UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC., Plaintiff, v. F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH, and HOFFMANN-LA ROCHE INC. Defendants.	)	CIVIL ACTION No.: 05-CV-12237WGY

ROCHE'S RESPONSE TO AMGEN INC.'S RULE 56.1 STATEMENT OF UNDISPUTED FACTS REGARDING NO OBVIOUSNESS-TYPE DOUBLE PATENTING

Leora Ben-Ami (*pro hac vice*)
Mark S. Popofsky (*pro hac vice*)
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
Vladimir Drozdoff (*pro hac vice*)
David L. Cousineau (*pro hac vice*)
Kaye Scholer LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836 8000

Lee Carl Bromberg (BBO# 058480)
Timothy M. Murphy (BBO# 551926)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
Bromberg & Sunstein LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292

Counsel for Defendants
F. Hoffmann-La Roche Ltd,
Roche Diagnostics GmbH, and
Hoffmann-La Roche Inc.

Dated: Boston, Massachusetts
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The Defendants ("Roche") hereby responds to Amgen's Rule 56.1 Statement of Undisputed Facts Regarding No Obviousness-Type Double Patenting ("Amgen's Statement"). The evidence of record in support of each response is the evidence already submitted in support of Defendants' Motion for Summary Judgment that the Claims of Patents-in-Suit are Invalid for Double Patenting over Amgen '016 Patent, the Second Declaration of Michael Sofocleous ("Second Sofocleous Decl."), the Declaration of John Lowe, Ph.D. ("Lowe Decl.") and the exhibits attached to the Second Declaration of Kimberly J. Seluga dated June 28, 2007.

PRELIMINARY STATEMENT

Roche below responds separately to each statement contained in Amgen's Statement. With respect to the Section of the Motion dealing with the Lin '008 patent, Roche's disputed issues of material fact are noted. As to the Section of the Motion addressing the Lai '016 patent, although certain disputes are noted, none are material to any issue raised by Roche's Motion for Summary Judgment that the Claims of Patents-in-Suit are Invalid for Double Patenting over Amgen's '016 Patent.

ROCHE'S RESPONSE TO AMGEN'S STATEMENT

1. Amgen's Statement ("AS") ¶ 1 is undisputed, except that it is misleading to only state the filing date of U.S. Patent No. 4,703,008 ("the '008 patent"), which has not been asserted against Roche and has now expired. Amgen has not disputed that the '349, '933, and '422 patent claims would be invalid for obviousness type double patenting, but for Amgen's reliance of 35 U.S.C. § 121. The filing dates of the applications that actually resulted in the patents-in-suit are the relevant filing dates, which are as follows:

> - U.S. Patent No. 5,547,933 ("the '933 patent") was filed June 7, 1995—more than eight years after the Patent Office issued its restriction requirement dated July 3, 1986 ("1986 restriction requirement") during the '298 application. *See* Ex. U[1] at 2. The '933 patent was also filed more than eight years after the '016 issued—

[1] "Ex. _" refers to Exhibits attached to the declarations of Kimberly J. Seluga dated June 7, 2007 and June 28, 2007.

even though Amgen could have filed the '933 patent before the '016 patent's filing date and could have filed it at any time during the pendency of the '016 patent. (Indeed, June 7, 1995 was the day before the law regarding the length of patent terms changed; if Amgen waited another day or so to file the '933 patent, it would have already expired under the new law.) *See* Exs. E and F; *see also* Second Sofocleous Decl. ¶ 8.

- U.S. Patent No. 5,618,698 ("the '698 patent") was filed June 6, 1995—more than eight years after the '016 issued—even though Amgen could have filed the '698 patent before the '016 patent's filing date and could have filed it at any time during the pendency of the '016 patent. *See* Exs. B and F; *see also* Second Sofocleous Decl. ¶ 9.

- U.S. Patent No. 5,756,349 ("the '349 patent") was filed June 6, 1995—also more than eight years after the Patent Office issued its 1986 restriction requirement during the '298 application. The '349 patent was also filed more than eight years after the '016 issued—even though Amgen could have filed the '349 patent before the '016 patent's filing date and could have filed it at any time during the pendency of the '016 patent. *See* Exs. C and F; *see also* Second Sofocleous Decl. ¶ 10.

- U.S. Patent No. 5,955,422 ("the '422 patent") was filed August 2, 1993—more than six years after the Patent Office issued its 1986 restriction requirement during the '298 application. The '422 patent also issued more than six years.after the '016 issued—even though Amgen could have filed the '422 patent before the '016 patent's filing date and could have filed it at any time during the pendency of the '016 patent. *See* Exs. D and F; *see also* Second Sofocleous Decl. ¶ 11.

