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

REPLY MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT OF CLAIM 1 OF PATENT NO. 5,955,422 AND CLAIMS 9 AND 12 OF PATENT NO. 5,547,933

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Dated: Boston, Massachusetts
July 9, 2007

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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 in support of their motion for summary judgment of non-infringement of Claim 1 of the '422 patent and claims 9 and 12 of the '933 patent. As detailed herein, nothing in Amgen's Opposition compels against granting Roche's motion.

On July 3, 2007, this Court issued its decision construing "[a] pharmaceutical composition comprising . . . a pharmaceutically acceptable diluent, adjuvant or carrier" to mean "a composition suitable for administration to humans, containing a diluent, adjuvant or carrier." *Amgen, Inc., v. F. Hoffmann-La Roche Ltd. et al.*, Slip Op. at 21 (D. Mass. July 3, 2007) (D.N. 613). While the Court did not decide whether "all three [diluent, adjuvant or carrier] need to be present or that just one suffices, " it stated that the claim terms must be given their "'ordinary and customary meaning.'" *Id.*

Amgen does not dispute that it own expert, Dr. Lodish, has admitted that MIRCERA is a pharmaceutical composition that is formulated by adding "a diluent **and** carrier." (Amgen's Response to Roche's Rule 56.1 Statement of Undisputed Material Facts Regarding Its Motion for Summary Judgment of Non-Infringement of Claim 1 of the '422 Patent and Claims 9 and 12 of the '933 Patent at 3 (D.N. 584); Declaration of Howard S. Suh in Support of Defendants' Motion for Summary Judgment of Non-Infringement of Claim 1 of Patent 5,955,422 and Claims 9 and 12 of Patent 5,547,933 Ex F ¶ 92 (D.N. 481-6)) (emphasis added). Thus, this issue is ripe for summary judgment because the only dispute regarding infringement is legal, not factual: whether the claim limitation at issue covers only pharmaceutical compositions containing only one of the specified alternatives, i.e., only a diluent or an adjuvant or a carrier, and not, for example, a combination of a diluent and a carrier. The answer, as a matter of law, under the Federal

Circuit's holding in *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1281 (Fed. Cir. 2003), is that summary judgment should be granted in favor of Roche. Amgen does not offer any reason why *Abbott Labs.*, or for that matter any other authority, would dictate a different result. Moreover, the "ordinary and customary" meaning that should be accorded to the limitation warrants the same result. Consequently, Roche's motion for summary judgment of non-infringement should be granted.

II. ARGUMENT

A. "Wherein R is" is Not Required to Turn the Claim Limitation "Containing a Diluent, Adjuvant or Carrier" into a Closed Markush Group

Amgen's only argument that the claims at issue do not embrace a Markush group is that they do not recite the "wherein R is" language. (*See* Plaintiff's Memorandum of Law in Opposition to Defendants' Motion for Summary Judgment of Non-Infringement of Claim 1 of the '422 Patent and Claims 9 and 12 of the '933 Patent at 4-5) (D.N. 583). Amgen's absurd contention has no support in the law. As set forth in *Abbott Labs.*, the operative language for proper Markush claiming is "selected from the group consisting of A, B, C and D" or "A, B, C or D" not "wherein R is."

> A Markush group is a listing of specified alternatives of a group in a patent claim, typically expressed in the form: a member selected from the group consisting of A, B and C. Therefore, "if 'wherein R is a material selected from the group consisting of A, B, C and D' is a proper limitation then 'wherein R is A, B, C or D' shall also be considered proper.

Abbott Labs., 334 F.3d at 1280 (citations omitted) (emphasis added). Thus "A, B, C or D," without "wherein R is" is acceptable for Markush claiming. *See e.g. Schering Corp. v. Geneva Pharms. Inc.*, 339 F.3d 1373, 1375-76, 1380 (Fed. Cir. 2003) ("3. A compound having the structural formula [chemical structure] or a pharmaceutically acceptable salt thereof" is "claimed in the alternative Markush format.") (emphasis added); Robert C. Faber, Landis on Mechanics of

Patent Claim Drafting § 50 (4th ed. 1999) ("one could recite a 'stripe of copper, silver or aluminum. . . .' This is much simpler and covers the same thing as a regular Markush form.") (emphasis added).

