Amgen Inc. v. F. Hoffmann-LaRoche LTD et al Doc. 1165 Att. 2

EXHIBIT B

Dockets.Justia.com

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' SUPPLEMENTAL 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.

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

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

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

(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

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

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.

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

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).

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

SUPPLEMENTAL RESPONSE

Roche supplements this response with the following chart showing which of the asserted claims of the patents-in-suit are invalid by certain defenses.

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

Claims Asserted by Roche to Be Invalid

'080 Patent Claim	35 U.S.C. §102	35 U.S.C. §103	35 U.S.C. §112	Double Patenting / 35 U.S.C. § 101
3. A non-naturally occurring erythropoietin glycoprotein having the in vivo biological activity of causing bone marrow cells to increase production of reticulocytes and red blood cells, wherein said erythropoietin glycoprotein comprises the mature erythropoietin amino acid sequence of FIG. 6.	✓	✓	✓	✓
4. A pharmaceutical composition comprising a therapeutically effective amount an erythropoietin glycoprotein product according to claim 1, 2 or 3	✓	✓	✓	✓
6. A method for treating a kidney dialysis patient which comprises administering a pharmaceutical composition of claim 4 in an amount effective to increase the hematocrit level of said patient.		✓	✓	✓

'868 Patent Claim	35 U.S.C. §102	35 U.S.C. §103	35 U.S.C. §112	Double Patenting / 35 U.S.C §101
1. A process for the production of a glycosylated erythropoietin polypeptide having the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells comprising the steps of: (a) growing, under suitable nutrient conditions, mammalian host cells transformed or transfected with an isolated DNA sequence encoding human erythropoietin; and (b) isolating said glycosylated erythropoietin polypeptide therefrom..		✓	✓	✓
2. The process according to claim 1 wherein said host cells are CHO cells.		✓	✓	✓

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

'698 Patent Claim	35 U.S.C. §102	35 U.S.C. §103	35 U.S.C. §112	Double Patenting / 35 U.S.C §101
4. A process for the production of a glycosylated erythropoietin polypeptide having the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells comprising the steps of: a) growing, under suitable nutrient conditions, vertebrate cells comprising promoter DNA, other than human erythropoietin promoter DNA, operatively linked to DNA encoding the mature erythropoietin amino acid sequence of FIG. 6; and b) isolating said glycosylated erythropoietin polypeptide expressed by said cells.		✓	✓	✓
5. The process of claim 4 wherein said promoter DNA is viral promoter DNA.		✓	✓	✓
6. A process for the production of a glycosylated erythropoietin polypeptide having the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells comprising the steps of: a) growing, under suitable nutrient conditions, vertebrate cells comprising amplified DNA encoding the mature erythropoietin amino acid sequence of FIG. 6; and b) isolating said glycosylated erythropoietin polypeptide expressed by said cells.		✓	✓	✓
7. The process of claim 6 wherein said vertebrate cells further comprise amplified marker gene DNA.		✓	✓	✓
8. The process of claim 7 wherein said amplified marker gene DNA is Dihydrofolate reductase (DHFR) gene DNA.		✓	✓	✓
9. The process according to claims 2, 4 and 6 wherein said cells are mammalian cells		✓	✓	✓

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

'349 Patent				
Claim	35 U.S.C. §102	35 U.S.C. §103	35 U.S.C. §112	Double Patenting/ 35 U.S.C §101
7. A process for producing erythropoietin comprising the step of culturing, under suitable nutrient conditions, vertebrate cells according to claim 1, 2, 3, 4, 5 or 6.		✓	✓	✓

'422 Patent				
Claim	35 U.S.C. §102	35 U.S.C. §103	35 U.S.C. §112	Double Patenting / 35 U.S.C §101
1. A pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant or carrier, wherein said erythropoietin is purified from mammalian cells grown in culture.	✓	✓	✓	✓

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

'933 Patent Claim	35 U.S.C. §102	35 U.S.C. §103	35 U.S.C. §112	Double Patenting / 35 U.S.C §101
3. A non-naturally occurring glycoprotein product of the expression in a mammalian host cell of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin said product possessing the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells.	✓	✓	✓	✓
7. The glycoprotein product according to claim 3, 4, 5 or 6 wherein the host cell is a non-human mammalian cell.	✓	✓	✓	✓
8. The glycoprotein product according to claim 7 wherein the non-human mammalian cell is a CHO cell.	✓	✓	✓	✓
9. A pharmaceutical composition comprising an effective amount [sic. of] a gylcoprotein product effective for erythropoietin therapy according to claim 1, 2, 3, 4, 5 or 6 and a pharmaceutically acceptable diluent, adjuvant or carrier.	✓	✓	✓	✓
11. A method for treating a kidney dialysis patient which comprises administering a pharmaceutical composition of claim 9 in an amount effective to increase the hematocrit level of said patient.		✓	✓	✓
12. A pharmaceutical composition comprising an effective amount of a glycoprotein product effective for erythropoietin therapy according to claim 7 and a pharmaceutically acceptable diluent, adjuvant or carrier.	✓	✓	✓	✓
14. A method for treating a kidney dialysis patient which comprises administering a pharmaceutical composition of claim 12 in an amount effective to increase the hematocrit level of said product [sic. patient?].		✓	✓	✓

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

With respect to double patenting, Roche contends that at least claims 1, 2, 4, 5, 6, 7, 8, 23, 24, 25, 26, and 27 of U.S. Patent No. 4,703,008 render the asserted claims of the patents-in-suit invalid as identified above.

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;

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

(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.

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

DATED: February 9, 2007

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

By its attorneys,

/s/ Thomas F. Fleming
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

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

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

Gary Groblewski