FEDERAL CIRCUIT PATENT LAW CASE UPDATE

Novo Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp., 04-1581 (Fed. Cir. Oct. 5, 2005) (Schall, J.)

The court affirmed that claim 1 of Novo's patent for a process to produce a human growth hormone using recombinant DNA techniques is invalid and unenforceable, but vacated the district court's judgment that claim 2 is invalid. Claim 2 was not evaluated at trial, but claim 1 was anticipated. Moreover, the patent was unenforceable due to Novo's use of prophetic examples, stated in the past tense, when the tests had not been successfully undertaken.

Novo owns U.S. Pat. No. 5,633,352, for a "Biosynthetic Human Growth Hormone."

> The '352 patent is directed to a process for producing "ripe" human growth hormone ("hGH") protein in E.Coli bacteria through the use of recombinant DNA techniques. . . . Prior to the '352 patent, numerous attempts were made to produce biosynthetic hGH that would function in vivo in the same manner as pituitary-derived hGH. . . . [T]here was a need for a method to produce "pure" hGH, or hGH containing the 191 amino acid sequence identical to that of pituitary-derived hGH.

The term "ripe" refers to the need to cleave the protein produced by the bacteria in order to trim away a pre-cursor called the "pre-hGH fusion protein." "The '352 patent discloses a process whereby a proteolytic enzyme, preferably the enzyme dipeptidyl aminopeptidase I (DAP I), cleaves a pre-hGH fusion protein in order to produce 'ripe' hGH protein."

A significant and detailed procedural history relates to the appeal, including an interference, priority issues in the early 1980s, and a prior appeal in the present case.

> [T]he district court found that claim 1 of the '352 patent was anticipated by a December 1981 article by George N. Pavlakis, published in the journal Biochemistry and entitled "Expression of two human growth hormone genes in monkey cells infected by simian virus 40 recombinants" ("the 1981 Pavlakis article"). . . . Based upon that finding, the court ruled claims 1 and 2 invalid under 35 U.S.C. § 102(a). . . . In addition, the court held that the '352 patent was unenforceable based on inequitable conduct during prosecution of the '856 application and during the interference proceeding before the Board.

The court agreed with the district court's anticipation analysis for claim 1, and then considered Novo's argument that the district court improperly applied to a publication the Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355 (Fed. Cir. 2003) presumption that a prior art patent was enabled.

> As far as enablement is concerned, in our view, a fair reading of the district court's opinion is that the court did not rely solely on the Amgen presumption in finding that the 1981 Pavlakis article was enabled.

The court vacated the claim 2 judgment however, because that claim was not separately evaluated at trial.

It also upheld the judgment that the patent was unenforceable because the priority application stated in the past tense, discussing "Example 1," that the fusion protein was purified, evaluated, and then treated.

> [I]t is undisputed, that when the 1983 PCT application was filed on December 10, 1983, the inventors had not successfully prepared hGH with LAP using recombinant DNA technology. . . . Novo contends that there is no evidence that Dr. Christensen, the co-inventor who wrote Example 1, subsequently learned that the drafting of a prophetic example in the past tense was not a good procedure at the PTO, or that he subsequently told any of Novo's attorneys that Example 1 was prophetic. Thus, Novo asserts, because it is impossible to disclose the unknown, the district court's finding of inequitable conduct is reversible error . . . .

The court did not agree with Novo's argument.

> It is undisputed that Dr. Christensen was aware that Example 1 was prophetic and that Novo never successfully produced ripe hGH through the use of "pure LAP" enzyme. It also is undisputed that, during prosecution of the '856 application, Dr. Christensen was one of four Novo representatives present during the January 7, 1994 interview with the examiner, during which one of the issues addressed was enablement of the 1983 PCT application, of which the '081 application was the U.S. counterpart. As noted, other representatives included Novo's in-house patent attorney and in-house patent advisor.

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