

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

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

AMGEN’S RESPONSE TO ROCHE’S RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS REGARDING ITS MOTION FOR SUMMARY JUDGMENT THAT THE ASSERTED CLAIMS OF THE ’933 PATENT ARE INVALID FOR INDEFINITENESS AND LACK OF WRITTEN DESCRIPTION

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-LaRoche Inc. (collectively “Roche”)’s Statement of Undisputed Facts in support of their motion for summary judgment that the asserted claims of U.S. Patent No. 5,547,933 (“the ‘933 Patent”) are invalid for indefiniteness and lack of written description [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 Inc.’s Memorandum of Law in Opposition to Defendants’ Motion

for Summary Judgment That the Asserted Claims of the '933 Patent Are Invalid for Indefiniteness and Lack of Written Description [hereinafter Amgen's Brief].

Roche's "Statement of Fact" No. 1

In this action, Plaintiff Amgen Inc. ("Amgen") alleges that Roche infringes claims 3, 7-9, 11-12 and 14 of the '933 patent. (Suh Decl., Ex. K at p. 3).

Amgen's Response to Statement No. 1

Undisputed. Amgen does not contest that it has alleged that Roche infringes Claims 3, 7-9, 11-12, and 14 of the '933 Patent.

Roche's "Statement of Fact" No. 2

In *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 126 F.Supp. 2d 69, 91 (D. Mass. 2001) ("Amgen I"), this Court construed the term "non-naturally occurring," as used in the claims of the '933 patent, to mean "not occurring in nature." The Court stated that "[b]y including this limitation, the applicant "meant to stand clear of the unpatentable, naturally occurring products. He intended nothing more." *Id.*

Amgen's Response to Statement No. 2

Disputed. Amgen does not contest that the Court has construed the '933 Patent claim term "non-naturally occurring" to mean "not occurring in nature." Amgen does not contest that Roche has accurately quoted selected portions of the Court's opinion in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69 (D. Mass. 2001) [hereinafter *Amgen I*], but objects to any inferences Roche may attempt to draw through such selective quotation. For example, Roche fails to quote the Federal Circuit's statement that the term "non-naturally occurring" "mean[s] just what [it] says . . . [it] limits only the source from which the EPO is obtained." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 n.5 (Fed. Cir. 2003) [hereinafter *Amgen II*].

Roche's "Statement of Fact" No. 3

The '933 patent describes only one supposed physical distinction between the non-naturally occurring erythropoietin glycoproteins of the claims and naturally occurring erythropoietin, i.e., glycosylation. (Suh Decl., Ex. A: col. 10:28-40; 28:51-29:7).

Amgen's Response to Statement No. 3

Disputed. Amgen submits that the statement made in paragraph 3 of Roche's Purported Facts is not a statement of fact as required under D. Mass. LR 56.1, and, as such, does not require a response. Amgen further states that the statement made in paragraph 3 is not material to the instant motion. To the extent paragraph 3 does contain a statement of material fact requiring a response, Amgen contests the statement to the extent it implies that the physical distinction between the non-naturally occurring erythropoietin glycoprotein claimed in the '933 Patent and naturally-occurring erythropoietin glycoproteins is merely "supposed." *See* Amgen's Brief at 11-17. Amgen further contests the statement's use of the phrase "only one" to imply that the above distinction comprises only a difference of glycosylation. The claimed non-naturally occurring erythropoietin glycoprotein and naturally-occurring erythropoietin glycoproteins differ physically in a number of ways, as set forth more fully in Amgen's Brief. *See id.* Moreover, Amgen states that the statement of paragraph 3 is not material to the instant motion because Amgen does not assert that the "non-naturally occurring" negative source limitation is the only basis for novelty of the asserted claims. *See id.*

Roche's "Statement of Fact" No. 4

In *Amgen I*, this Court held that because the glycosylation of naturally occurring EPO varies, claims 1, 2 and 9 of the '933 patent, which distinguish the claimed non-naturally occurring erythropoietin glycoproteins from naturally occurring erythropoietin based on the "glycosylation" or "average carbohydrate composition," were not infringed or, alternatively, were invalid for indefiniteness ("one of ordinary skill would be unable to determine whether a particular erythropoietin has a glycosylation which differs from that of human urinary erythropoietin") and lack of written description ("the patent fails to convey to one of ordinary skill in the art as of 1984 that Dr. Lin invested in erythropoietin product having glycosylation which differs from human urinary erythropoietin"). *Amgen I*, 126 F. Supp. 2d at 155-56.

Amgen's Response to Statement No. 4

Disputed. Amgen does not contest that, in *Amgen I*, the Court held that Claims 1, 2, and 9 of the '933 Patent were not infringed or, alternatively, were invalid for indefiniteness and inadequate support by the written description. Amgen does not contest that Roche has accurately quoted selected portions of the Court's opinion in *Amgen I*, but reserves the right to object to any inferences Roche may attempt to draw through such selective quotation. As to the remainder of paragraph 4 of Roche's Purported Facts, Amgen submits that the language contained therein is not a statement of fact as required under D. Mass. LR 56.1, and, as such, does not require a response. To the extent such language contains material facts requiring a response, Amgen contests the statement to the extent it suggests that the Court's holding in *Amgen I* regarding the invalidity of claims containing the "having a glycosylation which differs from that of human urinary erythropoietin" limitation has any relevance to the validity of the presently asserted claims, none of which contain such limitation. As discussed more fully in Amgen's Brief, that holding is not relevant to the validity of the presently-asserted claims. *See* Amgen's Brief at 2-3, 13-16.

