Doc. 388 Att. 18

Case 1:05-cv-12237-WGY

Document 388-19

Filed 04/13/2007

Page 1 of 18

Exhibit 17

DAY CASEBEER MADRID & BATCHELDER LLP

20300 Stevens Creek Blvd., Suite 400

Cupertino, CA 95014 Telephone: (408) 873-0110 Facsimile: (408) 873-0220 Deborah E. Fishman (408) 342-4587 dfishman@daycasebeer.com

January 19, 2007

VIA EMAIL & FACSIMILE

Pat Carson, Esq. Kaye Scholer LLP 425 Park Avenue New York, NY 10022-3598

Re: Amgen Inc. v. F. Hoffmann La-Roche Ltd., et al. (05-CV-12237 WGY)

Dear Pat:

For our call of early next week, I enclose an updated chart that sets forth each of the deficiencies that we have identified to date in Roche's responses. Please be prepared to identify those deficiencies that Roche is willing to redress through supplementation of its Interrogatory Responses.

Thank you.

Very truly yours,

DAY CASEBEER

MADRID & BATCHELDER LLP

Deborah E. Fishman

Enclosure

cc: Howard Suh

Thomas F. Fleming Michele Moreland Mark Israelewicz

Amgen's Interrogatories	Deficiencies in Roche's Response
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.	 Fails to set forth claim construction for each claim on a limitation-by-limitation basis; Fails to provide any claim construction for Claims 7 and 8 of the '933 Patent; Fails to identify any documents and/or testimony in support of each construction; Fails to set forth claim constructions for limitations that provide the basis for non-infringement contention in Interrogatory No. 2 below.
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	 Fails to state on a claim-by-claim basis whether its non-infringement contention is based on direct or indirect infringement; Fails to identify each and every limitation on which Roche bases its non-infringement contentions; Fails to identify each person, other than counsel, who furnished information or was consulted regarding your response to this interrogatory; Fails to identify the three individuals affiliated with Roche, other than counsel, most knowledgeable regarding the subject matter of this interrogatory.

543280_1

Amgen's Interrogatories	Deficiencies in Roche's Response
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;	 Fails to identify each document and the relevant pages that supports or refutes or mentions non-infringement contention based on 35 U.S.C. § 271(g); Fails to identify every test, experiment or data upon which Roche relies in support of its contention that its MIRCERA product is "materially changed"; Fails to identify each person, other than counsel, who furnished information or was consulted regarding your response to this interrogatory; Fails to identify the three individuals affiliated with Roche, other than counsel, most

Amgen's Interrogatories	Deficiencies in Roche's Response
(b) the factual basis for any contention that EPO is a "trivial and nonessential component" of MIRCERA;	knowledgeable regarding the subject matter of this interrogatory.
(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	 Fails to identify 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; Fails to identify each location where the cell line or cells derived from the cell line are currently stored;

Amgen's Interrogatories	Deficiencies in Roche's Response
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.	 Fails to identify each person, other than counsel, who furnished information or was consulted regarding your response to this interrogatory; Fails to identify the three individuals affiliated with Roche, other than counsel, most knowledgeable regarding the subject matter of this interrogatory.
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.	 Fails to identify by name or other designation a list of each ESP made, considered, or investigated by Roche; Amgen is reviewing the documents identified in Roche's response and will notify Roche whether such an answer is sufficient once that review is complete; Fails to identify each person, other than counsel, who furnished information or was consulted regarding your response to this interrogatory.
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	 Amgen is reviewing the statements and documents identified in Roche's response and will notify Roche whether such an answer is sufficient once that review is complete; Fails to identify each person, other than counsel, who furnished information or was consulted

Amgen's Interrogatories	Deficiencies in Roche's Response
beta, RECORMON®, NEORECORMON®, EPOGEN®, EPREX®, and/or PROCRIT®), 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.	regarding your response to this interrogatory.
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	 Fails to 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; Fails to identify all date(s) on which and all locations to which such product was provided; Fails to identify the purpose(s) for which such product was provided; Fails to identify the quantity of product provided; Fails to identify 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; Fails to identify each person, other than counsel,

