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 ORAL ARGUMENT SET FOR JULY 17, 2007

ROCHE'S REPLY TO AMGEN'S MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT THAT CLAIM 10 OF THE '933 PATENT IS INVALID FOR FAILURE TO COMPLY WITH CLAIM DIFFERENTIATION UNDER § 112, ¶ 4

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I. INTRODUCTION

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, And Hoffmann-La Roche Inc. (collectively, "Roche") respectfully submit this reply memorandum to Amgen's Memorandum In Opposition To Defendants' Motion For Summary Judgment That Claim 10 of The '933 Patent Is Invalid For Failure To Comply With Claim Differentiation Under § 112, ¶ 4 ("Amgen Opposition"). Amgen asserts in its opposition that dependent claim 10 of the '933 patent is valid despite this Court's current claim construction of independent claim 9 that claims a subject matter broader than that covered by dependent claim 10. This broadening of dependent claim 10 is in clear violation of § 112, ¶ 4.

Amgen's argument rests on an unfounded presumption that an independent composition claim and a method of use claim from which it depends are not subject to claim differentiation requirements of 35 U.S.C. § 112, ¶ 4. Amgen's current stance on this issue is further contrary to the position it argued for, and received, during claim construction.

II. BACKGROUND

On June 11, 2007, Roche moved for summary judgment that claim 10 of the '933 patent is invalid pursuant to 35 U.S.C. § 112, ¶ 4 under this Court's tentative claim construction.[1] On April 17, 2007, this Court tentatively construed the term "a pharmaceutical composition comprising" to mean "a composition suitable for administration to humans containing a diluent, adjuvant or carrier."[2] The Court confirmed this claim construction on July 3, 2007.[3] Claim 10, which depends from claim 9, recites "[a] method of providing erythropoietin therapy to a

[1] Defendants' Motion For Summary Judgment That Claim 10 Of The '933 Patent Is Invalid On The Grounds Of Failure To Comply With Claim Differentiation Under § 112 (DN 473).
[2] Declaration Of Howard S. Suh In Support Of Defendants' Motion For Summary Judgment That Claim 10 Of The '933 Patent Is Invalid On The Grounds Of Failure To Comply With Claim Differentiation Under § 112, ¶ 4, Ex. B at pp. 76:24-77:4 (emphasis added) (DN 475).
[3] See 7/3/07 Memorandum & Order at 21 (D.N. 613).

mammal comprising administering an effective amount of a pharmaceutical composition of claim 9."[4] As currently construed, claim 10 is broader than claim 9 because claim 10 is directed to therapy to mammals which covers a larger scope than therapy to humans which claim 9 has been construed to cover.

To comply with § 112, ¶ 4, claim 10 must incorporate all of the limitations of claim 9 and further limit the subject matter of claim 9. However, under the current claim construction, dependent claim 10 broadens the scope of the subject matter claimed in claim 9 in direct violation of § 112, ¶ 4. A dependent claim should be no broader in scope than the independent claim from which it depends.[5] Hence, at least claim 10 of the '933 patent should be invalidated under 35 U.S.C. § 112, ¶ 4 should the Court decide not to revisit its claim construction.

III. HAVING ARGUED FOR THIS CLAIM CONSTRUCTION DURING *MARKMAN*, AMGEN CAN NOT PROPERLY ASSERT A DIFFERENT CONSTRUCTION NOW

The language of Claim 9 of the '933 patent reads:

> "A pharmaceutical composition comprising an effective amount of a glycoprotein product effective for erythropoietin therapy according to claim 1, 2, 3, 4, 5 or 6 and a pharmaceutically acceptable diluent, adjuvant or carrier."[6]

In its proposed claim construction, Amgen argued that the claim limitation "a pharmaceutical composition comprising" should be construed as "a composition **suitable for administration to humans** . . . ."[7] This Court afforded Amgen its proposed claim construction.[8]

Faced with a clear failure to meet the requirements of 35 U.S.C. § 112, ¶ 4, Amgen now asserts there are no limitations in claim 9 requiring the claimed composition be administered to

[4] DN 475, Ex. A, col. 39, ll.5-7.
[5] *See AK Steel Corp., v. Sollac*, et al., 344 F. 3d 1234, 1242 (Fed Cir. 2003).
[6] DN 475, Ex. A, col. 39, ll.1-4.
[7] Amgen Inc.'s Response To Defendants' Claim Construction Brief at 12-14 (DN 323); Amgen Inc's Response To The Court's Questions Regarding Precedential Effect Of Prior Claim Constructions And Defendants' Reply Brief Regarding Claim Construction at 10-12 (DN 370).
[8] DN 475, Ex. B at pp. 76:24-77:4; see also D.N. 613 at 21.

humans, or administered at all.[9] This argument is contrary to the position Amgen adopted during *Markman*. Amgen presented its claim construction arguments in three briefs, two of which specifically discussed the proposed claim construction on independent claim 9.[10] Roche, on the other hand, proposed a claim construction which did not limit the administration of the pharmaceutical composition to humans. Instead, Roche advocated a broad definition of "pharmaceutical composition" to mean "a mixture" having the active ingredient specified in the claim.[11] Under Roche's claim construction, paragraph 4 of the Section 112 would not apply to invalidate claim 10, since that claim would not be broader than the claim it depends on. It was Amgen that asked this Court to limit the composition of claim 9 as suitable for administration to humans. If, under Amgen's proposed claim construction (as adopted by the Court), "suitable for administration to humans" does not mean that the pharmaceutical composition must be directed to humans, then what can it possibly mean? The patent specification makes clear that "suitable" in the context of therapy means actual administration.[12]

