UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

AMGEN'S RESPONSE TO ROCHE'S RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT THAT AMGEN IS ESTOPPED FROM ASSERTING INFRINGEMENT UNDER THE DOCTRINE OF EQUIVALENTS OF THE ASSERTED CLAIMS OF THE '698 AND '868 PATENTS

Amgen disputes the following statements in Roche's Rule 56.1 Statement of Undisputed Facts In Support Of Defendants' Motion For Summary Judgment That Amgen Is Estopped From Asserting Infringement Under The Doctrine Of Equivalents Of The Asserted Claims Of The '698 and '868 Patents:

1. Responding to paragraph 4, Amgen disputes the characterization of the patents-in-suit as claiming priority to the expired U.S. Patent No. 4,703,008. Rather, the patents-in-suit claim priority to the 675,298 application that was filed on November 30, 1984.

2. Responding to paragraph 5, Amgen disputes this paragraph as an incomplete characterization of the prosecution history of the '008 patent. For example, file claim 17 stated "A purified and isolated DNA sequence coding for procaryotic or eucaryotic host expression of a

polypeptide having part or all of the primary structural conformation and one or more of the biological activities of erythropoietin," (7/3/07 Rizzo Decl., Ex. 4 (Docket No. 627) at 99 ('008 File History, Application for United States Letters Patent, Application Serial No. 675,298); Declaration of Katie J.L. Scott in Support of Amgen Inc.'s Opposition to Defendants' Motion for Summary Judgment that Amgen is Estopped From Asserting Infringement Under the Doctrine of Equivalents of the Asserted Claims of the '698 and '868 Patents ("Scott Decl."), Ex. 7 at 3 ('008 File History, Paper 12, Applicant's Amendment and Reply Under 35 U.S.C. §§1.111 and 1.115)), not "a DNA sequence for use in expressing 'a polypeptide having part or all of the primary structural conformation' of naturally occurring EPO" as Roche states in paragraph 5.

3. Responding to paragraph 6, Amgen disputes this paragraph because it is incomplete and mischaracterizes the prosecution history of the '008 patent. For example, no claims were amended in Paper 15 of the '008 file history as Roche states. Rather, certain claims were canceled and new claims were entered. 7/3/07 Rizzo Decl., Ex. 5 (Docket No. 627). Roche's description of the new claims as "describing" certain polypeptides is also a mischaracterization of the numerous claims to DNA sequences "coding for" various polypeptides.

4. Responding to paragraph 7, Amgen disputes this paragraph as mischaracterizing the prosecution history of the '008 patent. Roche's statement that "[t]he examiner again rejected the claims" suggests that the same claims that had previously been rejected were "again" rejected. That, however, is not true. Also, the examiner does not expressly state that the rejection regarding the DNA sequences is for non-enablement, as the text of the rejection implies it may be related to enablement "and/or" written description. Scott Decl., Ex. 6 at 2-3 ('008 patent file history, Paper 17, 6/18/87 Office Action).

5. Responding to paragraph 8, Amgen disputes this paragraph as an incomplete

description of the file history of the '008 patent and mischaracterizes the rejection related to the language "a DNA sequence encoding a polypeptide having an amino acid sequence sufficiently duplicative of that of erythropoietin." In particular, Roche fails to include that the language of '008 issued claim 7 also contains language "similar to" language suggested by the examiner in the 6/18/87 Office Action: "The embodiments of claims 77 and 96 could properly be expressed as for example an isolated DNA sequence consisting of a DNA sequence encoding a polypeptide having the structure sufficiently duplicative of that of naturally-occurring erythropoietin to allow possession of the biological properties of being able to cause bone marrow cells to increase hemoglobin synthesis and iron uptake and stimulate reticulocytes response." Scott Decl., Ex. 6 at 3 ('008 patent file history, Paper 17, 6/18/87 Office Action).