Amgen's Interrogatories	Deficiencies in Roche's Response
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.	who furnished information or was consulted regarding your response to this interrogatory; • Fails to identify the three individuals affiliated with Roche, other than counsel, most knowledgeable regarding the subject matter of this interrogatory.
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	 Fails to 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; Fails to identify the date(s) and all locations of each such use; Fails to identify the purpose(s) of each such use; Fails to identify 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; Fails to identify each person, other than counsel,
(d) each person, other than counsel, who furnished	who furnished information or was consulted regarding your response to this interrogatory

Amgen's Interrogatories	Deficiencies in Roche's Response
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.	Fails to identify the three individuals affiliated with Roche, other than counsel, most knowledgeable regarding the subject matter of this interrogatory.
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;	 Fails to provide a claim chart separately addressing each of the claims of the patents-in-suit that Roche contends are invalid; Fails to set forth the legal and factual basis for its invalidity contentions for each claim on a limitation-by-limitation basis; Fails to identify each claim (or any claim) that Roche contends are invalid for same invention
 (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; 	 double patenting and fails to provide the legal and factual bases for such a contention; Fails to identify what claim(s) of U.S. Patent 4,703,008 renders each (or any) Asserted Claim that Roche contends is invalid for obviousness-type double patenting; Fails to set forth factual bases for its contentions of obviousness, including the specific combinations of references Roche alleges would render obvious
(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	particular claims, any motivation to combine such references, and any bases for a reasonable expectation of success in practicing such combinations;

Amgen's Interrogatories	Deficiencies in Roche's Response
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.	 Fails to identify each claim (or any claim) that Roche contends are invalid for obviousness-type double patenting; Fails to identify any basis or support for its contention that § 121 does not apply to continuation applications; Fails to identify any factual or evidentiary basis for Roche's contention that consonance with restriction requirements was not maintained; Fails to set forth 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; Fails to compare earlier and later claims and fails to provide any reasons for why an artisan of ordinary skill would have found later claims obvious in light of earlier claims; Fails to explain how Amgen's traversal of this exact attack during the course of the '868 prosecution is not dispositive here; Fails to provide any evidentiary support whatsoever for its §112 arguments or its inventorship allegation; Fails to explain how the Fritsch v Lin interferences, and Amgen v. Chugai, each finding priority for Lin over Fritsch are not conclusive adjudications of §102(g); Fails to identify each person, other than counsel, who furnished information or was consulted regarding your response to this interrogatory; Fails to identify the three individuals affiliated

543280_1

Amgen's Interrogatories	Deficiencies in Roche's Response
	with Roche, other than counsel, most knowledgeable regarding the subject matter of this interrogatory.

543280_1

Amgen's Interrogatories	Deficiencies in Roche's Response
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.	 Fails to set forth the legal and factual basis for its \$ 102 contentions for each claim on a limitation-by-limitation basis; Fails to disclose where, on a limitation-by-limitation basis, you contend each claim limitation is disclosed in the prior art; Fails to provide citing references for 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; Fails to provide 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; Fails to specify the factual bases for its contentions of obviousness by using open-ended language such as "may rely on at least the following prior art"; Fails to identify each person, other than counsel, who furnished information or was consulted regarding your response to this interrogatory; Fails to identify the three individuals affiliated with Roche, other than counsel, most knowledgeable regarding the subject matter of this interrogatory.

