

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	Civil Action No.: 05-12237 WGY
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.	)	
_____	)	

**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**

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## I. INTRODUCTION

Plaintiff Amgen Inc. (“Amgen”) respectfully submits this memorandum in support of its opposition to 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.<sup>1</sup>

Roche’s motion is premised on a fundamentally incorrect reading of Claims 9 and 10 of the ‘933 patent, and an apparent misunderstanding of the distinction between a composition claim and a method-of-use claim. Despite Roche’s efforts to read limitations into ‘933 Claim 9, Claim 9 is a *composition* claim that is not limited to administration of the claimed pharmaceutical composition to humans. In fact, Claim 9 contains no limitation requiring it to be administered at all. By contrast, dependent Claim 10 is a *method-of-use* claim containing an additional limitation of “providing erythropoietin therapy to a mammal” by administering the claimed pharmaceutical composition of Claim 9.

The Court’s claim construction of the term “pharmaceutical composition comprising” to mean “a composition suitable for administration to humans containing a diluent, adjuvant or carrier”<sup>2</sup> does not convert Claim 9 into a method-of-use claim. Only Claim 10 contains a limitation on how the claimed pharmaceutical composition is used. Thus Claim 10 satisfies the requirements of § 112, ¶ 4 because it specifies a further limitation of the subject matter of Claim 9, and is therefore valid.

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<sup>1</sup> See Docket No. 474 [hereinafter Roche Mem.]; Docket No. 473 [hereinafter Roche Mot.]. The ‘933 patent was previously filed at Docket No. 534, Ex. 3.

<sup>2</sup> 4/17/07 *Markman* Hearing Tr. at 72:24-77:4, Docket No. 514, Ex. 40.

**II. ROCHE’S MOTION FOR SUMMARY JUDGMENT OF INVALIDITY SHOULD BE DENIED BECAUSE CLAIM 10 OF THE ’933 PATENT COMPLIES WITH 35 USC § 112, ¶ 4**

**A. CLAIM 9 OF THE ’933 PATENT IS DIRECTED TO A COMPOSITION OF MATTER AND IS NOT LIMITED TO ANY METHOD OF USE**

Roche contention that Claim 9 of the ’933 patent is directed to “therapy to humans”<sup>3</sup> and *requires* “administration [of the claimed composition] to humans”<sup>4</sup> is demonstrably false. Claim 9 is not a method claim. Claim 9 is a composition claim. The Court’s construction of the claim term “pharmaceutical composition” does nothing to alter this fundamental truth.

Claim 9 of the ’933 patent reads as follows:

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.<sup>5</sup>

The Court correctly construed the term “pharmaceutical composition comprising” to mean “a composition suitable for administration to humans containing a diluent, adjuvant or carrier.”<sup>6</sup>

This construction gives meaning to the “pharmaceutical” nature of the claimed composition, defining a qualitative aspect of the composition. The claim does not confine the invention by the uses to which the pharmaceutical composition may be put.<sup>7</sup>

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<sup>3</sup> Roche Mem. at 4.

<sup>4</sup> Roche Mem. at 5.

<sup>5</sup> ’933 Patent at 39:1-4, Docket No. 534, Ex. 3.

<sup>6</sup> 4/17/07 *Markman* Hearing Tr. at 72:24-77:4, Docket No. 514, Ex. 40.

<sup>7</sup> Roche’s motion appears to be a thinly-veiled attempt to convince the Court to revisit claim construction. Amgen believes that the Court has correctly construed “pharmaceutical composition.” However, should the Court be inclined to re-visit claim construction, Amgen would request an opportunity to brief this issue. Amgen has not done so herein as the issue was not directly raised in Roche’s motion.

The Federal Circuit has properly recognized that claims broadly directed to compositions of matter should not be limited to any particular method of use that may be described in the patent.<sup>8</sup> In *Union Oil Co. v. Atlantic Richfield Co.*, the Federal Circuit expressly rejected the argument that claims reciting “an unleaded gasoline suitable for combustion in an automotive engine” or “an unleaded gasoline fuel suitable for combustion in a spark ignition automotive engine” were limited to any particular use of that composition described in the patent, reasoning that, if such an argument were permitted, “these composition claims would mutate into method claims.”<sup>9</sup> Thus Roche’s attempt to read method-of-use limitations into Claim 9 is improper and should be rejected.

**B. CLAIM 10 INCLUDES AN ADDITIONAL LIMITATION OVER CLAIM 9 AND THEREFORE SATISFIES § 112, ¶ 4**

Section 35 U.S.C. § 112, ¶ 4 sets forth the requirements for a validly drafted dependent claim:

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.<sup>10</sup>

Specifically, § 112, ¶ 4 requires that a dependent claim, in addition to incorporating all of the limitations of the independent claim, must specify a further limitation of the subject matter claimed. Nothing in the language of Claim 9 requires the claimed composition to be administered to any recipient, whether human or not. It is the narrowing limitation of dependent

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<sup>8</sup> See, e.g., *Union Oil Co. v. Atl. Richfield Co.*, 208 F.3d 989 (Fed. Cir. 2000) (holding that claims directed to compositions of matter were not limited to certain uses of those compositions).

<sup>9</sup> *Id.* at 995.

