

EXHIBIT 12

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

AMGEN INC.,	)	
	)	
Plaintiff,	)	CIVIL ACTION No.: 05-cv-12237WGY
vs.	)	
	)	
F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH, AND HOFFMANN- LA ROCHE INC.,	)	
	)	
Defendants.	)	

**DEFENDANTS' THIRD SET OF INTERROGATORIES (NOS. 19-40)**

Pursuant to Federal Rule of Civil Procedure 33, applicable local rules of the District of Massachusetts, and the Court's November 7, 2007 Scheduling Order, Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche, Inc. (collectively "Roche") request that Plaintiff Amgen, Inc. ("Amgen") answer the following interrogatories within thirty days of service.

**DEFINITIONS AND INSTRUCTIONS**

Respondents incorporate by reference the Definitions and Instructions set forth in DEFENDANTS' FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS AND THINGS. In addition:

22. The terms "identify," "identity" and "identification," when referring to a person, mean to give, to the extent known, the person's full name, present or last known address, and, when referring to a natural person, the present or last known place of employment, and when referring to documents, mean to give, to the extent known, (a) the type of document; (b) the

general subject matter; (c) the date of the document; (d) the author(s), addressee(s), and recipient(s) of the document, and (e) the Bates number of the document.

23. The term "Patents-In-Suit" shall mean or refer to U.S. Patent No. 5,547,933; U.S. Patent No. 5,621,080; U.S. Patent No. 5,441,868; U.S. Patent No. 5,756,349; U.S. Patent No. 5,955,422 or U.S. Patent No. 5,618,698.

### **INTERROGATORIES**

#### **INTERROGATORY NO. 19**

Separately, in claim chart form for each asserted claim of Amgen's patents-in-suit, state in complete detail and identify for each claim limitation all evidence you contend demonstrates that each limitation has adequate written description and is enabled pursuant to 35 U.S.C. § 112, including portions of the respective specifications identified by column and line number and/or figure and any specific documents, statements therein, testimony, and/or prior court rulings that you rely on as evidence; identify each person, other than counsel, who furnished information for or was consulted regarding your response to this interrogatory, stating the nature and substance of each such person's knowledge or information; and identify the three individuals, other than counsel or person employed by the PTO, most knowledgeable regarding the subject matter of this Interrogatory, stating the nature and substance of each such person's knowledge or information.

#### **INTERROGATORY NO. 20**

For each allegation of inequitable conduct relating to the patents-in-suit (including, but not limited to, the allegations set forth in paragraphs 33-88 of "Defendants' [Proposed] First

Amended Answer and Counterclaims to Plaintiffs' Complaint," dated December 8, 2006 and any response by Roche to "Plaintiff Amgen Inc.'s Third Set of Interrogatories to Defendants (No. 26)", separately and specifically describe all legal, factual and evidentiary bases that support, refute or otherwise relate to such allegation of a material omission and/or material misrepresentation and corresponding intent to deceive the PTO (including any allegation of good faith by applicants), including identifying the specific documents, statements therein, witness, testimony, and things that support, refute or otherwise relate to such allegation; identify each person, other than counsel, who furnished information for or was consulted regarding your response to this interrogatory, stating the nature and substance of each such person's knowledge or information; and identify the three individuals, other than counsel or person employed by the PTO, most knowledgeable regarding the subject matter of this Interrogatory, stating the nature and substance of each such person's knowledge or information.

**INTERROGATORY NO. 21**

If you contend that non-obviousness of the asserted claims of the patents-in-suit is supported by any secondary considerations or objective evidence of non-obviousness including commercial success, long-felt need, and/or unexpected results, or any other criteria, identify, on a claim by claim and patent by patent basis, each such secondary consideration, state and describe in detail your contention as to why this secondary consideration applies and how it satisfies the requirements of proving non-obviousness, the basis for each such secondary consideration's nexus to the alleged invention of the asserted claim, including any improvement over any relevant prior art, identify all facts concerning such secondary consideration, and identify, by Bates number, documents supporting or contradicting each such secondary consideration and its

nexus to an alleged invention of the asserted claims, and identify the three people at Amgen most knowledgeable about these issues.

**INTERROGATORY NO. 22**

For each of the date ranges below, identify each project that Dr. Fu-Kuen Lin was working on other than the EPO Project, the percent of his time spent working on each project, and which other individuals were involved. In addition, identify all documents and things that support or otherwise refute Amgen's response to this Interrogatory.