> Similarly, to the extent that polypeptide products of the invention share the in vivo activity of natural EPO isolates they are conspicuously suitable for use in erythropoietin therapy procedures practiced on mammals, including humans, to develop any or all of the effects herefore attributed in vivo to EPO...[13]

The fact is that Amgen asked the Court to construe the claim as being directed to humans during *Markman* but is now attempting to read that limitation out of the construction in order to preserve the validity of claim 10. Amgen simply cannot have it both ways. If Amgen is now proposing that "suitable for administration to humans" does not mean that the composition has to

[9] Amgen Inc.'s Memorandum In Opposition To Defendants' Motion For Summary Judgment That Claim 10 of the '933 Patent Is Invalid For Failure To Comply With Claim Differentiation Under § 112, ¶ 4, at 1 (DN 553)
[10] DN 323, submitted on March 19, 2007; DN 370, submitted on April 11, 2007.
[11] Defendants' Opening Memorandum In Support Of Their Proposed Claim Construction, at 2 (DN 311).
[12] Indeed, the specification clearly supports Roche's claim construction of "pharmaceutical composition" because it clearly does not limit the administration to humans, but all mammals.
[13] DN 475, Ex. A, '933 patent, col. 33, ll.19-24.

be administered only to humans, then it should have agreed with Roche's broader claim construction.

IV. AMGEN'S POSITION IS NOT GROUNDED IN PRECEDENT OR SUPPORTED BY STATUTORY LAW

Amgen further rests its position on an unfounded assumption that an independent claim directed to a composition and a dependent claim directed to a method of use of said composition need not comply with the claim differentiation requirements of 35 U.S.C. § 112, ¶ 4. Importantly, neither the statute itself nor its legislative history confers any support that differential treatment should be afforded to claims based on the subject matter to which they are directed.[14] Further, the courts do not make any distinction between method of use claims and composition claims for the purposes of determining claim validity under § 112, ¶ 4.

Amgen cites two cases in support of a faulty proposition that an independent composition claim and a dependent claim directed to a method of use of said composition should not be held invalid under § 112, ¶ 4.[15] Neither case makes any distinction between an independent composition claim and method of use claim dependent on that composition for the purposes of claim differentiation analysis under § 112, ¶ 4. The requirements of § 112, ¶ 4 apply evenhandedly to all claims irrespective of the subject matter.

Union Oil Co. v. Atl. Richfield Co., 208 F.3d 989 (Fed. Cir. 2000) does not support Amgen's baseless assumption that an independent composition claim and a method of use claim from which it depends are not subject to § 112, ¶ 4. Instead, the court in *Union Oil* discussed the

[14] *See Ex parte Adrianus P.M.M. Moelands, et. al.*, 3 U.S.P.Q.2D 1474 (B.P.A.I. 1987)

[15] Roche does not agree that claim 9 is a composition claim and claim 10 is a method of use claim. Roche's position is that even if Amgen is correct in its classification of said claims, the distinction is irrelevant for § 112, ¶ 4 analysis.

proper scope of claim construction for the purpose of a § 102 analysis.[16] Importantly, the *Union Oil* court does not even address § 112, ¶ 4, much less confirm Amgen's unfounded theory that a composition claim limited by method of use claim is not subject to the requirements of this section.

Moreover, *Ex parte Porter,* 25 U.S.P.Q.2D 1144, (B.P.A.I. 1992), cited by Amgen, fully supports Roche's position. In *Ex parte Porter,* the Board of Patent Appeals and Interferences of U.S. Patent and Trademark Office held that "…a claim that incorporates by reference all of the subject matter of another claim, that is, the claim is not broader in any respect, to be in compliance with the fourth paragraph of *35 USC Section 112.*"[17] Here however, claim 10 is directed to mammals, while claim 9 from which it depends is directed narrowly to humans. Hence, claim 10 fails to recite all of the elements of claim 9, and further broadens claim 9 in violation of the statute.

Again, contrary to Amgen's line of reasoning, the fact that independent claim 9 is a composition claim has no bearing on whether the claim is invalid under § 112, ¶ 4, because claim 9 is directed to humans while a dependent claim 10 is directed to mammals, in clear violation of proper dependent claim scope under § 112, ¶ 4. Amgen cannot now disagree with the Court's claim construction since it was Amgen that proposed the construction "a composition suitable for administration to humans" to the Court. Instead, defying logic, Amgen is trying to convince this Court that a claim directed to "humans" is somehow narrowed by a claim directed broadly to "mammals."

[16] *See Union Oil Co v. Atl. Richfield Co.,* 208 F.3d 989, 995 (Fed. Cir. 2000).
[17] *Ex parte Porter,* 25 U.S.P.Q.2D 1144, 1147 (B.P.A.I. 1992).

V. CONCLUSION

For the foregoing reasons and the reasons provided in Roche's Motion for summary judgment that claim 10 of the '933 patent is invalid, it is respectfully requested that Roche's motion be granted and that claim 10 of the '933 patent be held invalid for failure to comply with claim differentiation under § 112, ¶ 4.

DATED: Boston, Massachusetts
July 9, 2007

Respectfully submitted,

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