If Amgen's illogical and unsupported reasoning is followed, then the "wherein R is" language would also be required every time to turn the recitation "selected from a group consisting of A, B, C and D" into a Markush group. That is simply not the law. *See e.g. Application of Noznick*, 391 F.2d 946, 946-47 (CCPA 1968) ("The coating agents disclosed are listed in the Markush group of claim 55. . . a coating assisting agent selected from the group consisting of gum acacia, gum tragacanth . . . and casein . . .") (emphasis added). Indeed, Amgen itself admits that "selected from the group consisting of" is sufficient for proper Markush claiming by stating, "the language cited by Roche actually confirms that those prosecuting the application knew how to draft a claim to include a Markush group ("selected from the group consisting of")." (D.N. 583 at 9).[1]

[1] Moreover, the relevant inquiry for a proper Markush group is not whether it contains the "wherein R is" language, but whether the elements of the grouping are so related that they can be recited in the conventional manner or alternatively. *See In re Harnisch,* 631 F.2d 716, 723 (CCPA 1980) ("When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively.") (emphasis added); *Application of Weber,* 580 F.2d 455, 457 (Cust. & Pat.App. 1978) (same); MPEP § 2173.05(h), Suh Decl., Ex. I ("The materials set forth in the Markush group ordinarily must belong to a recognized physical or chemical class or to an art-recognized class" . . . [and] may be recited in the conventional manner, or alternatively."). Furthermore, the members of the Markush group should be "alternatively usable for the purposes of the invention." *Abbott Labs.*, 334 F.3d at 1280. (citations omitted). Here, the recited members of the Markush group, adjuvant, carrier or diluent, belong to a recognized class of additives to pharmaceutical compositions. They are alternatively usable, as recited in the claim, and thus constitute a proper Markush group**.**

B. Under *Abbott Labs.* and the Plain Meaning of the Claim Language, the Claims Cover Only Pharmaceutical Compositions Containing One of the Specified Alternatives, a Diluent, or an Adjuvant, or a Carrier

Abbott Labs. requires that when a specified list of alternative claim elements is not modified by qualifying language such as "'and mixtures thereof' and 'at least one member of the group,'" the claim is properly construed to allow for one and only one of the listed alternatives. *Abbott Labs*., 334 F.3d at 1281. Like *Abbott Labs*., the claims here do not have any such qualifying language. Amgen offers nothing to show why *Abbott Labs*. is inapplicable here. Instead, Amgen confirms that in *Abbott Labs*. the Federal Circuit did hold that the claims which recited a Markush group without the qualifying language "required [only] a single [member of the group] Lewis acid [be] present . . . ." (D.N. 583 at 5-6).

"The appropriate starting point [in claim construction] is always ... the language of the asserted claim itself." *Comark Comm., Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998) (citing to *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "While . . . claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims." *Comark*, 156 F.3d at 1186. Thus, while the specification can supply the meaning of unclear terms, it should never trump the clear meaning of the claim terms. *Id*. at 1187. Here, the operative words "a" and "or" clearly do not require any special interpretation. A plain reading of the phrase "containing a diluent, adjuvant or carrier" warrants the conclusion that the pharmaceutical composition claimed contains only one of the claimed members. Thus,

giving the claim terms their "ordinary and customary" meaning results in the same outcome as under *Abbott Labs*. [2]

Amgen states that the "appropriate construction" requires that the pharmaceutical composition comprise "at least" one diluent, adjuvant or carrier. (D.N. 583 at 1). However, the Court's claim construction shows that that limitation has been read out of Amgen's proposed claim construction. Suh Decl. Ex. C at 77:1-3 (D.N. 481-4); (D.N. 613 at 21).

C. The Term "Comprising" Cannot Open A Closed Markush Group

Amgen ignores this Court's construction of the claim limitation at issue. Instead, Amgen simply reargues the position it took before the Court's claim construction, that the transitional term "comprising" makes the entire claim open-ended. (*See* D.N. 583 at 3-4, 6-7). Amgen is wrong as a matter of law.

