UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

BENCH MEMORANDUM ON BINDING EFFECT OF REPRESENTATIONS IN THE PATENT SPECIFICATION

Roche should be permitted to present testimony and argument as part of its invalidity case, particularly related to the issue of obviousness, concerning the statements contained in the common specification of Amgen's patents-in-suit. The Federal Circuit has consistently and clearly held that statements contained in a patent specification are binding upon the patentee in a later inquiry into the obviousness of the inventions claimed in the patent. *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1362 (Fed. Cir. July 9, 2007). This is partly because the U.S. Patent and Trademark Office ("PTO") relies on representations in the patent application identifying and characterizing relevant prior art. An inventor and all those prosecuting a patent before the PTO owe a duty of candor to the PTO. 37 U.S.C. § 1.56. All inventors and their agents, including Dr. Lin and Amgen's agents, as a matter of law, represent to the PTO that the information contained in the background sections of their patents is true. When an applicant, including Dr. Lin and Amgen's representatives file an application, identifying prior art and making explanatory statements characterizing that prior art, the applicant is stating what

is to be considered as prior art in determining obviousness of its improvement. *See In re Nomiya*, 509 F.2d 566, 571 (C.C.P.A. 1975). Roche should be allowed to present this evidence and have its witnesses and the jury rely on the representations made in Amgen's patent specification, including representations regarding the prior art.

As a patentee is bound to statements contained within its specification, Amgen cannot contradict or argue to the jury that the statements in its specification are not true. Likewise, Roche should be allowed to present these statements to the jury. As recently as July 9, 2007, the Federal Circuit reiterated the clear proposition that the patentee is bound by statements contained in its patent specification, including statements concerning the prior art. In the *PharmaStem* case, the Federal Circuit stated that "Admissions in the specification regarding prior art are binding on the patentee for purposes of a later inquiry into obviousness." 491 F.3d at 1362. This includes any statements that something is contained in the prior art or that a reference is prior art. *Constant v. Advanced Micro Devices, Inc.*, 848 F.2d 1560, 1570 (Fed. Cir. 1988) ("A statement in the patent that something is in prior art is binding on the applicant and patentee for determinations of anticipation and obviousness."); *Sjolund v. Musland*, 847 F.2d 1573, 1577-79 (Fed. Cir. 1988) (patent specification admitted certain matter was prior art, and thus "the jury was not free to disregard [that matter]" and "must have accepted [it] as prior art, as a matter of law"); *In re Fout*, 675 F.2d 297, 300 (CCPA 1982); *In re Nomiya*, 509 F.2d 566, 571 (CCPA 1975). In *PharmaStem*, patentee's invention related to a process for collecting, testing, storing and using the blood from newborn infant's umbilical cords based on the presence of particularly useful stem cells present in the blood. In the patent specification, patentee represented that the prior art disclosed stem cells in cord blood. *Id.* At trial, the patentee tried to take the position that prior to the inventions claimed in its patent, stem cells had not been proven to exist in cord

blood, contradicting the specification. *Id*. The Federal Circuit held that the patentee could not contradict representations in the specification of the patent, and that it was not unfair to hold inventors to the consequences of their admissions. *Id*. Roche should therefore be allowed to present these statements to the jury in its obviousness case.

In its opposition to Roche's motion *in limine* regarding the binding effect of statements in the specifications of Amgen's patents, Amgen mischaracterizes Roche's argument and Federal Circuit precedent when it suggests that under Roche's and the Federal Circuit's position, Amgen would be unable to dispute that any patent cited in the specification is enabled.[1] What the law very clearly states is that when the patentee makes a representation in the specification, either that some reference is prior art, what that reference states, or that something is contained in the prior art, then it cannot later contradict it. *PharmaStem* and its predecessors are clear that the patentee is bound to representations it made in the patent specification, and Roche should be allowed to present these statements to the jury.

DATED: September 5, 2007
Boston, MA

F. HOFFMANN-LA ROCHE, LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE INC.

By its attorneys,

/s/ *Peter Fratangelo*
Leora Ben-Ami (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)

[1] Amgen Inc.'s Opposition to Roche's Motion *in Limine* to Preclude Amgen from Making Assertions That Contradict Statements Made in Specifications of Patents-In-Suit, D.I. 881, filed 8/27/07.

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