EXHIBIT A

CONTAINS RESTRICTED ACCESS CONFIDENTIAL BLA/IND MATERIAL
PURSUANT TO PROTECTIVE ORDER

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,	:	
Plaintiff,	:	
v.	:	
F. HOFFMANN-LA ROCHE LTD, a Swiss Company, ROCHE DIAGNOSTICS GmbH, a German Company and HOFFMANN-LA ROCHE INC., a New Jersey Corporation,	:	Civil Action No.: 05-12237 WGY
Defendants.	:	

DEFENDANTS' RESPONSES AND OBJECTIONS TO PLAINTIFF AMGEN INC.'S FIRST SET OF INTERROGATORIES TO DEFENDANTS (NOS. 1-15)

Defendants F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") make the following objections and responses to Plaintiff Amgen Inc.'s ("Amgen") First Set of Interrogatories (Nos. 1-15).

GENERAL OBJECTIONS

The following general objections apply to all of Defendants' responses and shall be incorporated in each response as if fully set forth therein. To the extent specific General Objections are cited in response to a specific interrogatory, those specific General Objections are provided because they are believed to be particularly applicable to the specific interrogatory and are not to be construed as waiver of any other General Objections applicable to the interrogatory.

Defendants object to each and every interrogatory to the extent it seeks information protected by the attorney-client privilege, the attorney work product doctrine and/or any other applicable privilege. All answers herein shall be subject to this objection, and no provision of information herein may act as a waiver of these objections.

INTERROGATORY NO. 9

Separately, in claim chart form for each claim of Amgen's patents-in-suit that you contend in your Fifth and Sixth Affirmative Defenses or Tenth Counterclaim is invalid, identify:

(a) on a limitation-by-limitation basis, the legal and factual grounds on which you contend that such claim is invalid;

(b) the level of skill of a person having ordinary skill in the art to which the subject matter of the patents-in-suit pertains at the time of the claimed inventions;

(c) all evidence on which you rely in support of each contention, including all documents, testimony, prior knowledge, or public uses tending to support your contention(s), every test, experiment, and/or data upon which you rely in support of each contention that a claim is invalid;

(d) each person, other than counsel, who furnished information or was consulted regarding Roche's response to this interrogatory including the nature and substance of each such person's knowledge or information; and

(e) the three individuals affiliated with Roche, other than counsel, most knowledgeable regarding the subject matter of this interrogatory, stating the nature and substance of each such person's knowledge or information.

RESPONSE:

Defendants object to this interrogatory as unduly vague, ambiguous and overly broad. Moreover, Defendants object to this interrogatory to the extent that it calls for information

protected by the attorney-client privilege or work-product immunity. Defendants also object to this interrogatory because it constitutes multiple interrogatories and should be counted against Amgen as such for purposes of the 40 interrogatory limit imposed by the Court.

Defendants also object to this interrogatory because it is premature and calls for expert testimony. The asserted claims of the patents-in-suit have not been construed and the Court does not expect a *Markman* hearing on these claims until April 2, 2007.

Defendants reserve the right to modify or supplement this response at any time upon receipt of relevant materials from any source during discovery.

Subject to and without waiver of these Specific Objections and General Objections set forth above which are incorporated herein by reference, Defendants respond as follows.

A. Obviousness-Type Double Patenting and Same Invention Double Patenting under Section 101

All of the asserted claims of the patents-in-suit are invalid for obviousness-type double patenting over Amgen's now expired U.S. Patent No. 4,703,008 ("the '008 patent"). The '008 patent claims, among other things, the isolated DNA sequence encoding EPO as well as mammalian host cells transformed with this DNA sequence in a manner allowing these cells to express biologically active and glycosylated EPO protein. The '008 patent and the patents-in-suit all share the same specification and single inventor, and demonstrate that Amgen possessed only a single invention with minor obvious variations: mammalian host cells that can express the EPO protein using recombinant DNA technology to produce reliable quantities of EPO.

Amgen already convinced the Board of Patent Appeals of PTO during interference proceedings with Genetics Institute and Chugai, that once the skilled worker had isolated the EPO gene - as claimed in the '008 patent - there was nothing novel or inventive in the process of expressing that gene in host cells and then isolating the biologically active glycoprotein - as

claimed in the patents-in-suit. In those same proceedings, Amgen categorically stated that the EPO gene of the '008 patent and the process for making biologically active EPO, as claimed by the patents-in-suit, "are only different manifestations of the same invention." *See* Brief for the Senior Party Lin, Interference No. 102,097, dated 7/29/91 at 25-26.

In particular, during these Interference Proceedings, Amgen stated that the Counts to Interference Nos. 102,096 and 102,097 were directed to the same invention. The Count to Interference No. 102,096 was as follows, and is identical to claim 2 of the '008 patent:

> A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin.

The Count to Interference No. 102,097 was as follows, and covers all the essential elements of the asserted claims of the patents-in-suit:

> A process for the preparation of an in vivo biologically active glycosylated polypeptide comprising steps of 1. growing mammalian cells transformed with DNA encoding a polypeptide sufficiently duplicative of human EPO to have the in vivo biological properties of increasing red blood cells and reticulocytes, 2. transcribing the DNA to mRNA, 3. translating the mRNA into a polypeptide, 4. glycosylating the polypeptide in a manner sufficiently duplicative of the glycosylation of natural human EPO to effect the recited biological activity and 5. isolating the glycosylated polypeptide.

