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. 4 THAT DR. ORKIN SHOULD BE PRECLUDED FROM TESTIFYING THAT IN 1983 THERE WAS UNCERTAINTY THAT THERE WAS A COMMERCIAL MARKET FOR AN EPO DRUG PRODUCT, BECAUSE SUCH TESTIMONY WOULD CONTRADICT BINDING ADMISSIONS IN AMGEN'S PATENTS

In his June 1, 2007 report, Dr. Orkin states that "it certainly was not clear [in 1983] that a human EPO drug product would be as valuable as it turned out to be," and that it was "believed that some chronically anemic patients, who would constitute the principle 'market' for commercially available EPO, might not respond to EPO." (Supplemental Rebuttal Expert Statement of Stuart H. Orkin, M.D. at ¶12). These assertions contradict admissions in the patent specifications that, as of the filing date of the patents-in-suit, "it ha[d] recently been estimated that the availability of erythropoietin in quantity would allow for treatment each year of anemias of 1,600,000 persons in the United States alone," and that "recent studies ha[d] provided a basis for projection of efficacy of erythropoietin therapy in a variety of disease states, disorders and states of hematologic irregularity: Vedovato, et al., Acta.Haematol, 71, 211-213 (1984) (beta-thalassemia); Vichinsky, et al., J.Pediatr., 105(1), 15-21 (1984) (cystic fibrosis); Cotes, et

al., Brit.J.Obstet.Gyneacol., 90(4), 304-311 (1983) (pregnancy, menstrual disorders); Haga, et al., Acta.Pediatr.Scand., 72, 827-831 (1983) (early anemia of prematurity); Claus-Walker, et al., Arch.Phys.Med.Rehabil., 65, 370-374 (1984) (spinal cord injury); Dunn, et al., Eur.J.Appl.Physiol., 52, 178-182 (1984) (space flight); Miller, et al., Brit.J.Haematol., 52, 545-590 (1982) (acute blood loss); Udupa, et al., J.Lab.Clin.Med., 103(4), 574-580 and 581-588 (1984); and Lipschitz, et al., Blood, 63(3), 502-509 (1983) (aging); and Dainiak, et al., Cancer, 51(6), 1101-1106 (1983) and Schwartz, et al., Otolaryngol., 109, 269-272 (1983) (various neoplastic disease states accompanied by abnormal erythropoiesis)." '933 patent at col. 6, lns. 35-59. Dr. Orkin should be precluded from offering testimony on the opinions in paragraph 12 of his June 1st report, since such testimony would directly contradict Amgen's binding admissions in the patents-in-suit.

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, the Court should preclude Dr. Orkin from offering opinions that those of skill in the art in 1983-84 did not recognize the potential market value of an EPO drug product, as such testimony would be directly contrary to Amgen's binding admissions in the specifications of the patents-in-suit.

DATED: September 26, 2007

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and
HOFFMANN-LA ROCHE INC.

By its attorneys,

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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) on the above date.

/s/ Thomas F. Fleming
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