UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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| AMGEN INC.,<br><br>Plaintiff,<br><br>vs.<br><br>F. HOFFMANN-LA ROCHE LTD; ROCHE DIAGNOSTICS GmbH; and HOFFMANN-LA ROCHE INC.<br><br>Defendants. | CIVIL ACTION No.: 05-CV-12237WGY |

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT OF THE '080 PATENT**

## I. INTRODUCTION

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche, Inc. (collectively "Roche") submit this memorandum of law in support of their motion for summary judgment of noninfringement, under the doctrine of issue preclusion (collateral estoppel) of claims 3, 4 and 6 of U.S. Patent No. 5,621,080 (the "'080 patent").[1]

All of the asserted claims of the '080 patent contain the operative limitation "wherein said erythropoietin glycoprotein comprises the mature erythropoietin amino acid sequence of FIG. 6." In prior litigation, the Federal Circuit construed this limitation to mean that the claimed product necessarily includes the 166 amino acid residues specified in Figure 6 of the patent. In

[1] Roche requested that Amgen withdraw the '080 patent some time ago. Amgen, however, refused on the basis of Amgen's pending petition for certiorari to the United States Supreme Court. On May 14, 2007, the Supreme Court denied certiorari. Roche then renewed its request. Amgen committed to providing a response by May 16th. On May 16th Amgen requested two more days to respond. On Friday, May 18th , having yet to receive a response, Roche informed Amgen that it would file this motion on Monday if no response was received by then.

addition, the Federal Circuit held that Amgen is barred by prosecution history estoppel from arguing that this limitation in the claims of the '080 patent can cover a 165 amino acid protein under the doctrine of equivalents.

Roche's accused product "CERA" is a new erythropoiesis stimulating agent ("ESA") that is chemically synthesized by combining a reactive succinimidyl ester of methoxy PEG-succinimidyl butanoic acid with epoetin beta. CERA does not "contain" EPO of any kind, be it 165 or 166 amino acids. Nonetheless, to the extent that Amgen asserts that CERA "contains" EPO, even Amgen maintains that CERA "contains" only 165 amino acids, not 166. Thus, Amgen claims infringement of the '080 claims only under the doctrine of equivalents. However, the Federal Circuit has already foreclosed this precise argument and Amgen is collaterally estopped by the prior holding.

Consequently, there are no fact issues and summary judgment should be granted holding that Roche does not infringe any of the asserted claims of the '080 patent.

## II. STATEMENT OF UNDISPUTED FACTS

The following facts are beyond genuine dispute and, as a matter of law, compel summary judgment that Roche does not infringe any of the asserted claims of the '080 patent.

In this case, Amgen has asserted claims 3, 4 and 6 of the '080 patent against Roche. (*See* Declaration of Kimberly J. Seluga, Exhibit 1, Pl.'s Supp. Resp. to Defs.' First Set of Interrogs. (Nos. 1-12) No. 1, at p. 3).

Claims 3, 4 and 6 of the '080 patent all contain the operative limitation "wherein said erythropoietin glycoprotein comprises the mature erythropoietin amino acid sequence of FIG. 6." (*See* Declaration of Kimberly J. Seluga, Exhibit 2, '080 patent, claims 3, 4 and 6).

The Federal Circuit has construed this limitation to mean "that the claimed glycoprotein must have -- at minimum -- all 166 amino acids shown in Figure 6." *Amgen v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1345 (Fed. Cir. 2003) (hereinafter "*Amgen II*").

Amgen's expert witness, Dr. Harvey F. Lodish, characterizes the accused Roche product as a "165-amino-acid gylcosylated EPO polypeptide" (*See* Declaration of Kimberly J. Seluga, Exhibit 3, Expert Report of Harvey F. Lodish, Ph.D. Regarding Infringement ¶ 117).[2]

Amgen maintains that Roche infringes the '080 patent under the doctrine of equivalents. Amgen asserts that Roche's product "comprises the equivalent of the mature erythropoietin amino acid sequence of Figure 6 of the '080 Patent because the difference" -- between Roche's product and the 166 amino acids of Figure 6 -- "is insubstantial." (*See* Declaration of Kimberly J. Seluga, Exhibit 4, Pl.'s Supp. Resp. to Defs.' First Set of Interrogs. (Nos. 1-12), Ex. A at 46).

The Federal Circuit has held that Amgen is foreclosed, by prosecution history estoppel, from arguing that the claims of the '080 patent can cover a 165 amino acid protein under the doctrine of equivalents. *Amgen v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1316 (Fed. Cir. 2006) (hereinafter *"Amgen IV").*

## III. ARGUMENT

### A. STANDARD FOR SUMMARY JUDGMENT

Summary judgment is appropriate where no genuine issue of material fact exists and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56; *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 93 (D. Mass. 2001) (hereinafter "*Amgen I*"). The grant of summary judgment under Fed. R. Civ. P. 56 is as appropriate in a

[2] While Roche disagrees with Dr. Lodish's characterization, for the purpose of this summary judgment motion as detailed herein, even if this statement is true there is no infringement of the '080 claims.

patent case as in any other case. *Barmag Barmer Maschinenfabrik AG v. Murata Machinery Ltd.*, 731 F.2d 831, 835 (Fed. Cir. 1984); *Amgen I*, 126 F. Supp. 2d at 93.

