EXHIBIT A

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

CONTAINS RESTRICTED ACCESS BLA/IND CONFIDENTIAL INFORMATION

SUBJECT TO PROTECTIVE ORDER

FOURTH EXPERT STATEMENT OF RICHARD A. FLAVELL, PH.D.
IN RESPONSE TO VARIOUS ARGUMENTS RAISED BY AMGEN'S EXPERTS

concerning the standard to be used in the assay makes it impossible to determine whether, in fact, a sample contains a given number of Units of EPO using RIA.

67. Claim 7 of the '349 patent is invalid for lack of enablement for several reasons. First, the patent fails to disclose sufficient information to teach one of skill to correlate RIA results with biological assay results. The patents further fail to instruct how to determine the number of Units of erythropoietin in an unknown sample having an unknown specific activity. The limitation in the claim therefore invites one of skill to *guess* the specific activity or *assume* that it is equal to that of the standard used in the assay. Finally, Claim 7 is not enabled because there is no instruction on how to discriminate between "erythropoietin" according to the claims and erythropoietin fragments or analogs, or other materials that are not erythropoietin.

IV. MY OPINION DOES NOT CHANGE THAT THE CLAIMS ~~LACK~~ ARE INDEFINITE ~~INDEFINITENESS~~ AND LACK WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112

68. In his Supplemental Expert Report,[74] Dr. Lodish presents a lengthy rebuttal of the invalidity positions I raised in my Corrected Supplemental Expert Report dated May 8, 2007. Dr. Bradshaw presents similar opinions in his Rebuttal Report.[75] If I understand Amgen's experts' positions correctly, Drs. Lodish and Bradshaw believe that the patent specification provides "sufficient guidance to a person of ordinary skill in the art to understand the metes and bounds of Dr. Lin's claimed inventions."[76] For the same reasons, Amgen's experts opine that the specification adequately describes "human erythropoietin" as defined by Amgen and accepted by

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[74] Supplemental Expert Report of Harvey F. Lodish, Ph.D. dated June 4, 2007 (the "Lodish Supplemental Report").

[75] *See generally* Rebuttal Report of Ralph A. Bradshaw, Ph.D. to New Non-Infringement Arguments Raised in the Rebuttal Reports of Defendants' Experts dated June 1, 2007.

[76] Lodish Supplemental Report ¶ 13.