- U.S. Patent No. 5,441,868 ("the '868 patent") was filed October 23, 1987—more than five months after the '016 issued—even though Amgen could have filed the '868 patent before the '016 patent's filing date and could have filed it at any time

during the pendency of the '016 patent. (Indeed, Amgen waited until just four days before the '008 patent issued before filing the '868 patent. If Amgen waited five more days before filing the '868 patent, the '868 patent could not have been a continuation of the '008 patent, and accordingly, Amgen would have been statutorily barred from getting the '868 patent allowed.) *See* Exs. A and F; *see also* Second Sofocleous Decl. ¶ 12.

2. AS ¶ 2 is disputed in that it states that Amgen was "forced … to select one of six invention groups …." Amgen was not "forced" to select one of the six groups. Patent applicants have the right to traverse restriction requirements; however, Amgen voluntarily forwent that right. *See, e.g.,* Ex. U at 3; *see also* Manual of Patent Examining Procedure ("MPEP") § 818 (8th ed., Rev. 5, Aug. 2006). Furthermore, Amgen was not "forced" to delay the filing of the continuation applications. Indeed, Amgen was legally entitled to file a continuation or divisional application for each group of non-selected claims at the time of its selection (April 23, 1986) or even before its selection. Amgen nevertheless chose to delay the filing of and the prosecution of the non-selected claims until much later. *See* Second Sofocleous Decl. ¶¶ 6-15.

3. AS ¶ 3 is disputed in that it states that Amgen made its election "[i]n response to the July 3, 1986 restriction requirement." In its April 23, 1986 Preliminary Amendment during the prosecution of the '008 patent, Amgen had already made a "preliminary election" prior to the actual 1986 restriction requirement. *See* in particular Ex. V.

Moreover, as stated above, instead of filing divisional applications based on the 1986 restriction requirement, Amgen waited 16 months until it began submitting a series of continuation applications which eventually resulted in the patents-in-suit. *See* Exs. A, B, C, D and E. For the '349 patent, Amgen filed continuation applications No. 113,179 in October 23, 1987 and No. 468,369 in June 6, 1995. For the '933 patent, Amgen filed continuation application No. 113,178 in October 23, 1987, No. 202,874 in February 28, 1994, and No. 487,774 in June 7, 1995. For the '422 patent, Amgen filed continuation applications No. 113,179 in October 23, 1987, No. 609,741 in November 6, 1990, No. 957,073 in October 6,

1992, and No. 100,197 in August 2, 1993. *See* Exs. C, D and E. Importantly, when Amgen submitted its '179 and '178 continuation applications (which resulted in all of the patents-in-suit), Amgen re-filed all of the original claims of the original '008 patent application, rather than adhere to the 1986 restriction requirement. *See* Exs. W and Y.

4. AS ¶ 4 is undisputed except that it is Amgen's position that all the claims-in-suit have support in the '178 application (and that all the claims-in-suit have support in the '008 patent's disclosure). Accordingly, all of the claims-in-suit could have been filed in the '178 application. Indeed all the claims-in-suit could have been filed in continuation applications that could have been filed before the '178 application was filed (and could have been filed in continuation applications filed before the '016 application was filed). *See* Second Sofocleous Decl. ¶¶ 5-8. Importantly, even though the 1986 restriction requirement separated Group I from the Group V claims, Amgen broke consonance with this requirement when it filed both group of claims within the same application. *See, e.g.,* Exs. W and X.

5. AS ¶ 5 is undisputed except that it is Amgen's position that all the claims-in-suit have support in the '179 application (and that all the claims-in-suit have support in the '008 patent's disclosure). Accordingly, all of the claims-in-suit could have been filed in the '179 application. Indeed all the claims-in-suit could have been filed in continuation applications that could have been filed before the '179 application was filed (and could have been filed in continuation applications filed before the '016 application was filed). *See* Second Sofocleous Decl. ¶¶ 5-12.

6. AS ¶ 6 is disputed. The claims of the '933 patent asserted against Roche lack consonance with Group I and Group V of the 1986 restriction requirement. For example, the claims-in-suit of the '933 patent all require a "non-naturally occurring glycoprotein product." This language was not present in the claims of Group I and V, and this new language breaks the consonance with the restriction requirement. *See* Ex. Z at 1.

Amgen again broke consonance when it combined the polypeptide claims from Group I of the 1986 restriction requirement with pharmaceutical composition/method of treatment claims

of Group V. As stated above, the Patent Office clearly told Amgen to separate these claims into separate divisional applications. *See* Ex. U at 2. However, Amgen ignored the restriction requirement, and as a result, Amgen has asserted claims from the '933 patent that include both polypeptide claims (claims 3,7, and 8) and claims directed to pharmaceutical compositions and methods of treatment (claims 9, 11,12 and 14).

