

**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. 05-12237 WGY

U.S. District Judge Young

**ORAL ARGUMENT REQUESTED**

**MEMORANDUM 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**

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche, Inc. (collectively "Roche") respectfully submit this memorandum in support of their motion for summary judgment that claim 10 of U.S. Patent No. 5,547,933 ("the '933 patent") is invalid under 35 U.S.C. § 112 because it fails to comply with claim differentiation under ¶ 4 of that section. As tentatively construed by the Court, dependent claim 10 has a broader scope than claim 9, which is not permitted under the statute. Summary judgment is ripe because there are no issues of factual dispute.

**I. NATURE AND STAGE OF THE PROCEEDINGS**

On November 8, 2005, Amgen filed suit against Roche alleging infringement of six patents, including U.S. Patent No. 5,547,933, the subject of Roche's instant motion for summary judgment. On November 6, 2006, Roche answered Amgen's complaint denying infringement of the patents-in-suit and asserting affirmative defenses based upon the invalidity and unenforceability of those patents. In its Answer, Roche counterclaimed for a declaratory

judgment that the six patents-in-suit are invalid and unenforceable and that Roche's patents do not infringe; Roche also lodged anticompetitive counterclaims against Amgen due to actions resulting in the restraint of trade in numerous markets. Roche set forth additional defenses and counterclaims in its First Amended Answer and Counterclaims to Plaintiff's Complaint filed on March 30, 2007.

Roche moves here for summary judgment that claim 10 of the '933 patent is invalid pursuant to 35 U.S.C. § 112, ¶ 4 as under the Courts tentative current claim construction, dated April 17, 2007. Under that claim construction, claim 10 is broader than, and does not limit the subject matter of, claim 9 as required by the statute.

## **II. STATEMENT OF FACTS**

The following facts are beyond genuine dispute and compel summary judgment as a matter of law that claim 10 of Amgen's '933 patent is invalid under 35 U.S.C. § 112, ¶ 4.

1. Claim 9 reads as follows:  
  
"A pharmaceutical composition comprising an effective amount 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."  
(Suh Decl., Ex. A, column 39, ll.1-4)
2. On April 17, 2007, this Court tentatively held that "a pharmaceutical composition comprising," as recited in claim 9, means "a composition suitable for administration to humans containing a diluent, adjuvant or carrier." (Suh Decl., Ex. B at pp. 76:24-77:4 (emphasis added)).
3. However, Claim 10, which depends upon claim 9, reads as follows:  
  
"A method of providing erythropoietin therapy to a mammal comprising administering an effective amount of a pharmaceutical composition of claim 9."

(Suh Decl., Ex. A, column 39, ll. 5-7 (emphasis added))

Thus, under the Court's tentative claim construction, dependant claim 10 (therapy to a mammal) is broader in scope than claim 9 (for administration to humans). As demonstrated herein, this is not permitted under 35 U.S.C. § 112, ¶ 4.

### **III. ARGUMENT**

#### **A. Standard for Summary Judgment**

The grant of summary judgment under Fed. R. Civ. P. 56 is as appropriate in a patent case as in any other case. *Barmag Barmer Maschinenfabrik AG v. Murata Machinery Ltd.*, 731 F.2d 831, 835 (Fed. Cir. 1984); *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 93 (D. Mass. 2001) (hereinafter "*Amgen I*"). Summary judgment is appropriate where no genuine issue of material fact exists and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56; *Celotex Corp. v. Catreft*, 477 U.S. 317, 322 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *Amgen I*, 126 F. Supp. 2d at 93. The moving party bears the initial burden of demonstrating the absence of any genuine issue of material fact. *Anderson*, 477 U.S. at 256. After the moving party makes a showing that there is no genuine issue of material fact, the nonmoving party has the burden of coming forward with evidence of specific facts showing there is a genuine issue of material fact requiring trial. *Celotex*, 477 U.S. at 325.

When making a determination as to whether there is a genuine issue of material fact, the court, "may not simply accept a party's statement that a fact is challenged." *Barmag*, 731 F.2d at 835-36. Enough evidence must favor the non-moving party's case such that a reasonable jury could return a verdict in its favor. Evidence that is merely colorable or not significantly probative will not avoid summary judgment. *Anderson*, 447 U.S. at 249-50. Further, "[m]ere denials or conclusory statements are insufficient." *Barmag*, 731 F.2d at 836.

**B. Invalidity under 35 U.S.C. § 112 ¶ 4**

Section 35 U.S.C. § 112 ¶ 4 requires that:

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers. 35 U.S.C. § 112 ¶ 4.

An applicant for a patent must satisfy all relevant procedural and technical requirements before a patent can be granted. *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1292 (Fed. Cir. 2006). Finding claims invalid under 35 U.S.C. § 112 ¶ 4 is consistent with the overall objective of patent statutory scheme. *Id.* A dependent claim must incorporate by reference all the limitations of the claim to which it refers and then also specify a further limitation of the subject matter claimed. *Id.* An independent claim is usually afforded a greater scope of claimed subject matter as compared with its dependent claim. *See RF Del., Inc. vs Pac. Keystone Techs., Inc.*, 326 F. 3d 1255, 1264 (Fed. Cir. 2003). A dependent claim is presumed to be narrower in scope than the independent claim from which it depends under the doctrine of claim differentiation. *See AK Steel Corp., vs. Sollac, et al.*, 344 F. 3d 1234, 1242 (Fed Cir. 2003)

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.” (Suh Decl., Ex. B, at pp. 76:24-77:4 (emphasis added)). Claim 10 is dependent on claim 9, reciting “[a] method of providing erythropoietin therapy to a mammal comprising administering an effective amount of a pharmaceutical composition of claim 9.” (Suh Decl., Ex. A, column 39, ll. 5-7 (emphasis added)). Obviously, as currently construed, claim 10 is broader than claim 9 because therapy to mammals covers a larger scope than therapy to humans.

To comply with § 112 ¶ 4, claim 10 must incorporate all limitations of claim 9 and further limit the subject matter of claim 9. However, dependent claim 10 actually broadens the scope of the subject matter claimed in claim 9 in violation of § 112 ¶ 4. A dependent claim should be no broader in scope than the independent claim from which it depends.” *See AK Steel Corp.*, 344 F. 3d at 1242.

In *Pfizer*, the Federal Circuit invalidated a dependent claim when it failed to "incorporate by reference all the limitations of the claim to which it refer[ed]" and failed to "then specify a further limitation of the subject matter," as required by § 112 ¶ 4. *Pfizer, Inc.*, 457 F.3d at 1292. Thus, the Court invalidated the dependent claim because “claim 6 [dependent claim] d[id] not narrow the scope of claim 2; instead, the two claims deal[t] with non-overlapping subject matter.” *Id.*

Here, as tentatively construed by the Court, dependent claim 10 also does not narrow the scope of claim 9, but actually broadens its coverage, since it expands the claimed therapy from “administration to humans” to “therapy to a mammal.”

Roche recognizes that the Court’s claim construction was only tentative. However, as set forth by the Court, at least claim 10 of the ‘933 should be invalidated under 35 U.S.C. § 112 ¶ 4 should the Court decide not to revisit its tentative claim construction.

#### **IV. CONCLUSION**

Based on the foregoing, Roche respectfully requests that its motion for summary judgment of invalidity of claim 10 of the ‘933 patent is granted.

Dated: June 11, 2007  
Boston, Massachusetts

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

By its attorneys,

/s/ Keith E. Toms

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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 (NEF) and paper copies will be sent to those indicated as non registered participants on the above date.

/s/ Keith E. Toms

Keith E. Toms