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[2] Amgen states that Roche has not shown an explicit disavowal or disclaimer by Amgen that the claims are limited to only one of the alternatives, a diluent, adjuvant or carrier. (*See* D.N. 583 at 7-9). Amgen clearly misses the import of Roche's argument. As explained *supra*, according the claim terms their "ordinary and customary" meaning, the claim limitation covers pharmaceutical compositions, which contain only one of the claimed members, a diluent, or an adjuvant or a carrier, not any combination thereof. In the absence of ambiguity of the claim language, the broader language in the specification does not expand the claim. Roche points to the open language in the specification, "diluents, adjuvants and/or carriers" only to show that Amgen knew which language it could use to make the claim open ended, but chose not to. The fact that the specification uses "and/or" in the written description but the claims recite only "or" language, is more reason to limit the claims as suggested by Roche. *See Maxwell v. J. Baker Inc.*, 86 F.3d 1098, 1106 (Fed. Cir. 1996) (disclosed but unclaimed subject matter is dedicated to the public.). In addition, Amgen's belabored point that there was no interference (*see* D.N. 583 at 7-8) is wasted because it does not change the fact that applicant Lin knew which language to use to claim multiple members of the Markush group, but chose not to. Moreover, Roche stated in its Memorandum in support of this motion that applicant Lin proposed the count which contained the language in question in "attempting to provoke an interference with another party based on what eventually became claim 2 of the '422 patent." (*See* Memorandum of Law in Support of Defendants' Motion for Summary Judgment of Non-Infringement of Claim 1 of Patent 5,955,422 and Claims 9 and 12 of Patent 5,547,933 at 6-7) (D.N. 479).

None of the cases relied upon by Amgen involves the use of the term "comprising" or "a" or "an" in conjunction with "comprising," with Markush group claims, and thus are inapplicable to the claims at issue. Indeed, Amgen has not cited to a single case in which the term "comprising" or "containing" operates to open a closed Markush group, nor can it.

The law is clear that a claim containing a Markush group may also have the transitional phrase word "comprising" after the preamble; however, the "comprising" language does not extend to the Markush expression within the claim, which by nature is closed. In fact, the claims at issue in *Abbott Labs*. also contained "comprising" language within the preamble, but the Federal Circuit still held as a matter of law that the Markush group within the claim was closed. As Amgen illustrates in its Opposition, claim 1 in *Abbott Labs*. reads as follows:

> An anesthetic composition comprising:
>
> a quantity of sevoflurane; and
>
> a Lewis acid inhibitor in an amount effective to prevent degradation by a Lewis acid of said quantity of sevoflurane, said Lewis acid inhibitor selected from the group consisting of water, butylated hydroxytoluene, methyparaben, propylparaben, propofol, and thymol.

(D.N. 583, *citing Abbott Labs*, 334 F.3d at 1276-1277).

Despite the "comprising" language in the preamble of the claim, the Federal Circuit ruled that the claims required only a single Lewis acid member present in an effective amount. *Abbott Labs*., 334 F.3d at 1281. The "comprising" language opens the claim to the extent one can add other ingredients in addition to sevoflurane and a Lewis acid inhibitor. But as demonstrated above, the transitional phrase within the preamble does not open the closed Markush group.

Similarly, claim 1 of the '422 patent reads:

> A pharmaceutical composition comprising
> a therapeutically effective amount of human erythropoietin and
>
> a pharmaceutically acceptable diluent, adjuvant, or carrier,

> wherein said erythropoietin is purified from mammalian cells grown in culture.

