UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMAN-LAROCHE LTD ROCHE DIAGNOSTICS GmbH and HOFFMAN-LA ROCHE INC. Defendants.	CIVIL ACTION No: 05-CV-12237WGY

OPPOSITION TO DEFENDANTS' MOTION *IN LIMINE* TO PRECLUDE AMGEN FROM REFERRING TO ITS INVENTIONS AS PIONEERING

This Court[1], the Federal Circuit[2], textbooks on Biotechnology[3] and countless media references have recognized Dr. Lin as a pioneer for his invention of recombinant human EPO. By its motion Roche seeks the extraordinary relief of precluding Amgen from saying just that. Roche has no legitimate basis for this request. At trial Amgen will present evidence that Dr. Lin's inventions are indeed pioneering. This evidence is not unfairly prejudicial. It has been established as truth again and again.

Moreover, contrary to Roche's position, the law is clear that the pioneering nature of an invention is relevant to the jury's analysis of obviousness, enablement and equivalence. Thus,

[1] *Amgen v. Hoechst Marion Roussel, Inc.*, 339 F. Supp. 2d 202, 214 (D. Mass. 2004) (stating "Amgen is recognized as the pioneer in the production of a therapeutically effective amount of EPO via recombinant EPO techniques.")

[2] *Amgen v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1321 (Fed. Cir. 2003) (stating "The first successful method of production of a therapeutically effective amount of erythropoietin used recombinant EPO techniques; Amgen is recognized as the pioneer.")

[3] *See* Molecular Biology and Biotechnology: A Comprehensive Desk Reference 108 (Robert A. Meyers ed., VCH Publishers 1995).

whether Dr. Lin's inventions are pioneering is an important consideration for the jury and Roche's request for a limiting instruction is improper and contrary to law.

I. Amgen is Entitled to Prove to the Jury that recombinant human EPO Was A Pioneering Invention.

The pioneering nature of an invention is a long-established concept in patent law that is an important consideration in evaluating defenses to a patent's validity. Amgen intends to present evidence at trial that Dr. Lin's recombinant human EPO inventions are pioneering. As described above, this Court, the Federal circuit and numerous third parties have already recognized that Dr. Lin is a pioneer for his recombinant human EPO inventions.

As numerous courts have found, evidence of a pioneering invention is directly relevant to several issues in this matter, including that Dr. Lin's recombinant human EPO inventions were not obvious, that peg-EPO is an equivalent of Dr. Lin's claimed recombinant human EPO, and that Dr. Lin's patents enabled the production of the recombinant human EPO in Roche's peg-EPO. The well-established "objective indicia of non-obviousness" include long-felt but unresolved need and the failure of others to make the invention.[4] Whether an invention was pioneering specifically relates to analysis of these objective indicia. Moreover, the Federal Circuit has concluded that "[a] pioneer invention is entitled to a broad range of equivalents[5]" and that "pioneer status is relevant to means-plus function equivalency determination.[6]" Similarly, as to enablement, the U.S. Court of Customs and Patent Appeals has stated that "whether

[4] *Amgen v. Hoechst Marion Roussel*, 339 F. Supp. 2d 202, 314-315 (D. Mass. 2004) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)).

[5] *Perkin-Elmer Corp. v. Westinghouse Electric Corp.*, 822 F.2d 1528, 1532 (Fed. Cir. 1987). *See also BFGoodrich FlightSystems, Inc. v. Insight Instruments Corp.*, 1992 U.S. Dist. LEXIS 12212, 46-47 (D. Ohio 1992) (holding that because the patent "was of the pioneering genre entitles it to a broader scope of equivalents than would otherwise be available added").

[6] *Texas Instruments v. U.S. Int'l Trade Comm.*, 805 F.2d 1558, 1569 – 71 (Fed. Cir. 1986) (pioneer status relevant to means-plus function equivalency determination).

appellants' invention is of 'pioneer' status . . . may influence the decision required on remand … As pioneers, if such they be, they would deserve broad claims to the broad concept."[7] Thus, the fact that Dr. Lin's recombinant human EPO inventions were pioneering is significant to any analysis of the claims in this matter.

The two cases Roche cites do not support Roche's position. In *Upjohn Co. v. Riahom Corp*., the Delaware District Court determined that the patentee's blanket assertion that the invention was "pioneering" did not enable the court to grant a preliminary injunction.[8] But as the court held, "[t]he Court, and not one of the parties, will make the determination whether the [patent] is entitled to pioneer status.[9]" And in *Augustine Medical v. Gaymar Industries, Inc*., the Federal Circuit specifically recognized that the patentee's claim to pioneering status relied "on this court's early statements that pioneering inventions deserve a broader range of equivalents."[10]

II. Roche's request for a limiting instruction is baseless and improper.

Roche's request that this Court instruct the jury that the "pioneering" status of Dr. Lin's inventions has no bearing on the jury's determination has no basis in law. As set forth above, courts routinely consider whether inventions are pioneering. Indeed, the Federal Circuit recently affirmed a jury instruction that charged that a jury must take the pioneering nature of an invention into consideration when determining equivalents.[11] In that case, the Federal Circuit found it appropriate that the jury was instructed that "[a]pplication of the doctrine of equivalents always depends upon the character of the invention involved. In the event an invention achieves

[7] *In re Hogan*, 559 F.2d 595, 606 (C.C.P.A. 1977).

[8] 641 F.Supp. 1209, 1219 (Del. 1986)

[9] *Id.*

[10] 181 F.3d 1291, 1301 (Fed. Cir. 1999)

[11] *Molten Metal Equipment Innovations v. Mettaulics Systems Co*., 56 Fed. Appx. 475 (Fed. Cir. 2003).

a major or extraordinary advance over the prior art, and as such may properly be characterized as a pioneering invention, the claims are entitled to a broad or liberal range of equivalents…." In light of the well-established law regarding pioneering inventions and the Federal Circuit's approval of jury instructions supporting the notion that claims to pioneering inventions are accorded greater weight and broader equivalence, Roche's request for a limiting instruction is clearly improper.

Because Dr. Lin's recombinant human EPO inventions were pioneering and because this fact is relevant and highly probative to the claims and defenses in this case, the Court should deny Roche's Motion *in Limine*.

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Respectfully Submitted,

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