



UNIVERSITY OF
MARYLAND
SCHOOL OF LAW

**PATENT LAW
UPDATE**

***Bio-Technology
Gen. Corp.
v.
Genentech, Inc.***

Nos. 00-1223,
-1267
Federal Circuit
Sept. 27, 2001

“When scientific certainty is not available, and the scientific theories and evidence are within a reasonable range of difference of scientific opinion, resolution of such difference based on weight and credibility of evidence is the province of the trier of fact.”

On September 27, 2001, the Federal Circuit reversed and remanded the district court’s judgment as a matter of law that claim 2 of U.S. Patent No. 4,601,980, is invalid for lack of enablement. The patented technology related to a method of producing human growth hormone (hGH) using the recombinant techniques of bacterial reproduction and gene expression. The Federal Circuit noted:

BTG argues that the method of the ‘980 patent produces only met-hGH, and because the leader methionine may not be cleaved intracellularly by the E. coli (or if cleavage occurs, such cleavage will not produce a “substantial amount” of mature hGH), claim 2 is invalid for failure to enable the production of mature hGH. Genentech responds that the invention of claim 2 is enabled by the production of met-hGH, and that in any event it suffices if the ‘980 process produces any amount of mature hGH along with the met-hGH. . . .

Extensive testimony and argument was presented by both sides. Although the issues are not matters of common experience, the witnesses for both sides testified with clarity, and did not differ significantly in their statements concerning the underlying science; they differed in the inferences drawn at the edges where there was not sufficient evidence or knowledge for scientific certainty. For example, they discussed intracellular cleavage of the methionine, and disputed the effects of the asserted differences between the Genentech and the BTG procedures. Thus the trial testimony showed reasonable scientists differing as to whether mature hGH could be produced by intracellular cleavage in recombinant procedures. The weighing of conflicting evidence is a jury function. When scientific certainty is not available, and the scientific theories and evidence are within a reasonable range of difference of scientific opinion, resolution of such difference based on weight and credibility of evidence is the province of the trier of fact. . . .

Genentech explained at trial, and the witnesses for both sides agreed, that the product of the gene expression is met-hGH, and that any mature hGH results from the cleavage of the methionine from the expression product. . . .

Genentech does not dispute that the expression product of the method shown in the ‘980 patent is met-hGH. Instead, Genentech argues that this does not exclude the formation of some mature hGH through intracellular cleavage, referring, *inter alia*, to its United States Patent No. 4,755,465, which was pending before the same examiner as the application issuing as the ‘980 patent. . . .

Claim 2, read in light of the specification, neither requires nor excludes intracellular cleavage to remove the methionine. The fact that the ‘980 patent produces met-hGH, or at most small amounts of mature hGH, does not invalidate the claims for lack of enablement. The court in BTG I set no requirement that the methionine must be cleaved. Thus it was incorrect to hold claim 2 invalid on the ground that the product of the procedures of the ‘980 patent was met-hGH. The district court’s judgment of invalidity is reversed.