

# **Exhibit**

# **3**

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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

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

Plaintiff Amgen Inc. ("Amgen"), pursuant to Fed. R. Civ. P. 33 and L.R. 33.1, requests that Defendants Roche Holding Ltd., F. Hoffmann-La Roche Ltd., Roche Diagnostics GmbH, and Hoffmann La Roche Inc. answer the following interrogatories fully and separately under oath, pursuant to Fed. R. Civ. P. 33(a)(1), and where applicable, produce and make available for inspection and copying each of the documents and things specified below at the offices of Amgen's counsel, in accordance with the Definitions and Instructions set forth below.

**DEFINITIONS**

Amgen incorporates by reference the Definitions set forth in Amgen's October 30, 2006 First Set of Requests for Production of Documents and Things.

**INSTRUCTIONS**

1. If Roche contends that any of the following interrogatories is objectionable in whole or in part, Roche shall state with particularity each objection, the basis for it, and the

categories of information to which the objection applies, and shall respond to the interrogatory insofar as it is not deemed objectionable.

2. If any of these interrogatories cannot be answered in full, answer to the extent possible, specifying the reasons for your inability to answer the remainder and stating whatever information, knowledge, or belief you have concerning the unanswered portion.

3. If Roche believes that the meaning of any term in these interrogatories is unclear, Roche shall assume a reasonable meaning, state the assumed meaning and respond to the interrogatory according to the assumed meaning.

4. Any reference to any corporation or entity herein includes any of its agents, consultants, representatives, officers, directors, employees, affiliates, predecessors or successors in interest, parents, divisions, subsidiaries, regional offices, assignees, trustees, experts and attorneys.

5. With respect to any claim of privilege by Roche relating to any information, document or communication sought by any of these discovery requests, Roche is hereby requested to identify each such communication, information, or document withheld on grounds of an alleged privilege, and specifically set forth the following:

- (a) the nature and basis of the privilege claimed;
- (b) the author(s);
- (c) the addressee(s), including the recipients of copies;
- (d) the date of the communication, document or information;
- (e) the subject matter of the communication, document or information;
- (f) if the privilege claimed is the attorney-client privilege, an indication of which author(s) or addressee(s) is/are attorneys; and

(g) any other information necessary to support the claim of privilege.

6. These interrogatories are deemed continuing to the fullest extent permissible under Fed. R. Civ. P. 26(e). These interrogatories require therefore not only that Roche provide all information known to it up to and including the date of response, but also that if Roche subsequently acquires additional responsive information, Roche should promptly furnish it in writing and under oath to undersigned counsel.

### **INTERROGATORIES**

#### **INTERROGATORY NO. 1**

Separately, in claim chart form for each asserted claim of Amgen's patents-in-suit that you contend in your Third Affirmative Defense or Eleventh Counterclaim will not be infringed by the manufacture, importation, offer for sale, sale, and/or use of MIRCERA in the U.S. after FDA approval, state in complete detail what construction you contend the Court should apply to each limitation of each claim and identify all evidence on which you rely in support of your proposed construction of each claim limitation, including all documents, prior court rulings and/or testimony upon which you rely in support of each construction.

#### **INTERROGATORY NO. 2**

Separately, in claim chart form for each asserted claim of Amgen's patents-in-suit that you contend in your Third Affirmative Defense or Eleventh Counterclaim will not be infringed by the manufacture, importation, offer for sale, sale, and/or use of MIRCERA in the U.S. after FDA approval:

(a) state, on a claim-by-claim basis, whether you contend that you do not infringe each claim literally or under the doctrine of equivalents, and whether you do not infringe each such claim directly or indirectly and for each claim that you contend you do not infringe, identify by claim limitation each and every limitation on which you base such contention;

(b) state, on a limitation-by-limitation basis, the factual basis for each contention that MIRCERA does not embody each such claim limitation;

(c) identify all evidence on which you rely in support of each contention in 2(a) and (b) above, including all documents, tests, experiments, and/or data upon which you rely in support of each contention; and

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

(e) identify 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.

### **INTERROGATORY NO. 3**

Separately, in claim chart form for each asserted claim of Amgen's patents-in-suit that you contend will not be infringed under 35 U.S.C. § 271(g) by the manufacture, importation, offer for sale, sale, or use of MIRCERA in the U.S. after FDA approval, and to the extent not stated in response to Interrogatory No. 2, describe the factual basis for each such contention, including:

(a) the factual basis for any contention that MIRCERA is "materially changed" from the product described in such claim;

(b) the factual basis for any contention that EPO is a "trivial and nonessential component" of MIRCERA;

(c) each document and the relevant page(s) and statements therein that tend to support or refute your contention(s) as well as all documents relating to, mentioning, or concerning the bases for such contention(s);

(d) every test, experiment, and/or data upon which you rely in support of your contention that a product of a process claimed in Amgen's patents-in-suit is "materially changed" or is "a trivial and nonessential component" of MIRCERA; and

(e) identify 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) identify 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.

**INTERROGATORY NO. 4**

Identify the EPO-producing cell line used in the manufacturing process for MIRCERA, including the name of the cell line, the originator(s) of the cell line, the date(s) on which each clone of the cell line and/or the predecessor cells from which the cell line was derived were transported from or to the United States, each location where the cell line or cells derived from the cell line are currently stored, each person, other than counsel, who furnished information or was consulted regarding your response to this interrogatory, the nature and substance of each such person's knowledge or information; and 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.

**INTERROGATORY NO. 5**

Describe the identity and structure of each ESP made, considered or investigated by Roche to stimulate erythropoiesis in vivo, including its amino acid sequence, the position(s) of attachment and structure(s) of any carbohydrate(s) attached to the ESP, and the position(s) of attachment and structure(s) of any polyethylene glycol attached to the ESP and identify each person, other than counsel, who furnished information or was consulted regarding your response to this interrogatory, the nature and substance of each such person's knowledge or information and 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.