Date Ranges:

- a. September 1, 1983 to November 30, 1984
- b. September 1, 1983 to September 28, 1983
- c. September 28, 1983 to October 10, 1983
- d. October 10, 1983 to November 3, 1983
- e. November 3, 1983 to December 3, 1983
- f. December 3, 1983 to January 10, 1984
- g. January 10, 1984 to February 7, 1984
- h. February 7, 1984 to March 1, 1984
- i. March 1, 1984 to April 5, 1984
- j. April 5, 1984 to May 16, 1984
- k. May 16, 1984 to July 1, 1984
- l. July 1, 1984 to August 27, 1984
- m. August 27, 1984 to September 28, 1984
- n. September 28, 1984 to October 18, 1984
- o. October 18, 1984 to November 30, 1984

**INTERROGATORY NO. 23**

For any Amgen Employee or Agent who had any involvement in (1) the prosecution of any of Amgen's EPO Patents in Europe or the United Kingdom (including but not limited to

Amgen's EP 0 148,605) or (2) any opposition proceeding or litigation in Europe or the United Kingdom involving any of Amgen's EPO Patents (including but not limited to Amgen's EP 0 148,605), or (3) any opposition proceeding or litigation involving Genetics Institute's EP 0 411 678 and EP 0 209 539, identify each such Employee or Agent, the time(s) of such involvement, the time(s) during which such Employee or Agent was involved in prosecution of Amgen's EPO Patents in the United States, and identify each instance where such Employee or Agent has provided any testimony, declaration or other evidence in any legal proceeding or in connection with any submissions to any regulatory agency, including the FDA or EMEA regarding the characterization of any recombinant human erythropoietin produced through mammalian cell expression, including any comparison of such a recombinant human erythropoietin with any erythropoietin isolated from, or present in any human source, including plasma or urine, including any comparison or analysis of data from different studies or experiments.

**INTERROGATORY NO. 24**

Describe all efforts by Amgen before 1984 to identify, and/or conduct any analysis of, any cell or tissue expressing, secreting and/or otherwise producing erythropoietin, including (a) any characterization of erythropoietin produced by any such cell or tissue, (b) the source of any such cell, tissue or erythropoietin, and (c) any communications by Amgen with any third party concerning such efforts.

**INTERROGATORY NO. 25**

Describe all efforts by Amgen before 1984 to identify, and/or conduct any analysis of any erythropoietin purified, isolated or otherwise derived from human urine, plasma, blood or other

body fluid, and identify the source of such erythropoietin and any communications by Amgen with any third party concerning such efforts.

**INTERROGATORY NO. 26**

Identify all analyses by Amgen or conducted on behalf of Amgen comparing any human erythropoietin purified, isolated or otherwise derived from any non-recombinant source (cell, tissue or body fluid) with any recombinant human erythropoietin produced through mammalian cell expression, including any communications by Amgen with any third party concerning such efforts.

**INTERROGATORY NO. 27**

Identify all efforts by Amgen prior to 1985, either planned and/or carried out, to express any biologically active glycosylated protein or polypeptide in any mammalian cell, including:

- a. all personnel involved in planning, conducting or supervising such efforts;
- b. all experimental techniques, approaches and methods considered or used by Amgen in connection with such efforts;
- c. the identity of each cell or cell line considered and/or used in connection with such efforts;
- d. all memoranda, reports, summaries and/or other documentation of such efforts;
- e. all communication, at any time, of such efforts to any individual involved in prosecution of Amgen's EPO Patents.

**INTERROGATORY NO. 28**

Identify all DNA libraries, including cDNA libraries and genomic libraries, that Amgen considered, used, constructed or attempted to construct in connection with any attempt to clone the human EPO gene, including all personnel involved in planning, conducting or supervising any efforts to use or construct such DNA libraries, the identity of each cell or cell line considered and/or used in connection with such efforts, and identify all documents (by specific Bates number) containing information about such DNA libraries.

