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 REQUESTING JURY INSTRUCTION REGARDING AMGEN'S FAILURE TO DEMONSTRATE THE REQUISITE NEXUS REGARDING SECONDARY CONSIDERATIONS OF NON-OBVIOUSNESS

Roche submits this bench memorandum to request that the Court instruct the jury regarding secondary considerations of non-obviousness in accordance with this memorandum. The overwhelming evidence demonstrates that Amgen should be foreclosed from arguing that long-felt need or failure by others 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 these considerations and its marketed EPO product, Epogen®, and the asserted claims.

Amgen cannot rely on its marketed product satisfying a long felt but unresolved need "for purposes of countering the challenge of obviousness" unless it can show that the secondary consideration "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). Amgen bears the burden of demonstrating the requisite nexus. *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 met its burden and the Court should not accord any weight to Amgen's alleged considerations of long felt need and failure of others. These are the only theories of secondary considerations even advanced at trial by Amgen witnesses. Yet, there was no nexus, as neither Nancy Spaeth (who could not even testify what medicine she received) nor Eli Friedman, who stated he was not competent to analyze the claims of the patents in suit, could provide that nexus.

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. *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. Moreover, none of the purported public praise is in

evidence. (*See* D.I. 1266).

Moreover, Amgen purported to present evidence through Dr. Orkin on the failure of others to developed the claimed invention. However, Amgen presented no evidence suggesting that Dr. Orkin's failure was due to anything other than the fact that unlike Dr. Lin, he did not have sufficient amounts of Dr. Goldwasser's EPO protein for sequencing. In fact, Dr. Orkin admitted as much. (Orkin 1603:20-1604:1, 1604:17-22, 1605:24-1606:1, 1607:23-25, 1649:6-1653:6; TRX 2097). Accordingly, the failure of others cannot be linked to any of the claims of the patents-in-suit.

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 be instructed in accordance with Roche's proposed jury instructions (*see* D.I. 1343, Roche's Proposed Jury Instruction 4.12) as well as the principles set forth in this memorandum.

DATED: October 10, 2007

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

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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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