**INTERROGATORY NO. 6**

List separately each study or analysis of the mechanism of action of MIRCERA, the pharmacodynamic ("PD") and/or pharmacokinetic ("PK") properties of MIRCERA, and/or any comparison of the mechanism of action or PK/PD properties of MIRCERA with those of EPO (including epoetin alfa, epoetin beta, RECORMON®, NEORECORMON®, EPOGEN®, EPREX®, and/or PROCIT®), and for each such study or analysis identify the study investigator(s), all tests and/or experiments performed in the study, the results of the study or analysis, 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 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.

**INTERROGATORY NO. 7**

Identify each individual and each entity in the United States (other than Roche) to whom Roche or its agents or attorneys have provided PEG-EPO (including MIRCERA) for any purpose at any time, stating separately for each such individual or entity:

- (a) all date(s) on which and all locations to which such product was provided;
- (b) the purpose(s) for which such product was provided;
- (c) the quantity of product provided; and
- (d) each document (excluding only patient-specific information) recording or

reflecting any communication, agreement, or understanding between each such individual or entity and Roche or its agents or attorneys for the provision of such product;

(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..

**INTERROGATORY NO. 8**

Identify each individual (other than patients) and each entity (other than Roche) that has ever used PEG-EPO (including MIRCERA) within the United States for any purpose at any time, stating separately for each such individual or entity:

- (a) the date(s) and all locations of each such use;
- (b) the purpose(s) of each such use; and



(c) each document (excluding only patient-specific information) recording or reflecting any communication, agreement, or understanding between each such individual or entity and Roche or its agents or attorneys regarding such use; and

(d) 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

(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.

**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.

**INTERROGATORY NO. 10**

Separately, in claim chart form for each claim of Amgen's patents-in-suit that you contend is invalid under 35 U.S.C. § 102, identify and describe on a limitation-by-limitation basis for each claim:

(a) where, on a limitation-by-limitation basis, you contend each claim limitation is disclosed in the prior art;

(b) how each such limitation is disclosed in the prior art, including specific references to pages, claims, columns and/or line numbers (if applicable) in each document supporting such contention;

(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), and 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 your 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.

**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.

**INTERROGATORY NO. 12**

Separately, for each patent-in-suit that you contend in your Second and Eighth Affirmative Defenses is unenforceable due to patent misuse or unclean hands, specifically describe separately as to each patent:

(a) all legal and factual grounds on which you contend that such patent is unenforceable due to patent misuse or unclean hands (including but not limited to all legal and factual grounds pertaining to or supporting your assertions at page 15 of Roche's Memorandum in Opposition to Amgen's Motion to Strike),

(b) all evidence on which you rely in support of each contention that a patent is unenforceable due to patent misuse or unclean hands, including all documents and testimony that you contend supports each such contention;

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

(d) 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.

**INTERROGATORY NO. 13**

Separately, as to each claim of each patent-in-suit that you contend in your Ninth Affirmative Defense should not result in an injunction against your importation, making, offering for sale, sale or use of PEG-EPO (including MIRCERA) in the United States because such an injunction would be contrary to public health and welfare, specifically describe:

(a) all legal and factual grounds on which you contend that an injunction with respect to such claim would be contrary to public health;

(b) all legal and factual grounds on which you contend that an injunction with respect to such claim would be contrary to public welfare;

(c) all evidence on which you rely in support of each contention, including all documents, analyses, studies, witnesses, tests, experiments, or data upon which you rely to support your contention(s);

(d) 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

(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.

**INTERROGATORY NO. 14**

Separately, in claim chart form for each claim of Amgen's patents-in-suit as to which you contend in your Eleventh Affirmative Defense that Amgen is barred from enforcing against PEG-EPO (including MIRCERA) by file wrapper estoppel, identify and describe on a limitation-by-limitation basis:

(a) what specific statement(s) or act(s) of Amgen you contend bar Amgen from asserting such claim against PEG-EPO;

(b) how each such statement or act of Amgen bars Amgen from asserting such claim against PEG-EPO;

(c) where each statement or act of Amgen on which you rely is found in the file wrapper of such patent; and

(d) 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

(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.

**INTERROGATORY NO. 15**

Separately, in claim chart form for each claim of Amgen's patents-in-suit as to which you contend in your Twelfth and Thirteenth Affirmative Defenses that Amgen is estopped from asserting infringement by PEG-EPO (including MIRCERA), identify and describe:

(a) all specific statement(s) or act(s) of Amgen you contend estop Amgen from asserting infringement of such claim by PEG-EPO (specifically including but not limited to identifying and describing all specific statements or acts pertaining to or supporting your assertions at pages 19-20 of Roche's Memorandum in Opposition to Amgen's Motion to Strike);

(b) all evidence pertaining to Roche's purported reliance to its detriment upon such statement or act;

(b) how each such statement or act of Amgen estops Amgen from asserting infringement of such claim by PEG-EPO;

(d) all evidence on which Roche relies in support of each contention, including all documents, analyses, studies, witnesses, tests, experiments or data upon which you rely to support your contention(s); and

(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.

Respectfully submitted,

AMGEN INC.,  
By its attorneys,



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December 11, 2006

**CERTIFICATE OF SERVICE**


I, Patricia R. Rich, hereby certify that I have served a copy of the foregoing document on counsel of record listed below, this 11th day of December, 2006, as follows:

**VIA OVERNIGHT MAIL TO:**

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**VIA HAND-DELIVERY TO:**

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\_\_\_\_\_  
Patricia R. Rich