

**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
IN SUPPORT OF ROCHE’S SECOND MOTION FOR SUMMARY JUDGMENT
THAT CLAIM 1 OF THE ‘422 PATENT IS INVALID FOR INDEFINITENESS AND
LACK OF WRITTEN DESCRIPTION**

Pursuant to LR, D. Mass. 56.1, Plaintiff Amgen Inc. hereby responds to Defendants F. Hoffmann-La Roche LTD, Roche Diagnostics GmbH and Hoffmann-La Roche, Inc.’s (“Roche’s”) Rule 56.1 Statement of Undisputed Material Facts in Support of its Second Motion for Summary Judgment that Claim 1 of the ‘422 Patent is Invalid Under 35 U.S.C. § 112 (“Roche’s Facts”).

1. Amgen does not contest the statement of fact contained in Roche’s Facts paragraph 1.

2. Amgen does not contest the statement of fact contained in Roche’s Facts paragraph 2 but further references Docket No. 613 at 19.

- Docket No. 613 at 19.

3. Amgen does not contest the statement of fact contained in Roche's Facts paragraph 3, except to state that additional issues were remanded to the Court.

- *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457, F.3d 1293, 1317 (Fed. Cir. 2006).

4. Amgen does not contest the statement of fact contained in Roche's Facts paragraph 4 except to affirmatively state that "purified from mammalian cells grown in culture" is a source limitation that imparts structural elements to the recited products that can be used to distinguish such products over previously known compositions. To the extent that Roche is using this finding to challenge the novelty of the claim 1 of the '422 patent, Amgen notes that such an argument is not relevant to the issue definiteness of '422 Claim 1 and that "purified from mammalian cells grown in culture" is a source limitation that imparts structural elements to the recited products that can be used to distinguish such products over previously known compositions and that '422 claim 1 is further distinguishable over such previously known compositions on the basis of the limitations "pharmaceutical composition" and "therapeutically effective amount."

- *See generally* Expert Report of Joseph W. Eschbach, M.D., attached as Exhibit 4 to the accompanying declaration of Deborah E. Fishman.

5. Amgen contests the statement of fact contained in Roche's Facts paragraph 5 because: (1) Roche's Fact refers to "erythropoietin glycoproteins of the claims" where as '422 claim 1 is directed to a "pharmaceutical composition comprising . . . human erythropoietin . . . purified from mammalian cells grown in culture;" and (2) besides glycosylation, there are additional bases for distinguishing the composition of '422 claim 1 from prior art preparations including differences in specific activity, accessibility to iodination, inactivation by iodination, trypsin inactivation, and circular dichroism.

- Docket No. 582, Ex. 2, 2/26/07 Goldwasser Tr. at 461:8-464:6, 471:19-473:8, 474:1-475:13, 475:15-476:16, 476:21-478:18, 463:12-464:6.

- Docket No. 502, Ex. E-4 (Miyake et al., “Purification of Human Erythropoietin,” *J. Biol. Chem.*, 252(15):5558-5564 (1977)) at 5563 (reporting specific activity for urinary EPO of 70,400 unites/mg of protein).

6. Amgen does not contest the statement of fact contained in Roche’s Facts paragraph 6, except to note that with the exception of the Court’s finding of indefiniteness, the remainder of the Court’s findings were vacated.

- *Amgen Inc. v. Hoechst Marion Roussell, Inc.*, 314 F.3d 1313, 1342 (Fed. Cir. 2003)

7. Amgen does not contest the statement of fact contained in Roche’s Facts paragraph 7, insofar as the statement is limited to information and data that was admitted into evidence as of May 2000, as such evidence relates to EPO’s glycosylation. Amgen disagrees with the statement to the extent that it is an attempt to preclude Amgen from presenting information and evidence discovered after this date in this proceeding regarding any differences between the claimed EPO products and human urinary EPO.

8. Amgen does not contest the statement of fact contained in Roche’s Facts paragraph 8, except as set forth above in response to the statements contained in Roche’s Facts at paragraph 7.

9. Amgen does not contest the statement of fact contained in Roche’s Facts paragraph 9 except to clarify that ‘933 claim 9 was found indefinite only as it depends on claims 1 or 2.

10. Amgen further refers to its Rule 56.1 Statements in support of its motion for summary judgment on validity, and in response to Roche’s 56.1 Statements in support of its motions for summary judgment of invalidity.

- Docket Nos. 533, 566, 581 and 629.

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 on-registered participants.

/s/ Patricia R. Rich
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