### B. THE DOCTRINE OF ISSUE PRECLUSION/COLLATERAL ESTOPPEL

It is well settled that

> [f]ive essential elements must be established for a successful application of issue preclusion: (1) the issue sought to be precluded must be the same as that involved in the prior action; (2) the issue must have been actually litigated; (3) the issue must have been determined by a valid and binding final judgment; (4) the determination of the issue must have been essential to the judgment; and (5) the party to the second action must be the same as or in privity with the parties in the first action. *See NLRB v. Donna-Lee Sportswear Co.*, 836 F.2d 31, 34 (1st Cir. 1987); *see also Grella*, 42 F.3d at 30. In addition, the parties in the first action must have had a "full and fair opportunity" to litigate the issue. *See, e.g., DeCosta v. Viacom Int'l, Inc.*, 981 F.2d 602, 605 (1st Cir. 1992), *cert. denied*, 509 U.S. 923, 125 L. Ed. 2d 725, 113 S. Ct. 3039 (1993).

*Boston Sci. Corp. v. Schneider (Europe) AG*, 983 F. Supp. 245, 255-56 (D. Mass. 1997). *See also Plumley v. Southern Container, Inc.*, 303 F.3d 364, 373 (1st Cir. 2002).[3]

### C. THE PRIOR FEDERAL CIRCUIT DECISIONS REGARDING THE '080 PATENT CLAIMS

In *Amgen II*, the Federal Circuit affirmed this Court's holding that the limitation "wherein said erythropoietin glycoprotein comprises the mature erythropoietin amino acid sequence of FIG. 6," which appears in claims 3, 4 and 6 of the '080 patent, "read properly in light of the term 'comprising,' . . . means that the claimed glycoprotein must have — at minimum — all 166 amino acids shown in Figure 6" of the '080 patent. *Amgen II*, 314 F.3d at 1345.

In *Amgen IV*, the Federal Circuit held that Amgen was foreclosed, under the doctrine of prosecution history estoppel, from maintaining that the "mature erythropoietin amino acid

[3] In patent cases, the Federal Circuit applies the issue preclusion law of the regional circuit. *Vardon Golf Co. v. Karsten Mfg. Corp.*, 294 F.3d 1330, 1333 (Fed. Cir. 2002).

sequence of Fig. 6" limitation in the claims of '080 patent could cover an EPO product containing a 165 amino acid sequence under the doctrine of equivalents. *Amgen IV*, 457 F.3d at 1316. The claims which became claims 3, 4 and 6 of the '080 patent had been added to the application by way of amendment in December 1996. (Third Preliminary Amendment and Terminal Disclaimer Pursuant to 37 C.F.R. § 1.321). The Federal Circuit observed that Amgen amended the claims knowing of the 165 amino acid sequence, and still "chose to limit the claims to the 166-amino acid sequence depicted in Figure 6" of the '080 patent specification. *Amgen IV*, 457 F.3d at 1316. The court pointed out that Amgen could have avoided being so limited by claiming mature human EPO "without reference to Figure 6." *Id.*

### D. AMGEN IS PRECLUDED FROM ARGUING THAT ROCHE'S 165 AMINO ACID PRODUCT INFRINGES THE '080 PATENT UNDER THE DOCTRINE OF EQUIVALENTS

Under the doctrine of issue preclusion (collateral estoppel), the Federal Circuit's *Amgen II* and *Amgen IV* decisions preclude Amgen from disputing in this case that (1) the limitation "erythropoietin glycoprotein compris[ing] the mature erythropoietin amino acid sequence of FIG. 6" means that in order to infringe the '080 patent claims literally, an erythropoietin glycoprotein product must include at least the 166 amino acid residues of Figure 6 of the patent; and (2) a 165 amino acid EPO glycoprotein does not infringe the claims of the '080 patent under the doctrine of equivalents. Indeed, all of the requirements for issue preclusion are met. Amgen was a party to the prior litigation where the issue of whether a 165 amino acid erythropoietin product could be held to satisfy the limitation "wherein said erythropoietin glycoprotein comprises the mature erythropoietin amino acid sequence of FIG. 6" in the claim of the '080 patent was fully litigated. The issue was decided by a valid and binding final judgment of the Federal Circuit; and the determination of this issue was essential to the Federal Circuit's non-infringement holding.

In sum, given Amgen's characterization of Roche's accused product as a "165-amino-acid glycosylated EPO polypeptide," Amgen is precluded from arguing that Roche's product satisfied the "wherein said erythropoietin glycoprotein comprises the mature erythropoietin amino acid sequence of FIG. 6" limitation either literally or under the doctrine of equivalents.

## IV. CONCLUSION

Based on the foregoing, Roche's motion for summary judgment of noninfringement of claim 3, 4 and 6 of the '080 patent should be granted in all respects.

Dated: May 21, 2007
Boston, Massachusetts

Respectfully submitted,

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