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

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

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Dated: Boston, Massachusetts
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I. INTRODUCTION

Based on the positions taken in interrogatory responses and advanced by its experts in their expert reports, plaintiff Amgen Inc. ("Amgen") intends to offer evidence, expert testimony and attorney argument at trial in support of its current assertion that the claims of the patents-in-suit[1] are not obvious in light of prior art disclosed in the now expired U.S. Patent No. 4,703,008 and U.S. Patent Nos. 5,441,868; 6,618,698; 5,756,349; 5,955,422; 5,547,933; and 5,621,080 ("Amgen's EPO patents"). Many of these arguments and much of the proposed evidence and testimony directly contradict statements made in the common specification of the patents-in-suit regarding prior art. Amgen should not be permitted to represent one thing to the Patent Office to distinguish its "invention" and obtain a patent, only to later disavow those statements in this Court when it becomes convenient for litigation. Courts, including the Federal Circuit, have consistently prohibited parties from reversing their positions on prior-art statements. Specifically, the Federal Circuit has ruled that statements regarding the prior art in a patent specification are to be considered admissions by the patentee. Accordingly, Roche respectfully requests that this Court preclude Amgen from offering evidence, testimony or attorney argument that contradicts assertions made in obtaining the patents-in-suit.

II. ARGUMENT

It is axiomatic that an invention must be novel and non-obvious over the prior art in order to issue as a valid patent. *See* 35 U.S.C. §§ 102, 103(a). To determine if a claimed invention is novel and non-obvious, the U.S. Patent and Trademark Office ("PTO") relies on, *inter alia*, representations in the patent application identifying relevant prior art. Those prosecuting the

[1] The patents-in-suit are U.S. Patent Nos. 5,441,868; 6,618,698; 5,756,349; 5,955,422; 5,547,933; and 5,621,080.

application on behalf of Amgen owed a duty of candor to the Patent Office. 37 U.S.C. § 1.56. As required by law, Amgen represented to the PTO that the information contained in the patents-in-suit was true, including the representations regarding the prior art. U.S. Patent No. 5,441,868 File History, Declaration for Patent Application at 167 (AM-ITC 00953127), attached as Exhibit A.

"Prior art", for purposes of § 103, refers to the statutory material contained in 35 U.S.C. § 102, as well as admissions the applicant made in filing and prosecuting the patent. *See Riverwood International Corporation v. R.A. Jones & Co., Inc.* 324 F.3d 1346, 1354 (Fed. Cir. 2003). By filing an application, identifying prior art and making explanatory statements, the applicant concedes what is to be considered as prior art in determining obviousness of its improvement. *See In re Nomiya*, 509 F.2d 566, 571 (CCPA 1975). The Federal Circuit recently noted that "Admissions in the specification regarding the prior art are binding on the patentee for purposes of a later inquiry into obviousness." *PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, --- F.3d ---, 2007 WL 1964863 at *17 (Fed. Cir. 2007) (citing *Constant v. Advanced Micro Devices, Inc.*, 848 F.2d 1560, 1570 (Fed. Cir. 1988); *Sjolund v. Musland*, 847 F.2d 1573, 1577-79 (Fed. Cir. 1988); *In re Fout*, 675 F.2d 297, 300 (CCPA 1982); *In re Nomiya*, 509 F.2d 566, 571 (CCPA 1975). In placing a greater emphasis on admissions in the patent process, the Patent Office amended Rule 106(c) in 1982 to provide that "In rejecting claims the examiner may rely upon admissions by the applicant, or the patent owner in a reexamination proceeding, as to any matter affecting patentability." 37 C.F.R. 1.106(c). The expressed intent of the Patent Office was "not to change current practice . . . but merely to emphasize the importance placed on admissions." *See Ex Parte McGaughey*, 6 USPQ 2d 1334, 1339 (Bd. Pat. App. & Int'f 1988).

Amgen's patents-in-suit identify, among other prior art, technology regarding EPO produced in vertebrate cells and synthetic gene technology. Given that Amgen made representations concerning this prior art and its relation to Amgen's pending applications to the PTO, and that Amgen's representations were ultimately published in the specifications of Amgen's EPO patents, Amgen should be held to its original representations for all of the prior art admissions in this Court.

As an example, the patents-in-suit identify a Farber *et al*. reference that reports production of EPO in frog oocyte cells. *See* U.S. Patent No. 5,441,868 col. 10, lns. 9-31, attached as Exhibit B. This reference confirms the production of EPO in vertebrate cells, as well as "allowing for the construction of an enriched human kidney cDNA library from which the desired gene may be isolated." *Id.* at col. 10, lns: 23-31. According to ***PharmaStem Therapeutics*** and the long line of concurring cases in the Federal Circuit, these identifications and representations constitute a binding admission on Amgen for future obviousness inquiries. As an admission, in the form of identifying the reference as prior art upon which Amgen allegedly improved, Amgen should be precluded from offering testimony or evidence, or arguing a position in this case, which denies the existence of EPO-producing cell lines in the prior art, or which denies that the cells identified in Farber produced EPO.

The patents-in-suit also identify synthetic gene technology describes and teaches manufacturing DNA sequences from component amino acid sequences. The patents-in-suit specifically identify the Alton *et al.* patent as a "superior means" to synthesize genes. *See id.* at col. 3, lns, 22-46. Identifying the Alton *et al*. reference, under ***PharmaStem Therapeutics***, is also a prior art admission for purposes of a later obviousness inquiry. Since Alton describes and teaches manufacturing DNA sequences from component amino acid sequences, Amgen should

be precluded from offering testimony or evidence, or arguing a position in this case, which denies that the prior art teaches methods by which one could directly manufacture DNA sequences from the component amino acid sequences. In addition to these two specific examples, other germane representations regarding the state of the prior art made by Amgen in the specification of the patents-in-suit are listed in the attached Appendix A.[2] For the reasons stated above, Amgen should also be precluded from offering testimony, evidence, or argument at trial that contradicts any of these representations.

III. CONCLUSION

In accordance with the facts and the principles of law set forth above, Roche respectfully requests that this Court preclude Amgen from offering evidence, testimony or argument that contradicts Amgen's statements made in the specifications of the patents-in-suit regarding prior art.

[2] Appendix A cites to U.S. Patent No. 5,441,868, as all of the patents-in-suit share a similar specification.

Dated: August 13, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

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