Just as in *Abbott Labs.*, the "comprising" language in the preamble would open the claim to cover ingredients other than the active ingredient and Markush group, such as a colorant. However, the Markush group itself remains closed. *See id.* at 1280-81 ("A Markush group, incorporated in a claim, should be 'closed,' i.e. it must be characterized with the transition phrase 'consisting of,' rather than 'comprising' or 'including.' . . . . Thus, 'members of the Markush group are used singly.'" (internal citations omitted)); *Ecolochem, Inc. v. Southern California Edison Co.*, 1996 WL 297601, at * 2-3 (Fed. Cir. 1996) (holding that the use of the term "comprising" does not open a closed Markush group reciting certain steps for a process; "Placement of 'comprising' before recitation of steps, however, results in a 'comprising' claim that would cover a process that includes additional steps, not one that uses an additional unrecited element for accomplishing the claimed step. . . . Thus all the claim requires, in step three, is that either a mixed bed resin or a cation exchange resin be used *exclusively* . . . a patentee may not import additional limitations into the steps of a process claim merely by using the word 'comprising' in the claim preamble."); *Maxma v. ConocoPhillips, Inc.*, 2005 WL 1690611, at *5 (E.D. Tex. 2005) ("Proper claim drafting requires the Markush group to be closed; therefore, the group must be characterized with the transitional phrase 'consisting of' rather than 'comprising' or 'including.'"); Landis on Mechanics of Patent Claim Drafting, § 50 (4th Ed. 1999) ("It is improper to use the term 'comprising' instead of 'consisting of.' In other words the group must be recited as closed ended.") (citations omitted).

D. Whether Roche's Proposed Construction of Claims at Issue Would Exclude Coverage of Amgen's Product EPOGEN® is Irrelevant

Amgen's commercial product EPOGEN® is not described in the '422 and '933 patents. As it is undisputed, EPOGEN® is the result of additional purification, downstream processing

techniques, and extensive human clinical trials. In fact, Example 10 of the patent, which is the only working example of human erythropoietin expressed in mammalian cells, uses a study of 7 mice to confirm in vivo biological activity. Suh. Decl. Ex. A. col. 28, ln. 28-44 (D.N. 481-2).

Amgen contends that EPOGEN® "comprises at least one diluent an at least one carrier" (*see* Opposition at 9-10) and would thus fall outside the scope of the claims at issue if construed to cover only pharmaceutical compositions containing only one of the specified alternatives, a diluent, carrier or adjuvant. Whether EPOGEN® meets the limitation of the claims at issue is not relevant to this Court's determination given that EPOGEN® is not a preferred embodiment of the claimed invention.

Finally, Amgen's reference to a "preferred method" of administering the pharmaceutical composition at col. 33, ln. 41 of the '422 patent (D.N. 481-2) is unavailing for a number of reasons. First, Amgen ignores well settled case law which states that preferred embodiments do not limit broader claims that are supported by the written description. *See Toro Co. v. White Consol. Industries, Inc.*, 199 F.3d 1295, 1301 (Fed. Cir. 1999); *Saunders Group, Inc. v. Comfortrac, Inc.*, 2007 WL 1827843, at *5 (Fed. Cir. 2007) ("A patent that describes only a single embodiment is not necessarily limited to that embodiment."); *Intamin Ltd. v. Magnetar Technologies, Corp.*, 483 F.3d 1328, 1337 (Fed. Cir. 2007) ("Nonetheless, this court has acknowledged that a claim need not cover all embodiments...A patentee may draft different claims to cover different embodiments."). Here, that the specification discusses a preferred embodiment that contains a combination of diluents, adjuvants, and carriers is of no moment, since Amgen deliberately chose to claim a broader invention in claim 1 of the '422 patent and claims 9 and 12 of the '933 patent.

Moreover, as stated above, Example 10, not col. 33, is the only working example of erythropoietin expressed in mammalian cells with any therapeutic activity, and that example is silent with respect to whether only an adjuvant, diluent, or carrier is used. Amgen's reference to col. 33, ln. 41 is only to a prophetic example which was not achieved until many years after the time of the invention, when Amgen actually conducted human clinical trials. This is further demonstrated by the fact that col. 33, ln. 41 discussed pharmacokinetic studies for erythropoietin monkey products, not human erythropoietin.

III. CONCLUSION

For the foregoing reasons, and for the reasons set forth in Roche's Memorandum in support of this motion, claim 1 of the '422 patent and claims 9 and 12 of the '933 patent are not infringed by Roche's importation and sale of MIRCERA™. Accordingly, Roche respectfully requests that the Court grant its motion for summary judgment of non-infringement of claim 1 of the '422 patent and claims 9 and 12 of the '933 patent.

Dated: July 9, 2007
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Respectfully submitted,

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