Case 1:05-cv-12237-WGY

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EXHIBIT 6

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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

PLAINTIFF'S SUPPLEMENTAL RESPONSE TO DEFENDANTS' FIRST SET OF INTERROGATORIES (NOS. 1-12)

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure ("FRCP"). Plaintiff/Counter Defendant Amgen Inc. ("Amgen") hereby supplements its objections and responses to Defendants' First Set of Interrogatories (Nos. 1-12).

PRELIMINARY STATEMENT

- Amgen's responses to Defendants' First Set of Interrogatories are made to the 1. best of Amgen's present knowledge, information and belief. Amgen's responses are subject to amendment and supplementation should future investigation indicate that amendment or supplementation is necessary. Amgen undertakes no obligation, however, to supplement or amend these responses other than as required by the Federal Rules of Civil Procedure of the Local Rules of the United States District Court for the District of Massachusetts.
- Amgen's responses to Defendants' First Set of Interrogatories are made according 2. to information currently in Amgen's possession, custody and control.
- 3. To the extent that Amgen responds to Defendants' First Set of Interrogatories by stating information that private, confidential, highly confidential, proprietary, trade secret or otherwise protected from disclosure, Amgen will respond pursuant to the terms of the Protective Order in this case.

The making, using, offering to sell or selling of ARANESP® is covered by one or more of the claims of the patents-in-suit either literally or under the doctrine of equivalents. Documents that support this response include the intrinsic record of the patents-in-suit and documents sufficient to show Aranesp's structure, function, method of production and method of use. These documents include AM-ITC-29667-30100, AM44 0220452-473, AM44 0220474-503 and documents currently in process for production.

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 8

Subject to and without waiver of these Specific Objections and General Objection set forth above which are incorporated herein by reference, and with reservation of its right to supplement or amend its response to this interrogatory after the claims have been construed and necessary discovery has been received, Amgen incorporates by reference its previous response and provides the following supplemental response to this interrogatory:

As set forth in the ARANESP® product label, Amgen contends that the importing, making, using, offering to sell or selling of ARANESP® is covered (literally or equivalently) under unasserted claim 1 of the '698 Patent. Amgen reserves the right to amend this response should the Court construe any claim term in a manner that differs from Amgen's proposed constructions stated in its Response to Interrogatory No. 1.

INTERROGATORY NO. 9:

Describe whether Amgen contends that CERA is not materially changed pursuant to 35 U.S.C. § 271(g) from "human erythropoietin," as that term is used in the asserted claims of the patents-in-suite, any basis and/or evidence, and the identity of all documents and things that support or otherwise refute Amgen's response to this interrogatory.

RESPONSE TO INTERROGATORY NO. 9:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this interrogatory: Amgen objects to this interrogatory to the extent that none of Amgen's asserted process claims (as defined in Amgen's Response to Interrogatory No. 1) refer to "human erythropoietin" as the product produced by the claimed processes. For purposes of responding to this interrogatory, Amgen assumes Defendants are seeking Amgen's contentions with respect to whether Defendants' peg-EPO product is "materially changed pursuant to 35 U.S.C. Section 271(g)" with respect to the product produced by Amgen's asserted process claims Amgen further objects to this interrogatory on the grounds that Amgen has only received limited discovery from Defendants, and that Defendants have refused to produce relevant evidence that is directly related to Amgen's infringement contentions. Until such time as Amgen has received such discovery, it cannot provide a complete response to this interrogatory. In particular, Amgen's ability to identify persons, documents, and things within Roche's possession, custody or control that relate to the subject matter of this interrogatory is limited by Roche's failure to provide fulsome and complete responses to Amgen's outstanding discovery requests.

Amgen further objects to this interrogatory to the extent that it prematurely calls for the opinions of Amgen's expert witnesses, which by the Court's order will be provided in the form of report(s) on April 27, 2007. Amgen objects that the interrogatory is overly broad and unduly burdensome to identify "all documents and things that support or otherwise refute Amgen's response to this interrogatory," particularly where such documents are cumulative to the information that Amgen has or will identify.

Subject to and without waiver of these Specific Objections and General Objection set forth above which are incorporated herein by reference, and with reservation of its right to supplement or amend its response to this interrogatory after the claims have been construed and necessary discovery has been received, Amgen provides the following response to this interrogatory:

Section 271(g), in pertinent part, provides: "Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such a process patent A product which is made by a patented process will, for the purposes of this title, not be considered to be so after-- (1) it is materially changed by subsequent processes" In construing § 271(g), the

Federal Circuit has considered whether (a) it would not be possible or commercially viable to make the accused product but for the use of the patented process and (b) the accused product is significantly changed in structure and properties from the product of the claimed process in a manner which changes the basic utility of the product.

Applying each of these tests to the products of the claimed and asserted processes, Amgen contends that CERA (i.e, peg-EPO) is not materially changed pursuant to 35 U.S.C. § 271(g) from the products of the asserted process claims of the patents-in-suit because peg-EPO comprises such products and those products confer peg-EPO's in vivo biological activity.

