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 BENCH MEMORANDUM REGARDING AMGEN'S FAILURE TO DEMONSTRATE THE REQUISITE NEXUS REGARDING SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

Roche submits this bench memorandum to make clear to the Court that Amgen is foreclosed from arguing that commercial success or long-felt need are indications of non-obviousness to be considered by the jury in deciding the issue of invalidity. Amgen has not shown the requisite nexus between the commercial success and any long-felt need satisfied by its marketed EPO product, Epogen®, and the asserted claims.

Amgen cannot rely on commercial success of its marketed product "for purposes of countering the challenge of obviousness, unless it can show that the commercial success of the product results from the claimed invention." *J. T. Eaton & Co. v. Atlantic Paste & Glue Co, 106 F.3d 1563, 1571 (Fed. Cir. 1997); see also Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1393 (Fed. Cir. 1988). Similarly, to be able to argue that Amgen's commercial product satisfied a long-felt need, Amgen had to prove the requisite nexus between the asserted claims and the marketed product. *See WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339,

1359 (Fed. Cir. 1999) ("[t]he patentee bears the burden of showing that a nexus exists between the claimed features of the invention and the objective evidence offered to show nonobviousness"); *see also B.E. Meyers & Co. v. United States*, 47 Fed. Cl. 375, 378 (Fed. Cl. 2000) (same). Only after Amgen proved the requisite nexus would the burden shift to Roche to prove that these secondary indicia are "instead due to other factors extraneous to the patented invention." *Demaco Corp.*, 851 F.2d at 1393 (Fed. Cir. 1988).

Amgen has not proven the requisite nexus. Amgen maintains that Epogen® is embraced by Example 10 of the common specification, but the evidence shows otherwise:

- Example 10 states that the cell culture media in the example are a "genetically heterogeneous population" of cells, but Amgen was required, in seeking FDA approval for Epogen®, to show that the cell culture was homogeneous. Amgen did not achieve this until well after the November 1984 filing date. (*See* Trial Tr. 1982:17-22, 1983:10-15; TRX 1, col. 26:66-67).

- Epogen is purified by a method that Dr. Strickland invented and patented after the November 1984 filing date, and this purification method necessarily affects the final EPO product. Therefore, Epogen® cannot be tied to the patents-in-suit. (*See* Trial Tr. 2148:14-2151:24; TRX 2011.201).

- Dr. Strickland's '298 patent shows that different purification techniques select different isoforms of human EPO produced in CHO cells and can result in a different final product with different specific activity. (Trial Tr. 2157:12-2165:4; TRX 2104).

- Amgen's expired '008 patent, not-in-suit, shares a common specification with the patents-in-suit and was the only Lin patent in force when Epogen® hit the market in 1989. Amgen enjoyed commercial success well prior to the issuance of the first patent-in-suit in 1995. Accordingly, any commercial success would only be attributed to the '008 patent. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005); *Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1335 (Fed. Cir. 1998).

- Similarly, any public praise for Amgen's cloning of the EPO gene is irrelevant because the EPO gene is not claimed in any of the patents-in-suit -- it is only claimed in the expired '008 patent. (*See* D.N. 1266).

In accordance with this memorandum, Amgen has failed to demonstrate any nexus between the claims-in-suit and its commercial Epogen® product. Accordingly, the jury should

not be permitted to consider secondary indicia of non-obviousness in assessing the obviousness of the claims-in-suit.

DATED: Boston, Massachusetts
October 3, 2007

Respectfully submitted,

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

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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). Pursuant to agreement of counsel dated September 9, 2007, paper copies will not be sent to those indicated as non registered participants.

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