7. AS ¶ 7 is disputed. The only claim of the '349 patent asserted against Roche—claim 7—lacks consonance with Group IV of the 1986 restriction requirement. For example, Group IV did not include a process claim, and claim 7 of the '349 patent is a process claim and, accordingly, lacks consonance with the restriction requirement. (Claim 7 of the '349 patent was not introduced into an Amgen patent application until December 24, 1996.) *See* Lowe Decl. ¶¶ 17-25. Claim 7 of the '349 patent more properly belongs to the Group II claims of the 1986 restriction requirement, along with claim 4 of the '698 patent. These claims cover the same subject matter, namely the process of growing vertebrate cells under suitable nutrient conditions to produce recombinant erythropoietin using non-human promoter DNA. *See id.*

8. AS ¶ 8 is disputed. Claim 1 of the '422 patent lack consonance with the 1992 restriction requirement. *See* Ex. CC at 2. Under that restriction, claims to pharmaceutical compositions containing EPO and human serum albumin (Group VII), were separated from claims drawn towards pharmaceutical compositions comprising just EPO, and without the serum albumin element (Group V). Amgen elected to pursue Invention Group VII in prosecuting the '422 patent. *Id*. at 4. However, late in the prosecution of this patent, Amgen added a claim that did not require human serum albumin. *See* Ex. DD at 3. This claim, which matured into claim 1 of the '422 patent, thus violated the 1992 restriction requirement by combining two restricted groups of claims (Group V and VII) within the same application.

9. AS ¶ 9 is undisputed.

10. AS ¶ 10 is undisputed, except that Amgen ignores the actual filing dates of the patents-in-suit, which are as follows: the '933 patent was filed June 7, 1995; the '698 patent was

filed June 6, 1995; the '349 patent was filed June 6, 1995; the '422 patent was filed August 2, 1993; the '868 patent was filed October 23, 1987. *See* Exs. A, B, C, D, E and F.

11. AS ¶ 11 is disputed. Roche reserves the right to present evidence at trial that the inventions claimed in the Lai/Strickland '016 patent were conceived on or prior to the filing date of the ‘008 patent, November 30, 1984. Furthermore, Amgen ignores that the inventions claimed in the Lai/Strickland ‘016 patent were conceived before the filing date of each of the patents-in-suit, and thus each of the patents-in-suit could have been filed as a continuation-in-part of the ‘016 patent. *See* Exs. A, B, C, D, E and F; *see also* Second Sofocleous Decl. ¶¶ 5-7.

12. AS ¶ 12 is disputed in that Amgen delayed the filing of the patents-in-suit throughout the entire pendency period of the ‘016 patent, from June 20, 1985 to May 19, 1987 and beyond. Furthermore, the ‘008 patent has not been asserted against Roche and has now expired, and therefore, whether the claims of the ‘008 patent would have been invalid for obviousness-type double patenting is irrelevant. *See* Exs. A, B, C, D, E and F; *see also* Second Sofocleous Decl. ¶¶ 8-15.

13. AS ¶ 13 is disputed. *See, e.g.*, Harlow Decl. ¶¶ 39, 42-44, 47 and 48.

14. AS ¶ 14 is disputed. *See, e.g.*, Harlow Decl. ¶¶ 39, 42-44, 47 and 48.

Dated: June 29, 2007
Boston, Massachusetts

Respectfully submitted,

F. HOFFMANN-LA ROCHE LTD,
ROCHE DIAGNOSTICS GMBH, and
HOFFMANN-LA ROCHE INC.

By its Attorneys,

/s/ Julia Huston
Lee Carl Bromberg (BBO# 058480)
Timothy M. Murphy (BBO# 551926)
Julia Huston (BBO# 562160)
Keith E. Toms (BBO# 663369)
Nicole A. Rizzo (BBO# 663853)
BROMBERG & SUNSTEIN LLP
125 Summer Street
Boston, MA 02110
Tel. (617) 443-9292
jhuston@bromsun.com

Leora Ben-Ami (*pro hac vice*)
Mark S. Popofsky *(pro hac vice)*
Patricia A. Carson (*pro hac vice*)
Thomas F. Fleming (*pro hac vice*)
Howard S. Suh (*pro hac vice*)
Peter Fratangelo (BBO# 639775)
Vladimir Drozdoff (*pro hac vice*)
David L. Cousineau (*pro hac vice*)
KAYE SCHOLER LLP
425 Park Avenue
New York, New York 10022
Tel. (212) 836-8000

CERTIFICATE OF SERVICE

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/s/ Julia Huston
Julia Huston

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