Amgen's Interrogatories	Deficiencies in Roche's Response
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;	 Fails to set forth the legal and factual basis for its \$ 103 contentions for each claim on a limitation-by-limitation basis; Fails to set forth factual bases for its contentions of obviousness, including the specific combinations of references Roche alleges would render obvious particular claims, any motivation to combine such references, and any bases for a reasonable expectation of success in practicing such combinations; Fails to identify each claim (or any claim) that Roche contends are invalid for obviousness-type double patenting; Fails to identify what claim(s) of U.S. Patent 4,703,008 renders each (or any) Asserted Claim that Roche contends is invalid for obviousness-
(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);	 type double patenting; Fails to provide any factual basis for the contention that an artisan of ordinary skill in the art would have found later claims obvious in light of earlier claims; Fails to identify any basis or support for its
(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	 contention that § 121 does not apply to continuation applications; Fails to identify any factual or evidentiary basis for Roche's contention that consonance with restriction requirements was not maintained;
(f) the three individuals affiliated with Roche, other than counsel, most knowledgeable regarding the subject matter of	Fails to identify all evidence in support of each contention, including all documents, testimony, prior knowledge, or public uses tending to support

Deficiencies in Roche's Response
 its \$103 contention(s), including every test, experiment or data upon which Roche intends to rely; Fails to identify each person, other than counsel, who furnished information or was consulted regarding your response to this interrogatory; Fails to identify the three individuals affiliated with Roche, other than counsel, most knowledgeable regarding the subject matter of this interrogatory.
 Fails to set forth all legal and factual grounds for contention of unenforceability due to patent misuse or unclean hands on a patent-by-patent basis; Fails to identify all evidence on which Roche will rely to support of each contention that a patent is unenforceable due to patent misuse or unclean hands, including all documents and testimony that it contends supports each such contention; Fails to identify each person, other than counsel, who furnished information or was consulted regarding your response to this interrogatory; Fails to identify the three individuals affiliated with Roche, other than counsel, most knowledgeable regarding the subject matter of this interrogatory.

Amgen's Interrogatories	Deficiencies in Roche's Response
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.	
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);	 Fails to provide all legal and factual grounds on which Roche contends that an injunction with respect to such claim would be contrary to public health and welfare; Fails to identify all evidence on which Roche intends to rely in support its contentions, including all documents, analyses, studies, witnesses, tests, experiments, or data; Fails to identify each person, other than counsel, who furnished information or was consulted regarding your response to this interrogatory; Fails to identify the three individuals affiliated with Roche, other than counsel, most knowledgeable regarding the subject matter of this interrogatory.
(d) each person, other than counsel, who furnished information or was consulted regarding your response to this	

Amgen's Interrogatories	Deficiencies in Roche's Response
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.	
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	 Fails to identify each claim Roche contends is barred by file wrapper estoppel; Fails to identify on a limitation-by-limitation basis which limitations provide a basis for file wrapper estoppel; Fails to identify which statements or acts that Roche contends are the basis for estoppel apply to which claim limitations; Fails to identify each person, other than counsel, who furnished information or was consulted regarding your response to this interrogatory; Fails to identify the three individuals affiliated with Roche, other than counsel, most knowledgeable regarding the subject matter of this interrogatory.

Amgen's Interrogatories	Deficiencies in Roche's Response
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 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	 Fails to provide the legal bases for Roche's contention that Amgen is estopped from asserting infringement on the basis of prosecution laches; Fails to provide any factual or evidentiary basis for Roche's contention that Amgen intended "to unreasonably delay prosecution of [its] claims"; Fails to provide any basis for Roche's contention that "intent is sufficient to support" a finding of prosecution laches estoppel; Fails to set forth each claim Roche contends is barred by equitable estoppel on a limitation-by-limitation basis; Fails to identify all statements or acts of Amgen that Roche contends estop Amgen from asserting infringement; Fails to identify each person, other than counsel, who furnished information or was consulted regarding your response to this interrogatory; Fails to identify the three individuals affiliated with Roche, other than counsel, most knowledgeable regarding the subject matter of this interrogatory.
(c) cach person, other than counser, who furnished	

Amgen's Interrogatories	Deficiencies in Roche's Response
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.	