EXHIBIT A

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

ROCHE'S [PROPOSED] REPLY MEMORANDUM IN FURTHER SUPPORT OF ROCHE'S MOTION *IN LIMINE* TO PRECLUDE AMGEN INC. FROM MAKING ASSERTIONS THAT CONTRADICT STATEMENTS MADE IN THE SPECIFICATIONS OF THE PATENTS-IN-SUIT

I. INTRODUCTION

Defendants F. Hoffmann-LaRoche, Ltd., Roche Diagnostics GmbH and Hoffmann-LaRoche Inc. (collectively "Roche") submit this reply memorandum in further support of their motion *in limine* to preclude Amgen from contradicting assertions made in the specifications of the patents-in-suit.

Amgen's opposition to Roche's motion misses the salient legal point made by the Federal Circuit in *PharmaStem Therapeutics* and its progeny.[1] Those cases stand for the common sense proposition that a patentee cannot contradict its own prior assertions in the patent specification during a later obviousness inquiry. Amgen should thus be held strictly to its representations in the specification and should not be allowed to change, at this point, its characterization of the state-of-the-art and prior art at the time of the patent filing.

II. ARGUMENT

The case law concerning a patentee's statements in the patent specification regarding the prior art is quite clear: the patentee cannot later disavow statements contained in the specification.[2] Less than two months ago, the Federal Circuit re-emphasized this point in *Pharmastem Therapeutics*. There, the patent specification cited references for the proposition that human umbilical cord blood contained stem cells.[3] However, at trial, the patentee tried to distance itself from those representations. "The cornerstone of [patentee's expert] testimony at

[1] *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1362 (Fed. Cir. 2007); *Constant v. Advanced Micro Devices, Inc.*, 848 F.2d 1560, 1570 (Fed. Cir. 1988) ("A statement in the patent that something is in the 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 that 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).

[2] *PharmaStem Therapeutics*, 491 F.3d at 1362.

[3] *Id.* at 1361-62.

trial was that none of the prior art showed that cord blood contains stem cells."[4] The court found this problematic and held the patentee to its representations in the specification, stating that "[a]dmissions in the specification regarding the prior art are binding on the patentee for purposes of a later inquiry into obviousness."[5] The Federal Circuit found no "unfairness in holding the inventors to the consequences of their admissions."[6] So too Amgen should be held to its statements regarding the production of EPO in frog oocyte cells, manufacturing DNA sequences from component amino acid sequences by synthetic gene technology, and the 24 previously identified statements in the patent specification regarding prior art highlighted in Roche's motion *in limine*.[7]

Amgen's claim that the Court's handling of the Sugimoto reference in the *TKT* litigation would somehow be inconsistent with granting Roche's motion here is without merit. In the *TKT* litigation, this Court found the Sugimoto reference not enabled -- a legal determination. That was not at odds with the factual representations that were made on the face of the patent. Granting this motion would be entirely consistent with this Court's handling of the Sugimoto reference in *TKT*. Amgen would still be free to raise legal distinctions and defenses, while fairly precluding it from reversing course factually.

Roche clearly identifies the statements in the specification of the patents-in-suit which Amgen may now attempt to deny. Those statements include the aforementioned reference to the EPO producing frog oocytes, the manufacturing DNA sequences from component amino acid

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[4] *Id.* at 1361.

[5] *Id*. at 1362.

[6] *Id*. at 1362.

[7] *See* U.S. Patent No. 5,441,868 col.10, l.9-31; col.3, l.22-46; Appendix A to Roche's Motion in Limine to Preclude Amgen Inc. From Making Assertions That Contradict Statements Made in Specifications of Patents-in-Suit dated 8/13/2007.

sequences by synthetic gene technology, and the 24 previously identified statements in the patent specification regarding prior art highlighted in Roche's motion *in limine*. Roche cannot be expected to forecast every particular way in which Amgen may depart from these statements. Moreover, the law does not require it to do so. *Pharmastem Therapeutics* teaches that because the patentee is bound to its prior representations in the patent specification, any expert testimony or attorney representation that does not accurately reflect the patent language should be precluded.[8]

III. CONCLUSION

Based on the foregoing, Roche's motion should be granted in all respects.

[8] *See PharmaStem Therapeutics*, 491 F.3d at 1362.

Dated: September 1, 2007
Boston, Massachusetts

Respectfully submitted,

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