**INTERROGATORY NO. 29**

If Amgen contends that at any time before 1985 one of skill could have, without undue experimentation, isolated or otherwise made a cDNA clone encoding the amino acid sequence of human erythropoietin and containing an open reading frame and 5' and 3' non-coding regions complementary to those found in any mRNA from human cells or tissue, or that Amgen before 1985 possessed any such cDNA clone, state all facts and identify all documents (by specific Bates number if produced) that support Amgen's contention that one of skill could have isolated such a cDNA clone or that Amgen possessed such a clone; identify each person, other than counsel, who furnished information for or was consulted regarding your response to this interrogatory, stating the nature and substance of each such person's knowledge or information; and identify the three individuals, other than counsel or person employed by the PTO, most knowledgeable regarding the subject matter of this Interrogatory, stating the nature and substance of each such person's knowledge or information.



**INTERROGATORY NO. 30**

If Amgen contends that before 1985, there was a known non-recombinant source for mRNA encoding human EPO, including any non-recombinant cell or tissue, state all facts and identify all documents (by specific Bates number if produced) that support Amgen's contention that before 1985, there was a known non-recombinant source for mRNA encoding human EPO; identify each person, other than counsel, who furnished information for or was consulted regarding your response to this interrogatory, stating the nature and substance of each such person's knowledge or information; and identify the three individuals, other than counsel or person employed by the PTO, most knowledgeable regarding the subject matter of this Interrogatory, stating the nature and substance of each such person's knowledge or information.

**INTERROGATORY NO. 31**

Describe all attempts by Amgen to make Pegylated ESA Compounds such that any chemical, physical, pharmacological and/or pharmacokinetic properties of the chemically modified compound differs from the EPO or ESA, including;

- (i) attempts by Amgen to modify EPO proteins or any ESA,
- (ii) attempts by Amgen to chemically modify the EPO protein such that its pharmacologic and/or pharmacokinetic profile is different from the active drug product in Epogen®, including increased half life and different erythropoiesis activity.

**INTERROGATORY NO. 32**

Identify the contribution, of any Amgen Employee or other Person of which Amgen is aware, other than Dr. Fu-Kuen Lin, to the claimed subject matter of Amgen's EPO Patents,

including the conception and reduction to practice of each claim element of the asserted claims of Amgen's EPO Patents, and to developing the subject matter disclosed in the specification of Amgen's EPO Patents, including, to the extent Amgen contends that such subject matter is described by Amgen's EPO patents: (a) cloning of the human erythropoietin gene, and (b) any method for expressing DNA encoding human EPO in mammalian host cells, including without limitation any vectors, host cells, and/or protocols or procedures for transforming host cells, culturing host cells, glycosylating the EPO protein so expressed and/or isolating the resulting EPO protein to make a product having biological activity *in vivo*; identify each person, other than counsel, who furnished information for or was consulted regarding your response to this interrogatory, stating the nature and substance of each such person's knowledge or information; and identify the three individuals, other than counsel or person employed by the PTO, most knowledgeable regarding the subject matter of this Interrogatory, stating the nature and substance of each such person's knowledge or information.

### **INTERROGATORY NO. 33**

For each of the asserted claims of Amgen's EPO patents, in claim chart form, identify the earliest effective filing date for each of the asserted claims, and state all facts and identify all documents supporting such a contention, including any and all factual support necessary to establish that the asserted claim is entitled to the filing date of any application that Amgen contends provides sufficient support to satisfy the written description, enablement and best mode requirements of 35 U.S.C. § 112, identify all documents that refer or relate to such facts, whether in support or contradiction, identify each person, other than counsel, who furnished information for or was consulted regarding your response to this interrogatory, stating the nature and

substance of each such person's knowledge or information; and identify the three individuals, other than counsel or person employed by the PTO, most knowledgeable regarding the subject matter of this Interrogatory, stating the nature and substance of each such person's knowledge or information.

**INTERROGATORY NO. 34**

Describe all Communications between Dr. Goldwasser and Amgen, including the transfer, exchange, provision or supply of information, know-how, or Things to Amgen from Dr. Goldwasser (or from Amgen to Dr. Goldwasser) concerning erythropoietin, crude or purified human urinary erythropoietin, erythropoietin radioimmunoassays, iodinated erythropoietin, erythropoietin purification methods, and antibodies to erythropoietin.

**INTERROGATORY NO. 35**

Describe all facts and circumstances known to Amgen supporting any contention by Amgen that to date there has been any act of infringement of the patents-in-suit by Roche; identify each person, other than counsel, who furnished information for or was consulted regarding your response to this interrogatory, stating the nature and substance of each such person's knowledge or information; and identify the three individuals, other than counsel or person employed by the PTO, most knowledgeable regarding the subject matter of this Interrogatory, stating the nature and substance of each such person's knowledge or information.