6. Responding to paragraph 10, Amgen disputes this paragraph to the extent it incompletely and inaccurately quotes the Federal Circuit's opinion. Amgen does not dispute that the Federal Circuit in *Amgen IV*, 457 F.3d at 1310, stated:

> As seen, after the first preliminary amendment, the claims of the '556 application broadly encompassed an isolated human EPO product. The application claimed an EPO product made using the human EPO DNA sequence set out in Figure 6 or the monkey EPO DNA sequence set out in Figure 5. With the second preliminary amendment, the patentee added claim 68, which claimed an EPO product made using the amino acid sequence for EPO set out in Figure 6 "or a fragment thereof." With the third preliminary amendment, the patentee removed all references to non-human monkey EPO and also deleted claims for an EPO product made using "a fragment" of the amino acid sequence of Figure 6. Instead, as of the third preliminary amendment, the '556 application claimed only a human EPO product having the complete amino acid sequence of Figure 6.

7. Responding to paragraph 13, Amgen disputes this paragraph to the extent it is an incomplete recitation of the file claim language and is unclear which claims included what language. For example, the language "DNA sequence encoding a polypeptide having a primary structural conformation sufficiently duplicative of that of EPO" described by Roche appears to come from file claim 64, which actually requires "a DNA sequence consisting essentially of a

DNA sequence encoding a polypeptide having a primary structural conformation sufficiently duplicative of that of erythropoietin . . . ." 7/3/07 Rizzo Decl., Ex. 8 (Docket No. 627) at 6 ('868 patent file history, Paper 7).

8. Responding to paragraph 14, Amgen disputes this paragraph as an incomplete description and mischaracterization of the file history of the '868 patent. In a second preliminary amendment, Applicant canceled claims 61-64 and entered new claims 65-69. 7/3/07 Rizzo Decl., Ex. 9 (Docket No. 627) at 3-4 ('868 patent file history, Paper 8).

9. Responding to paragraph 15, Amgen disputes this paragraph because it is an incomplete description of the file history of the '868 patent. In particular, Roche fails to mention that between the second preliminary amendment where claim 65 was entered, and the rejection described in paragraph 15, file claim 65 was allowed by the examiner. Scott Decl., Ex. 5 ('868 patent file history, Paper 16, Letter from Examiner). Then while prosecution was suspended pending an interference proceeding, file claim 65 was amended by the applicant so as to change "isolated DNA sequence encoding a polypeptide having a primary structural conformation sufficiently duplicative of that of naturally occurring human erythropoietin" to "isolated DNA sequence encoding human erythropoietin." Scott Decl., Ex. 3 at 1 ('868 patent file history, Paper 24).

10. Responding to paragraph 17, Amgen disputes Roche's statement that "[t]he disclosure of 'human erythropoietin' set forth in the '868 patent is a 166 amino acid sequence." The specification of the '868 patent does not define or otherwise alter the plain and ordinary meaning of the term "human erythropoietin."

11. Responding to paragraph 19, Amgen disputes this paragraph because it is an unsupported characterization of the prosecution history. Amgen disputes Roche's

characterization of the addition of the phrase "DNA encoding the mature erythropoietin amino acid sequence of Figure 6" as being "to avoid a double patenting rejection."

12. Responding to paragraph 20, Amgen disputes this paragraph because it is an incomplete characterization of the prosecution history of the '698 patent. In particular, the three process claims of the five proposed claims described in paragraph 20 all contained the language "*DNA encoding* the mature erythropoietin amino acid sequence of Figure 6." 7/3/07 Rizzo Decl., Ex. 11 (Docket No. 627) at 159-60 ('698 patent file history, Paper 7) (emphasis added). Moreover, of the two process claims (D and E) that Applicant proposed including, both included the "DNA encoding" language. 7/3/07 Rizzo Decl., Ex. 11 (Docket No. 627) at 160 ('698 patent file history, Paper 7).

13. Responding to paragraph 22, Amgen disputes this paragraph to the extent it mischaracterizes the purpose given by Applicant for the inclusion of the "mature erythropoietin amino acid sequence of FIG. 6" in the '080 claims. Roche asserts that this was for "patentability reasons" but provides no support for that assertion.

14. Responding to paragraph 27, "the claims" referred to in the Federal Circuit opinion described by Roche in paragraph 27 are the claims of the '080 patent, not the '698 patent.

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Respectfully Submitted,

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