection of Biotechnological Inventions (implemented in the UK only with prospective effect to new patents).

Interpreting the scope of claims

Kirin-Amgen v. Hoechst Marion Roussel Ltd [2005] RPC 169, HL. EPC 2000 does not introduce a "doctrine of equivalents".

Downstream protection for products of biotech processes

Monsanto Technology LLC v Cargill Intnl SA [2008] FSR 153, Pumfrey J:

- Claim to isolated DNA sequence does not cover bits of non-functional DNA molecules found in processed soya meal.

- Soya meal is not direct product of process of using DNA sequence to induce glyphosate resistance in plant.

Cf: *Pioneer Electronics v Warner Music Mfg* [1997] RPC 757, CA. CDs replicated from stamper made by claimed process.

Monsanto Technology LLC v. Cefetra B.V., 249983/ HA ZA 05-2885, reference to the ECJ from Hague District Court, Case C-428/08:

1. Must Article 9 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions be interpreted as meaning that the protection provided under that article can be invoked in a situation such as that in the present proceedings, in which the product (the DNA) is incorporated in a material and does not perform its function at the time of the alleged infringement, but has indeed performed that

function or would possibly again be able to perform that function after it has been isolated from that material and inserted into the cell of an organism?

2. Proceeding on the basis that the DNA sequence as described in claim 6 of the patent is present in the soy meal imported into the Community by Cefetra and ACTI, and that the DNA is incorporated in the soy meal for the purposes of Article 9 of the Directive and that it no longer performs its function therein:

   Does the protection of a patent on biological material as provided by the Directive, in particular under Article 9, preclude the national patent legislation(2) from conferring (in parallel) absolute protection on the product (the DNA) as such, regardless of whether the DNA performs its function, and must the protection provided under Article 9 therefore be deemed to be exhaustive?

3. Does it make any difference, for the purpose of answering the previous question, that the patent was applied for and granted (on 19 June 1996) prior to the adoption of the Directive? Is it possible, in answering the previous questions, to take into consideration the TRIPS Agreement, in particular Articles 27 and 30 thereof?"