# **EXHIBIT B**

## 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

## DEFENDANTS' 35 U.S.C. § 282 NOTICE

Pursuant to 35 U.S.C. § 282, Defendants F. Hoffmann-La Roche LTD, Roche

Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") hereby give notice of (i) each patent and publication that may be "relied upon as anticipation of [a] patent–in–suit or ... as showing the state of the art," and (ii) the names and addresses of each person "who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of [a] patent–in–suit."

With respect to United States Patent Nos. 5,441,868, 5,618,698, 5,756,349, 5,955,422 and 5,547,933 (the "patents-in-suit"), Roche gives notice of the following patents, publications, and persons:

#### A. <u>Patents</u>

Description DE 3316297 A1 - Goeddel and Pennica, Human tissue plasminogen activator, pharmaceutical compositions containing it, processes for making it, and DNA and transformed cell

Description
Lappin et al., "The Effect of Erythropoietin and Other Factors on DNA synthesis by Mouse Spleen Cells," Exp. Hematol., 11(7), 661-666 (Aug. 1983)
Lasky et al., "Production of an HSV Subunit Vaccine by Genetically Engineered Mammalian Cell Lines," Modern Approaches to Vaccines, pp. 189-194, Chanock et al., eds. Cold Spring Harbor Lab. (1984)
Lasne et al., "Detection of isoelectric profiles of erythropoietin in urine: differentiation of natural and administered recombinant hormones," Anal. Biochem. 311: 119-126 (2002)
Lasne et al., "Recombinant erythropoietin in urine" Nature 405: 635 (2000)
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Lau et al., "Amplification and expression of human $\alpha$ -globin genes in Chinese hamster ovary cells," Mol. Cell. Biol. 4:1469–75 (1984)
Laub and Ritter, "Expression of the Human Insulin Gene and cDNA in a Heterologous Mammalian System," J. Biol. Chem., 258(10), 6043-6050 (May 25, 1983)
Laub et al., "Synthesis of Hepatitis B Surface Antigen in Mammalian Cells: Expression of the Entire Gene and the Coding Region," J. Virol., 48(1), 271-280 (1983)
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Lawn et al., "The Isolation and Characterization of Linked.delta and.betaGlobin Genes from a Cloned Library of Human DNA," Cell, 15, 1157-1174 (Dec. 1978)
Ledeen et al., "Gangliosides: Structure, Isolation, and Analysis," Methods in Enzymology, 83 (Part D), 139-191 (1982)
Lee-Huang, "A New Preparative Method for Isolation of Human Erythropoietin With Hydrophobic Interaction Chromatography," Blood, 56(4), 620-624 (1980)
Lee-Huang, "Cloning and Expression of Human EPO cDNA in E. Coli, "Proc. Natl. Acad. Sci. (USA), 81, 2708-2712 (1984)
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Lee-Huang, "Monoclonal Antibodies to Human Erythropoietin," Abstract No. 1463, Fed. Proc., 41, 520 (1982)
Lee-Huang, "The Erythropoietin Gene," Oncogenes, Genes and Growth Factors, Chap. 7, pp. 199-222, ed. Gordon Garaff, John Wiley & Sons, Inc. (1987)
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Lerner et al., "Chemically synthesized peptides predicted from the nucleotide sequence of the hepatitis B virus genome elicit antibodies reactive with the native envelope protein of Dane particles," P.N.A.S. (USA), 78(6), 3403-3407 (1981)

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Li et al., "Biosynthesis of lipid–linked oligosaccharides," J. Biol. Chem. 254:1600–05 (1979)

### Description

Ullrich et al., "Insulin-like growth factor I receptor primary structure: comparison with insulin receptor suggests structural determinants that define functional specificity," EMBO J., 5(10), 2503-2512 (1986)

Ullrich et al., "Isolation of the Human Insulin-like Growth Factor I Gene Using a Synthetic DNA Probe," EMBO J. 3: 361-364 (February 1984)

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Wallace et al., "Oligonucleotide Directed Mutagenesis of the Human.beta.-globin gene: A General Method for Producing Specific Point Mutations in cloned DNA," Nucleic Acids Research, 9(15), 3647-3657 (1981)

Wallace et al., "The use of synthetic oligonucleotides as hybridization probes. II Hybridization

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# D. <u>Other</u>

# Description

Abstract Submission to American Federation of Clinical Research (November 1982) (FG 0000051–52)

Activities by Dr. Daniel Shouval and colleagues during 1981 through 1986 concerning development and characterization of EPO producing cells (including the RC–1 cell line and EPO producing tumors, and experiments documented in DS0000001–112)

Activities by Dr. Franklin Gaylis and colleagues during 1982 through 1984 concerning development and characterization of EPO producing cells (1411H), including communications between Dr. Gaylis and Amgen (Joan Egrie), Biogen (Fred Asselberg) and Dr. Eugene Goldwasser

Activities by Dr. James Fisher and colleagues during 1981 through 1985 concerning development and characterization of EPO producing cells (including EPO producing cell lines and tumors)

Activities from 1981 through 1985 conducted by and/or on behalf of Biogen concerning the cloning, characterization and expression of the human erythropoietin gene

Activities from 1981 through 1985 conducted by and/or on behalf of Genetics Institute concerning the cloning, characterization and expression of the human erythropoietin gene

Dordal M, Thesis (AM-ITC 00925913-926021)

Gaylis Grant Application (February 1983) [FG 000033-45]

Genentech Press Release, "Genentech has begun human evaluation of t-PA in heart victims," (2/21/84) accessible at http://www.gene.com/gene/news/press-releases/

Genentech, Inc., Product License Application for Activase<sup>™</sup> (Recombinant Human Tissue– Type Plasminogen Activator, rt–PA) clinical and pre–clinical study summaries (ROCHE–GNE 00001–00036, 00094–00136,00383–00578, 01277–01446, 01447–01959, 03009–03060)

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Goldwasser Application for Continuation of Grant (Dept. of Health and Human Servs.), "Erythropoietin:Purification, Properties, Biogenesis" (August 31, 1984)