IN THE UNITED STATES DISTRICT COURT
FOR THE 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-12237 WGY

ROCHE'S BENCH MEMORANDUM NO. 3 THAT DR. ORKIN SHOULD BE PRECLUDED FROM TESTIFYING THAT THERE WAS NO KNOWN SOURCE OF HUMAN EPO MRNA IN 1983 BECAUSE SUCH TESTIMONY CONTRADICTS ADMISSIONS IN THE SPECIFICATIONS OF AMGEN'S PATENTS

In his May 11, 2007 report, Dr. Orkin states that, in 1983, "there was no known source" of human erythropoietin ("EPO") mRNA. (Rebuttal Expert Statement of Stuart H. Orkin M.D. at ¶ 38). This assertion plainly contradicts what was established by Amgen's binding admission in the specifications of the patents-in-suit: that a 1983 study by Farber et al. "confirmed the human kidney as a site of erythropoietin expression" and "allowing for the construction of an enriched human kidney cDNA library from which the desired gene might be isolated"[1] *See, e.g.*, U.S. Patent No. 5,547,933 ("'933 patent") at col. 9 lns.42-63. Because such testimony would go against Amgen's binding admissions about the prior art, Dr. Orkin should be precluded from testifying as to any alleged absence of a tissue source of human EPO in 1983.

[1] Citing Farber et al., *Blood*, 62, No. 5, Supp. No. 1, Abstract 392, at page 122a (1983); Farber, *Clin. Res.* 31(4), 769(a) (1983).

The Federal Circuit recently reiterated 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.*, 491 F.3d 1342, 1362 (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 Noyima*, 509 F.2d 566, 571 (CCPA 1975)). By filing an application, identifying prior art, and making explanatory statements, a patent applicant concedes what is to be considered as prior art in determining obviousness of its improvement. *In re Noyima* at 571. When a patent specification admits that certain matter is prior art, the jury must accept it as prior art as a matter of law. *Sjolund v. Musland* at 1577-79.

Consequently, testimony by Dr. Orkin that contradicts Amgen's binding admissions in the patents-in-suit, including any testimony corresponding to the assertions in paragraph 38 of his June 1, 2007 report regarding the alleged lack of a tissue source of human EPO in 1983, should be precluded.

DATED: September 26, 2007

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

By its attorneys,

/s/ Thomas F. Fleming
Leora Ben-Ami (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)

Christopher T. Jagoe (*pro hac vice*)
Vladimir Drozdoff (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
Krista M. Rycroft (*pro hac vice*)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000

and

Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292

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) on the above date.

/s/ Thomas F. Fleming
Thomas F. Fleming