**INTERROGATORY NO. 36**

Describe all efforts by Amgen through 1987 to characterize any human erythropoietin, including (a) the characterization of any human erythropoietin purified, isolated or otherwise derived from any mammalian cell or cell culture, (b) the characterization of any erythropoietin purified, isolated or otherwise derived from human urine, plasma or blood, including any obtained through any collaboration with Eugene Goldwasser, or from any source material provided by Eugene Goldwasser; (c) any comparison of a recombinant human erythropoietin product produced through mammalian cell expression with any erythropoietin isolated from, or present in any human source, including plasma or urine, including any comparison or analysis of data from separate studies or experiments and including all memoranda, reports, summaries and/or other documentation concerning any comparison. and identify all personnel involved in planning, conducting or supervising such efforts, including their titles, roles and activities.

**INTERROGATORY NO. 37**

Describe all attempts by Amgen before 1984, successful or failed, to determine any portion of the amino acid sequence of human erythropoietin, including all memoranda, reports, summaries and/or other documentation concerning any such attempts and identify all personnel involved in planning, conducting or supervising such efforts, including their titles, roles and activities.

**INTERROGATORY NO. 38**

Identify all efforts by Amgen to characterize any human erythropoietin, where Amgen relied on, discussed, or referred to such characterization in connection with the prosecution of

any of Amgen's EPO patents, opposition proceedings in Europe to Genetics Institute's European patents EP 411 678 ("the '678 patent") and EP 209 539 ("the '539 patent"), opposition proceedings in Europe involving Amgen's European patent EP 148 605 ("the '605 patent"), including, (a) the characterization of any human erythropoietin purified, isolated or otherwise derived from any mammalian cell or cell culture, (b) the characterization of any erythropoietin purified, isolated or otherwise derived from human urine, plasma or blood, including any obtained through any collaboration with Eugene Goldwasser, or from any source material provided by Eugene Goldwasser; (c) any comparison of a recombinant human erythropoietin product produced through mammalian cell expression with any erythropoietin isolated from, or present in any human source, including plasma or urine, including any comparison or analysis of data from separate studies or experiments and including all memoranda, reports, summaries and/or other documentation concerning any comparison. and identify all personnel involved in planning, conducting or supervising such efforts, including their titles, roles and activities.

### **INTERROGATORY NO. 39**

Identify any comparisons, either experimental or otherwise (such as through the analysis of different studies) performed by Amgen, at the direction of, or for the benefit of Amgen of the active drug product in Aranesp® to recombinant human erythropoietin, including but not limited to comparisons to the active drug product in Epogen®, Procrit®, Eprex®, NeoRecormon® or any other ESA, including MIRCERA™, including comparisons regarding structure, composition, conformation, glycosylation, carbohydrate structure, sialic acid content, number and disposition, actual or apparent molecular weight, positional isomers, biological activity, interaction with the human erythropoietin receptor (including the equilibrium constant,

disassociation constant, association rate constant, change in free energy), pharmacodynamics, pharmacokinetics, immunogenicity and/or antigenicity, internalization and recycling by cells, and manner of clearance.

**INTERROGATORY NO. 40**

For each asserted claim of the patents-in-suit identified in response to Interrogatory No. 1, (i) separately describe each reason why the claim is not rendered invalid under the claims of U.S. Patent No. 4,667,016 to Lai *et al.* pursuant to obviousness-type double patenting, and the specific reasons for these contentions, (ii) to the extent that Amgen contends that an asserted claim is patentably distinct from the claims of U.S. Patent No. 4,667,016 to Lai *et al.*, separately list for each asserted claim each claim element or limitation of that asserted claim allegedly not found in the claims of U.S. Patent No. 4,667,016 to Lai *et al.*, and the specific reasons for these contentions, (iii) identify all documents and things that support, refute or otherwise relate to Amgen's response to this interrogatory; and (iv) identify all witnesses with knowledge of same.

Dated: March 2, 2007

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

By their attorneys,

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**CERTIFICATE OF SERVICE**

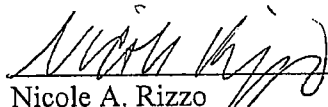
I hereby certify that a copy of this document was served upon the attorneys of record for the plaintiff (as listed below) by overnight mail on the above date and were served by hand on the firm of Duane Morris on the above date.

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