Roche's "Statement of Fact" No. 5

In *Amgen Inc. v. Hoescht Marion Roussel, Inc.*, Civil Action No. 97-10814-WGY (D. Mass), Amgen fully litigated whether the glycosylation of human urinary erythropoietin varies such that one of ordinary skill in the art as of 1984 reading the '933 patent would have understood that Dr. Lin invented an erythropoietin product having glycosylation which differed from the glycosylation of human urinary erythropoietin.

Amgen's Response to Statement No. 5

Disputed. Amgen submits that the statement made in paragraph 5 of Roche's Purported Facts is not a statement of fact as required under D. Mass. LR 56.1, and, as such, does not require a response. To the extent paragraph 5 does contain a statement of material fact requiring a response, Amgen contests the statement in that it improperly mischaracterizes the holding of

the Court in *Amgen I*. Amgen further contests the statement to the extent it suggests that the Court's holding in *Amgen I* regarding the invalidity of claims containing the "having a glycosylation which differs from that of human urinary erythropoietin" limitation has any relevance to the validity of the presently asserted claims, none of which contain such limitation. As discussed more fully in Amgen's Brief, that holding is not relevant to the validity of the presently-asserted claims. *See* Amgen's Brief at 2-3, 13-16.

Roche's "Statement of Fact" No. 6

In *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, Civil Action No. 97-10814-WGY (D. Mass.), Amgen fully litigated whether one of ordinary skill in the art reading the claims of the '933 patent would have been able to determine whether the glycosylation of a particular erythropoietin glycoprotein differed from the glycosylation of human urinary erythropoietin.

Amgen's Response to Statement No. 6

Disputed. Amgen submits that the statement made in paragraph 6 of Roche's Purported Facts is not a statement of fact as required under D. Mass. LR 56.1, and, as such, does not require a response. To the extent paragraph 6 does contain a statement of material fact requiring a response, Amgen contests the statement in that it improperly mischaracterizes the holding of the Court in *Amgen I*. Amgen further contests the statement to the extent it suggests that the Court's holding in *Amgen I* regarding the invalidity of claims containing the "having a glycosylation which differs from that of human urinary erythropoietin" limitation has any relevance to the validity of the presently asserted claims, none of which contain such limitation. As discussed more fully in Amgen's Brief, that holding is not relevant to the validity of the presently-asserted claims. *See* Amgen's Brief at 2-3, 13-16.

Roche's "Statement of Fact" No. 7

In *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003), the Federal Circuit affirmed this Court's holding that claims 1, 2 and 9 of the '933 patent were invalid for indefiniteness.

Amgen's Response to Statement No. 7

Undisputed. Amgen does not contest that, in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003) [hereinafter *Amgen II*], the Federal Circuit affirmed this Court's holding that Claims 1, 2, and 9 of the '933 Patent were invalid for indefiniteness.

Roche's "Statement of Fact" No. 8

Claims 3, 7-9, 11-12 and 14 of the '933 patent distinguish the structure of the claimed erythropoietin glycoproteins from naturally occurring erythropoietin based on the claimed products being "non-naturally occurring." The limitation was added to the claims to "distinguish the subject matter claimed from all prior art references relating to erythropoietin isolates." (Suh Decl., Ex. E, p. 7).

Amgen's Response to Statement No. 8

Disputed. Amgen submits that the statement made in paragraph 8 of Roche's Purported Facts is not a statement of fact as required under D. Mass. LR 56.1, and, as such, does not require a response. To the extent paragraph 8 does contain a statement of material fact requiring a response, Amgen contests the statement in that while Claims 3, 7-9, 11-12, and 14 of the '933 Patent include the limitation "non-naturally occurring," that limitation distinguishes the source, not the structure, of the claimed erythropoietin glycoprotein from that of naturally-occurring erythropoietin. *See* Amgen, Inc.'s Memorandum of Law in Opposition to Defendants' Motion for Summary Judgment That the Asserted Claims of the '933 Patent Are Invalid for Indefiniteness and Lack of Written Description [hereinafter Amgen's Brief] at 6-8. Amgen further contests the statement to the extent it misleadingly quotes a portion of the '933 Patent's prosecution history to imply that the only purpose of the insertion of the "non-naturally occurring" limitation was to overcome prior art. The "non-naturally occurring" negative source limitation was added to cure an indefiniteness rejection by the examiner. *See* Amgen's Brief at 7 (citing '933 Prosecution History, 12/20/95 Secondary Preliminary Amendment and Remarks at 6 (Docket No. 534, Ex. 25)).

Respectfully Submitted,

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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

Patricia R. Rich