It cannot be reasonably disputed by defendants that the EPO portion of CERA is a product produced by the claimed processes. The addition of one or more peg molecules to the EPO does not alter the molecule in any relevant manner. Peg-EPO contains the same amino acid sequence, the same glycosylation pattern, the same in vivo biological activity, and the same therapeutic use as the EPO products produced according to Amgen's asserted process claims. Defendants' attachment of polyethylene glycol to the products produced according to Amgen's asserted process claims adds only a single covalent bond out of over 4000 bonds in such products. Peg-EPO could not have been made but for the use of Amgen's asserted process claims.

Documents supporting these contentions include: ITC-R-BLA-00006254-ITC-R-BLA-ITC-R-BLA-00007319-ITC-R-BLA-00007353; ITC-R-BLA-00007469-ITC-R-BLA-00008113; ITC-R-BLA-00008438-ITC-R-BLA-00014798; ITC-R-BLA-00019393-ITC-R-BLA-00019401; ITC-R-BLA-00021211-ITC-R-BLA-00021406; ITC-R-BLA-00022202-ITC-R-BLA-00022365: ITC-R-BLA-00039684-ITC-R-BLA-00039789; ITC-R-BLA-00039813-ITC-R-BLA-00039816; ITC-R-BLA-00045779-ITC-R-BLA-00045802; ITC-R-BLA-00045826-ITC-R-BLA-00045829; ITC-R-BLA-00152415-ITC-R-BLA-00152527; ITC-R-BLA-00039890-ITC-R-BLA-00045284; ITC-R-BLA-00045543-ITC-R-BLA-00045553; ITC-R-BLA-00151978-ITC-R-BLA-00152000; ITC-R-BLA-00019402-ITC-R-BLA-00019484; ITC-R-BLA-00020144-ITC-R-BLA-00021210; ITC-R-BLA-00021407-ITC-R-BLA-00022143; ITC-R-BLA-00022366—ITC-R-BLA-00039498; ITC-R-BLA-00039875—ITC-R-BLA-00039889; ITC-R-BLA-00047373—ITC-R-BLA-00118973; ITC-R-BLA-00118975—ITC-R-BLA-00151977; ITC-R-BLA-00045320—ITC-R-BLA-00045328; ITC-R-BLA-00045330—ITC-R-BLA-00045373; ITC-R-BLA-0000029—ITC-R-BLA-00000193; ITC-R-BLA-0000692—ITC-R-BLA-00006253; and ITC-R-00091296-309.

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 9

Subject to and without waiver of these Specific Objections and General Objection set forth above which are incorporated herein by reference, and with reservation of its right to supplement or amend its response to this interrogatory after the claims have been construed and necessary discovery has been received, Amgen incorporates by reference its previous response and provides the following supplemental response to this interrogatory:

Additional documents supporting Amgen's response to this interrogatory include: ITC-R-00095645-53; ITC-R-00095939-42; the June 13, 2006 "CERA preliminary draft summary report" produced by Dr. Veng-Pedersen during his deposition (no bates number provided); ITC-R-00095886-895; and ITC-R-BLA-00007247.

INTERROGATORY NO. 10:

As to each asserted claim of the patents-in-suit identified in response to Interrogatory No. 1, describe the reasons why each claim is not rendered invalid under the claims of U.S. Patent No. 4,703,008 pursuant to obviousness-type double patenting, the reasons for this contention, including whether 35 U.S.C. § 121 applies as a defense to obviousness-type double patenting, and the identity of all documents and things that support or otherwise refute Amgen's response to this interrogatory.

RESPONSE TO INTERROGATORY NO. 10:

In addition to the foregoing General Objections, Amgen makes the following Specific Objections to this interrogatory: Amgen specifically objects to this interrogatory on the grounds that it is unduly burdensome and lacks relevance under Rule 26 in that it seeks information regarding non-double patenting before Roche has specified any basis that purportedly would

ITC 00991045-080; AM-ITC 00991081-083; AM-ITC 01004923-929; AM-ITC 01006613-756; AM-ITC 01006920-923; and AM-ITC 01007030-037.

Further information relevant to the failure of the work of Goldwasser is set forth in the published decisions regarding Dr. Lin's U.S. patents. The pleadings and Amgen's document production from each of these actions, including Dr. Lin's testimony and that of other relevant Amgen employees, have been provided to Roche in response to Roche's First Set of Requests for the Production of Documents and Things in the ITC proceeding.

SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 12

Subject to and without waiver of these Specific Objections and General Objection set forth above which are incorporated herein by reference, and with reservation of its right to supplement or amend its response to this interrogatory after the claims have been construed and necessary discovery has been received, Amgen incorporates by reference its previous response and provides the following supplemental response to this interrogatory:

The Goldwasser experiment did not demonstrate that Dr. Goldwasser's preparation constituted a "therapeutically effective amount of human erythropoietin" because, for example, it did not establish that erythropoietin in Dr. Goldwasser's preparation as administered to the three human subjects caused an increase in hematocrit levels, erythrocyte mass changes, reticulocyte response, and/or ferrokinetic effects.

February 10, 2007

AMGEN INC.,

By its attorneys,

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