UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD, a Swiss Company, ROCHE DIAGNOSTICS GMBH, a German Company, and HOFFMANN LA ROCHE INC., a New Jersey Corporation, Defendants.	)	Civil Action No.: 1:05-cv-12237 WGY

AMGEN'S RESPONSE TO ROCHE'S RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS REGARDING ITS MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT OF CLAIM 1 OF THE '422 PATENT AND CLAIMS 9 AND 12 OF THE '933 PATENT

Pursuant to D. Mass. LR 56.1, plaintiff Amgen Inc. ("Amgen") hereby responds to defendants F. Hoffman-La Roche Ltd., Roche Diagnostics GmbH, and Hoffman-La Roche Inc. (collectively "Roche")'s Statement of Undisputed Facts in support of their motion for summary judgment of non-infringement of claim 12 of the '422 patent and claims 9 and 12 of the '933 patent [hereinafter Roche's Purported Facts].

Amgen objects to Roche's Purported Facts to the extent Roche contends that such Purported Facts constitute all material facts that need be tried or otherwise found in order for Roche to prevail on its motion. Amgen states that Roche's Purported Facts do not comprise all such material facts, and furthermore contain statements that are not material facts as more fully set forth below and in Amgen Memorandum of Law in Opposition to Defendants' Motion for Summary Judgment of Non-infringement of Claim 1 of the '422 Patent and Claims 9 and 12 of the '933 Patent [hereinafter Amgen's Brief].

Roche's "Statement of Fact" No. 1

In this action, plaintiff Amgen Inc. alleges that Roche infringes claim 1 of the '422 patent and claims 9 and 12 of the '933 patent. (Suh Decl., Ex. D at p. 3).

Amgen's Response to Statement No. 1

Undisputed. Amgen does not contest that it has alleged that Roche infringes claim 1 of the '422 patent and claims 9 and 12 of the '933 patent.

Roche's "Statement of Fact" No. 2

Claim 1 of the '422 patent and claims 9 and 12 of the '933 patent all contain the limitation "a pharmaceutical composition comprising … a pharmaceutically acceptable diluent, adjuvant, or carrier." (*Id.* Ex. A, claim 1; Ex. B, claims 9 and 12).

Amgen's Response to Statement No. 2

Undisputed. Amgen does not contest that claim 1 of the '422 patent and claims 9 and 12 of the '933 patent contain the limitation "a pharmaceutical composition comprising … a pharmaceutically acceptable diluent, adjuvant, or carrier."

Roche's "Statement of Fact" No. 3

On April 17, 2007, this Court construed the phrase "a pharmaceutical composition comprising … a pharmaceutically acceptable diluent, adjuvant, or carrier" common to claim 1 of the '422 patent and claims 9 and 12 of the '933 patent to mean "a composition suitable for administration to humans containing a diluent, adjuvant or carrier." (*Id.*, Ex. C at 77:1-3).

Amgen's Response to Statement No. 3

Disputed. Amgen does not contest that the Court construed the phrase "a pharmaceutical composition comprising … a pharmaceutically acceptable diluent, adjuvant, or carrier" common to claim 1 of the '422 patent and claims 9 and 12 of the '933 patent to mean "a composition suitable for administration to humans containing a diluent, adjuvant or carrier." Amgen states that the Court indicated that it would take the parties' arguments over further construction of the phrase under advisement. *Markman* Hearing Tr., April 17, 2007 [Doc. No. 401] at 77.

Roche's "Statement of Fact" No. 4

Amgen's expert, Dr. Lodish, admits that during the formulation process Roche adds "a diluent and carrier" to the active ingredient CERA. (*See id.* Ex. F ¶ 92).

Amgen's Response to Statement No. 4

Disputed. Amgen submits that the statement made in paragraph 4 of Roche's Purported Facts accurately quotes Dr. Lodish. The statement made by Dr. Lodish in the paragraph cited by Roche is as follows: "To make peg-EPO, Roche takes purified recombinant glycosylated human PEO polypeptide product (epoetin beta) from its already existing manufacturing process for NeoRecormon in Germany, subjects it to a pegylation reactin, purifies the peg-EPO, formulates it into a pharmaceutical composition by adding a diluent and carrier, and fills it into vials or syringes." Suh. Decl. to Roche's Motion, Ex. F, ¶ 92.

Roche's "Statement of Fact" No. 5

The common specification of the '422 and '933 patents states that "[a]lso comprehended by the invention are pharmaceutical compositions comprising effective amounts of polypeptide products of the invention together with suitable diluents, adjuvants and/or carriers …" (*Id.* Ex. A at col. 12, ln. 5-8; Ex. B at col 12, ln. 1-4).

Amgen's Response to Statement No. 5

Undisputed. Amgen does not contest that the common specification of the '422 patent and the '933 patent contains the language quoted by Roche.

Roche's "Statement of Fact" No. 6

During an interference with U.S. Patent No. 4,806,524, applicant Lin's counsel suggested the count: "An erythropoietin preparation containing one or more selected from the group consisting of bovine serum albumin, human serum albumin and gelatin. (*Id.* Ex. J at 4; *see also* Ex. K; Ex. L).

Amgen's Response to Statement No. 6

Disputed. Amgen submits that the statement made in paragraph 6 of Roche's Purported Facts is incorrect. No interference was declared between any of the Lin patent applications and U.S. Patent No. 4,806,524. During prosecution of the 08/100,197 patent application ("the '197 application"), which issued as the '422 patent, Applicant Lin requested a declaration of

interference between then-pending claims 1 and 2 of the '197 application and U.S. Pat. No. 4,806,524 ("the '524 patent"). *See id.*, Ex. J at 3-4. The interference count proposed by Applicant Lin was: "An erythropoietin preparation containing one or more selected from the group consisting of bovine serum albumin, human serum albumin and gelatin." *Id.* Amgen further contests the statement to the extent it suggests that an interference was requested by Applicant Lin in the application leading to the '933 patent or that any such interference was declared. (Amgen Brief at 9; Suh Decl. to Roche Motion, Ex. J at 4).

Respectfully Submitted,
AMGEN INC.,
By its attorneys,

/s/ Patricia R. Rich

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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants on the above date.

/s/ Patricia R. Rich
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