Claim 10, and not Claim 9, that recites a particular method of use of the claimed composition, namely “providing erythropoietin therapy to a mammal.” Roche’s transparent effort to read non-existent use limitations into Claim 9 should be squarely rejected by the Court.

By asserting that “dependent claim 10 actually broadens the scope of the subject matter claimed in claim 9 in violation of § 112 ¶ 4.”<sup>11</sup> Roche is inappropriately reading limitations into Claim 9 to make it appear narrower than it is. However, properly read, Claim 9 is a composition claim having specified components and attributes without limitation as to how that composition might be used. By contrast, Claim 10 *does* restrict the uses to which the Claim 9 compositions may be put. Claim 10 of the ’933 patent reads as follows:

A method of providing erythropoietin therapy to a mammal comprising administering an effective amount of a pharmaceutical composition of claim 9.<sup>12</sup>

Therefore, contrary to Roche’s assertions, Claim 10 of the ’933 patent contains all of the limitations of Claim 9 and additionally specifies a further limitation as required by § 112, ¶ 4 of using the pharmaceutical composition for a particular use – to provide EPO therapy to a mammal.

Notably, the Board of Patent Appeals and Interferences has ruled that it is entirely proper under § 112, ¶ 4 for a method of use claim to depend from a composition of matter claim, even though these two claims are directed to distinct statutory classes.<sup>13</sup> In *Ex parte Porter*, the Board

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<sup>10</sup> 35 U.S.C. § 112, ¶ 4 (2006).

<sup>11</sup> Roche Mem. at 5.

<sup>12</sup> ’933 Patent at 39:5-7, Docket No. 534, Ex. 3.

<sup>13</sup> See *Ex parte Porter*, 25 U.S.P.Q.2d 1144, 1147 (B.P.A.I. 1992). See also M.P.E.P. § 608.01(n) (stating that a method claim may properly depend on a parent product claim and should not be objected to or rejected under § 112, ¶ 4).

of Patent Appeals & Interferences held that Claim 6 of the application, directed to a method of utilizing a nozzle, was properly dependent on Claim 7, broadly directed to a nozzle.<sup>14</sup> The Board determined that a dependent claim can satisfy § 112, ¶ 4 simply by reciting a method of using the claimed composition of an independent claim. Because ‘933 Claim 10 recites a method of using the claimed composition of independent Claim 9, thereby “specifying a further limitation” of Claim 9, it is clearly proper under 35 U.S.C. § 112, ¶ 4.

**C. ROCHE’S MOTION REGARDING UNASSERTED CLAIM 10 DOES NOT AFFECT ANY OF THE ASSERTED CLAIMS OF THE ’933 PATENT**

Roche’s motion only asserts the invalidity of Claim 10 of the ‘933 patent.<sup>15</sup> However, Amgen has not asserted ‘933 Claim 10 against Roche.<sup>16</sup> Furthermore, even if Claim 10 were defective, this would not invalidate any of the asserted claims of the ‘933 patent, in particular, ‘933 Claim 9 from which it depends.

Section 112, ¶ 4 requires that a dependent claim, in addition to incorporating all of the limitations of the independent claim, must specify a further limitation of the subject matter claimed. Nothing in 35 U.S.C. § 112, ¶ 4 addresses the independent claim or provides a basis for invalidity of an independent claim. While Roche relies on *Pfizer v. Ranbaxy* in support of its motion, *Pfizer* further demonstrates that § 112, ¶ 4 does not affect the validity of the independent claim from which a defective claim depends.<sup>17</sup> Notably, *Pfizer* is the sole instance where the

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<sup>14</sup> *Porter*, 25 U.S.P.Q.2d at 1147.

<sup>15</sup> Roche Mem. at 5.

<sup>16</sup> See Amgen’s Infringement Contentions, Pl. Resp. To First Set of Interrogs. (Nos. 1-12), Docket No. 252-4, Ex. C at 2-4.

<sup>17</sup> *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284 (Fed. Cir. 2006) (invalidating a dependent claim based upon § 112, ¶ 4, but not invalidating the independent claim on which it depended).



Federal Circuit has ever invalidated a claim for failure to comply with § 112, ¶ 4.<sup>18</sup> Thus, Roche's arguments regarding Claim 10, even if successful, would not invalidate asserted Claim 9.

### III. CONCLUSION

Roche's arguments regarding claim differentiation are premised on a fundamentally incorrect reading of Claims 9 and 10 of the '933 Patent, and an apparent misunderstanding of the difference between a composition claim and a method-of-use claim. When read properly, Claim 10 satisfies the requirements of § 112, ¶ 4. , Roche's motion is only directed to an unasserted claim in a thinly-veiled attempt to revisit claim construction. For the reasons set forth above, Amgen respectfully requests that the Court deny Roche's motion for summary judgment that Claim 10 of the '933 patent is invalid for failure to comply with claim differentiation under 35 U.S.C. § 112, ¶ 4.

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<sup>18</sup> *Id.* at 1291-92 (invalidating a claim based upon § 112, ¶ 4, and further noting that the recent *Curtiss-Wright* "suggested" that a violation of § 112, ¶ 4 may render a patent invalid), *citing Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006).

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Respectfully submitted,

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