During the 102,097 interference, Amgen argued that the Board should adopt the findings of the District Court and the Federal Circuit regarding priority and validity issues in *Amgen, Inc. v. Chugai Pharms.*, 927 F.2d 1200 (Fed. Cir. 1991). In *Amgen*, the District of Massachusetts and the Federal Circuit found that Amgen had been the first to invent the claimed DNA sequences and host cells of the '008 patent before Genetics Institute. *Id.* Therefore, Amgen took advantage of these courts' rulings by maintaining that it should apply to the interference proceedings. Amgen argued that even though the count of the 102,097 proceeding was directed to the

production of biologically active glycosylated EPO, and the litigation involved the DNA sequence and host cells of the '008 patent, this did not matter because they were the same invention. Amgen also made similar statements regarding the identity between the DNA claims and the protein claims during the prosecution of the patents-in-suit, as well as in foreign litigation.

The Patent Board agreed with Amgen's position and as a result, Amgen was allowed to proceed with the prosecution of the patents-in-suit and received a tangible benefit. As a result, Amgen is now judicially estopped from denying that the claims of the '008 invalidate the asserted claims of the patents-in-suit.

Importantly, Amgen is not shielded from this double patenting attack under 35 U.S.C. § 121 because among other things, Section 121 provides a safe harbor to patents issued from divisional applications whereas the patents-in-suit issued from continuations of the application that became the '008 patent. Moreover, Amgen did not maintain consonance with the restriction requirements *See Bristol-Myers Squibb Co. v. Research Corp. Tech.*, 361 F.3d 1343, 1348 (Fed. Cir. 2004); *Geneva,* 349 F.3d at 1381; *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1579 (Fed. Cir. 1991). ("Consonance requires that the line of demarcation between 'independent and distinct inventions' that prompted the restriction requirement be maintained. . . . Where that line is crossed the prohibition of the third sentence of Section 121 does not apply.").

Evidence supporting this contention can be found at Interference File History Nos. 102,096 and 102,097, *Fritsch v. Lin*, 21 U.S.P.Q.2d 1731 (Bd. Pat. App. & Interf. 1991), *Fritsch v. Lin*, 21 U.S.P.Q. 2d 1737 (Bd. Pat. App. & Interf. 1992), and *Amgen, Inc. v. Chugai Pharms.*, 927 F.2d 1200 (Fed. Cir. 1991).

INTERROGATORY NO. 11

Separately, in claim chart form for each claim of Amgen's patents-in-suit that you contend is invalid under 35 U.S.C. § 103 or for double patenting, identify and describe for each claim and for each asserted defense:

(a) where, on a limitation-by-limitation basis, you contend each claim limitation is found or disclosed in the prior art or earlier Lin patent claims;

(b) why the claim would have been obvious, including where the motivation to combine prior art disclosures or earlier Lin patent claims may be found;

(c) why 35 U.S.C. § 121 does not bar the application of the doctrine of obviousness-type double patenting;

(d) all evidence on which you rely in support of each contention, including all documents, testimony, prior knowledge, or public uses tending to support your contention(s), every test, experiment or data upon which you rely to support your contention(s);

(e) each person, other than counsel, who furnished information or was consulted regarding your response to this interrogatory including the nature and substance of each such person's knowledge or information; and

(f) the three individuals affiliated with Roche, other than counsel, most knowledgeable regarding the subject matter of this interrogatory, stating the nature and substance of each such person's knowledge or information.

RESPONSE:

See Objections and Response To Interrogatory No. 9 above.

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DATED: January 11, 2007

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

By its attorneys,

Patricia Carson / H. H.

Leora Ben-Ami (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
KAYE SCHOLER LLP
425 Park Avenue
New York, NY 10022
Tel: (212) 836-8000

and

Lee Carl Bromberg (BBO# 058480)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292

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CERTIFICATE OF SERVICE

I hereby certify that a copy of this document was served upon the attorneys of record for the plaintiff (as listed below) by overnight mail on the above date.

Lloyd R. Day, Jr. (*pro hac vice*)
David A. Madrid (*pro hac vice*)
Linda A. Sasaki-Baxley (*pro hac vice*)
DAY CASEBEER MADRID &
BATCHELDER LLP
20300 Stevens Creek Boulevard, Suite 400
Cupertino, CA 95014
Telephone: (408) 873-0110
Facsimile: (408) 873-0220

D. Dennis Allegretti (BBO#545511)
Michael R. Gottfried (BBO#542156)
Patricia R. Rich (BBO# 640578)
DUANE MORRIS LLP
470 Atlantic Avenue, Suite 500
Boston, MA 02210
Telephone: (617) 289-9200
Facsimile: (617) 289-9201

William G. Gaede III (*pro hac vice*)
McDERMOTT WILL & EMERY
3150 Porter Drive
Palo Alto, CA 94304
Telephone: (650) 813-5000
Facsimile: (650) 813-5100

Kevin M. Flowers (*pro hac vice*)
Thomas I. Ross (*pro hac vice*)
MARSHALL, GERSTEIN & BORUN LLP
233 South Wacker Drive
6300 Sears Tower
Chicago IL 60606
Telephone: (312) 474-6300
Facsimile: (312) 474-0448

Hank Heckel