

International News

France

French Court of Appeals Upholds Human Growth Hormone Patent

On 30 May, 1997, the Court of Appeals of Paris issued a major decision in a genetic engineering patent case, upholding a GENENTECH French patent (n° 80 14108, equivalents: US 5 424 199, EP 22 242, UK 2 121 048).

As it is the first decision in this field of the Court of Appeals of Paris - which decides a vast majority of patent cases in France - it deserves particular attention.

The case was brought in first instance by a GENENTECH's competitor, LILLY FRANCE, which submitted that claims 10 and 17 to 20 of French patent n° 80 14108 were invalid.

In a judgment issued on 21 January 1993, the Court of First Instance of Paris held that the patent was invalid because it was not capable of industrial application and because the disclosure was non enabling.

The judgment was completely reversed by the Court of Appeals which found the patent valid and struck out LILLY's claims.

The Court of Appeals of Paris reaches, therefore, the same conclusion as the Board of Appeals of the European Patent Office (TO 347 187) which found the corresponding EP 22 242 valid in all respects.

Claim 10 of the French patent n° 80 14108, the key issue, was drafted as follows:

A replicable bacterial plasmid capable, in a transformant bacterium, of expressing human growth hormone unaccompanied by extraneous conjugated protein.

It was under attack on four grounds:

- industrial application impossible,
- non enabling disclosure,
- lack of novelty,

- obviousness.

Overturning the first judgment, the Court dismissed LILLY's first ground of attack (invention not susceptible of industrial application) based on the contention that claim 10 was merely describing a result, not means for achieving it.

It held that "*in this very domain where there is a direct link between structure and function*", the claim of a replicable bacterial plasmid was not for a result but for a function, since the patent specified that the claimed plasmid was capable of expressing human growth hormone (because it includes a gene coding for this polypeptide) unaccompanied by extraneous conjugated protein.

As to sufficiency of disclosure, the Court of Appeals also reversed the decision of first instance.

It stated that "*claims covering an invention which opens a completely new domain may be drafted in more general terms than those for an invention which merely brings*

new features in a well known technical domain."

In view of this general statement, the Court found that specification and drawings provided those skilled in the art with all necessary technical information, thereby meeting the legal requirement of enabling disclosure.

LILLY's attack for lack of novelty - which the Court of First Instance had not considered in view of its decision of nullity on other grounds - is also rejected.

The Court of Appeals found that the two pieces of prior art invoked did not anticipate GENENTECH's patent claim.

STANFORD patent EP 0 009 930 is not considered because it merely mentions the process for obtaining growth hormone without disclosing any DNA sequence coding for human growth hormone.

GENENTECH's prior patent UK 2 007 676, referred to by the Court as the *Regulon* patent, is also considered as unable to destroy GENENTECH's patent FR 80 14108, because it discloses,

in a general manner, a basic process for obtaining bacterial plasmids allowing in turn obtention of heterolog proteins.

The Court found that it did not provide those skilled in the art with the main characteristics of a specific plasmid for obtaining human growth hormone. The Court of Appeals also dismissed LILLY's claim of obviousness.

After an in depth examination of various pieces of prior art, it found that "*several major prejudices, difficult to override, existed against the patented process*".

Claim 17 to 20 of French patent 80 14108 which relates to the process for obtaining the plasmid subject matter of Claim 10 are also held valid for similar reasons. French Courts have been slower than other countries to deal with genetic engineering patents.

However, the reported judgment shows that this first case was fully mastered.

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