Lowering the bar – the requirement of industrial application in biotech cases

The decision of the Supreme Court in HGS v ELI Lilly

The patent claims

- the isolated polynucleotide encoding Neutrokine-α;
- polypeptides encoded by the nucleotide;
- antibodies which bind to the polypeptides;
- pharmaceutical compositions and diagnostic compositions comprising such nucleotide, polypeptides or antibodies.

EPC

Art.52:

"(1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application."

Art.57:

"An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture."

Directive 98/44/EC (“the Biotech Directive”)

Recitals:

23. Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention;

24. Whereas, in order to comply with the industrial application criterion it is necessary in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs;

Art.5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

3. The industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application.

EPC Rules

Rule 26 implements Art 5 Biotech Directive.

Rule 42(1)(f):

> "The description shall indicate explicitly, where it is not obvious from the description or nature of the invention, the way in which the invention is industrially applicable."

What was known of TNF family members from the CGK?

- expressed by T cells and played a role in the regulation of T cell proliferation and T cell mediated responses;
- mediated by binding to receptors;
- some played a role in regulation of B cell proliferation and antibody secretion and some took part in T cell regulation of B cells;
- might have an effect on B-cell proliferation; and might play a role in the immune response and in the control of tumours and malignant disease;
- TNFα was the only ligand shown to have a therapeutic application.

Findings as to Patent teaching

- The inventors had no idea as to the activity of Neutrokine-α when drafting the patent.
- The patent teaches the skilled person nothing useful about its activity other than that Neutrokine-α is another member of TNF ligand superfamily.
- The skilled person would consider the patent does not itself identify any industrial application other than by way of speculation.
- The skilled person would be driven to the conclusion that the authors had no clear idea what the activities of the protein were and so included every possibility. To have included such a range of applications was no better than to have included none at all.

Approach of the High Court and CA

- Did the description disclose a practical way of exploiting the invention? Was there was a sound and concrete basis for recognising the contribution could lead to practical application?

- Was there a disclosure in definite technical terms of the purpose of the invention and how it could be used to solve a given problem? Or a real prospect of exploitation derivable directly from the specification, if not already obvious from its nature or the background?

- The purpose of a patent was not to reserve an unexplored field of research for the applicant.

- Using the claimed invention to find out more about its own activities was not in itself an industrial application.

Supreme Court - general

- A “plausible” or “reasonably credible” claimed use, or an “educated guess” can suffice.
- Such plausibility can be assisted by being confirmed by “later evidence”, although later evidence on its own will not do.
- The requirements of a plausible and specific possibility of exploitation can be at the biochemical, the cellular or the biological level.

Supreme Court - superfamily

- If all known members have a “role in the proliferation, differentiation and/or activation of immune cells” or “function in controlling physiology, development and differentiation of mammalian cells”, assigning a similar role to the protein may suffice.

- So “the problem to be solved” in such a case can be “isolating a further member of the [family]”.

- If the disclosure is “important to the pharmaceutical industry”, the disclosure of the sequences of the protein and its gene may suffice, even though its role has not “been clearly defined”.

Brenner, 383 US

- Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public.

Brenner

- … a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. [A] patent system must be related to the world of commerce rather than to the realm of philosophy.