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.: 1:05-cv-12237 WGY

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

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MISCELLANEOUS

I. INTRODUCTION

Roche's motion for summary judgment of non-infringement asks the Court to re-write Amgen's patent claims and ignore the relevant law. The claims of the '422 and '933 patents at issue in the instant motion recite "[a] pharmaceutical composition ***comprising*** … a pharmaceutically acceptable diluent, adjuvant or carrier." Roche improperly proposes to insert additional limitations into the claims to render the claims closed despite the plain, open-ended "comprising" language. There is no basis to restrict the claimed "composition" to containing only a single diluent or adjuvant or carrier, as Roche would have it.

Without support in the law or the intrinsic record, Roche's motion wanders far from the straightforward, unambiguous language of the claims ("a pharmaceutical composition ***comprising*** …"), never bringing forth the express and explicit disavowal of claim scope by Amgen required to support Roche's construction of the claims. The only appropriate construction of the claims at issue here requires that the pharmaceutical composition comprise at least one diluent, adjuvant or carrier. The issue of whether Roche's peg-EPO composition comprises at least one diluent, adjuvant, or carrier is addressed in Amgen's Motion for Summary Judgment of Infringement of '422 Claim 1, '933 Claim 3, and '698 Claim 6. There is no dispute that it does.

If the Court finds, as it should, that the disputed claim terms are not limited to compositions containing one and only one diluent or one adjuvant or one carrier, the Court must deny Roche's motion for summary judgment of non-infringement.

II. BACKGROUND

Roche's motion for summary judgment concerns claim 1 of the '422 patent and claims 9 and 12 of the '933 patent, which read as follows:

'422 patent, claim 1:

> 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.

'933 patent, claim 9:

> 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.

'933 patent, claim 12:

> A pharmaceutical composition ***comprising*** an effective amount of a glycoprotein product effective for erythropoietin therapy according to claim 7 and a pharmaceutically acceptable diluent, adjuvant or carrier.

At the April 17, 2007 *Markman* Hearing, the Court construed the language found in all three claims, namely "[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." *Markman* Hearing Tr., April 17, 2007 [Doc. No. 401] at 77. The Court took under advisement the parties' arguments concerning Roche's proposed construction to exclude pharmaceutical compositions comprising more than a single diluent or adjuvant or carrier. *Id.*

III. LEGAL AUTHORITY

As articulated by the Federal Circuit, "[i]t is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude'." *Philllips v. AWH Corp.,* 415 F.3d. 1303, 1312 (Fed. Cir. 2005). "It is well settled that, in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, *i.e.,* the patent itself, including the claims, the specification and, if in evidence, the prosecution history. *Vitronics Corp. v. Conceptronic, Inc.,* 90 F.3d. 1576, 1582 (Fed. Cir. 1996). The claim should be accorded the meaning it would have to a person or ordinary skill in the art at the time of the invention. *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.,* 381 F.3d 1111, 1116 (Fed. Cir. 2004).

IV. ARGUMENT

Roche's motion for summary judgment of non-infringement studiously ignores the bedrock principle of patent law that the claim language – viewed in light of the specification and

prosecution history – defines the meaning of claim terms in order to arrive at its restrictive and self-serving interpretation. Roche ignores the transitional open-ended term "comprising" found in the claims and the rest of the intrinsic record in making its argument that the claims are limited by a closed-end Markush group.[1]

A. THE CLAIMS AT ISSUE ARE NOT LIMITED TO ONE AND ONLY ONE DILUENT OR ONE ADJUVANT OR ONE CARRIER

1. The Transitional Term "Comprising" Permits the Claims to Include Additional, Unrecited Elements

The claims at issue recite "a pharmaceutical composition ***comprising*** [an element] and a pharmaceutically acceptable diluent, adjuvant or carrier," and therefore use the word "comprising" to transition from the preamble to the body of the claim. The Federal Circuit confirmed that such usage presumes that ***the entire claim is open-ended***. *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1371 (Fed. Cir. 2005) ("The word 'comprising' transitioning from the preamble to the body signals that the entire claim is presumptively open-ended.") (emphasis added); *see also Crystal Semiconductor corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1347 (Fed. Cir. 2001) ("The transition 'comprising' creates a presumption that the recited elements are only a part of the device, that the claim does not exclude additional, unrecited elements.") Since the claims at issue are open-ended, "a pharmaceutically acceptable diluent, adjuvant or carrier" is essential, "but other elements may be added and still form a construct within the scope of the claims." *Genentech, Inc. v. Chiron Corp.*,112 F.3d 495, 501 (Fed. Cir. 1997); *see also Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1345 (Fed. Cir. 2003) (en banc) ("[A] claim reciting a widget comprising A and B, for example, would be infringed by a widget containing A and B, no matter that C, D, or E might be present.")

[1] *Abbott Labs. v. Baxter Pharm. Prods.*, 334 F.3d 1274, 1280 (Fed. Cir. 2003) ("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.").

The use of "a" or "an" in claim language carries the meaning of "one or more" in open-ended claims containing the transitional phrase "comprising." *KCJ Corp. v. Kinetics Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000). Construing the claims at issue as providing for "one or more pharmaceutically acceptable diluent, adjuvant or carrier" is entirely consistent with this well-established view of "a" in the claim language.

The specification common to the '422 and '933 patents expressly confirms an "open" construction:

> Also comprehended by the invention are pharmaceutical compositions comprising effective amounts of polypeptide products of the invention together with suitable diluents, adjuvant and /or carriers.

See Suh Decl. to Roche Motion, Ex. B, col. 12, ln. 1-4.

Roche's substitution of the claim language "comprising" with the term "containing" from the Court's claim construction is unavailing, as it puts no additional limitations on the clams.[2,3] Nonetheless, Roche then uses the "containing" term as a springboard to make its argument that "containing a diluent, adjuvant, or carrier" is a closed Markush group, an argument that is glaringly legally incorrect for the reasons that follow.

2. Roche Misstates the Law Concerning Markush Groups

a. The language "A, B, or C" does not constitute a Markush group

Roche's motion urges that claim language in the format "A, B, C, or D" constitutes a Markush group. Roche Mem. at 4. Roche is wrong. A "Markush group" is a patent term of art having a legally-accepted format and scope. Suh Decl. to Roche Motion, Ex. I: Manual or Patent Examining Procedure ("MPEP") § 2173.05(h)(I)). As the *Abbott Labs* decision that Roche mistakenly relies on in support of its position actually states:

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[2] *See* Roche Mem. at 4 ("The claim limitation '***containing*** a diluent, adjuvant, or carrier' is a closed Markush group.") (emphasis added).

[3] *See Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376 (Fed. Cir. 2004) ("like the term 'comprising,' the terms 'containing' and 'mixture' are open-ended.)

> 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. v. Baxter Pharm. Prods., 334 F.3d 1274, 1280 (Fed. Cir. 2003) (*citing In re Harnisch*, 631 F.2d 716, 724 (CCPA 1980). *Abbott Labs* makes clear that the language of "wherein R is" is required to turn the recitation of "A, B, C or D" into a Markush group.[4] Dr. Lin's claims are not drafted in this format because they do not recite the "wherein R is" language.

Furthermore, Dr. Lin's claims' recitation of "a pharmaceutical composition comprising" corroborates that a Markush group is not an element of the claims: "[i]t is improper to use the term 'comprising' instead of 'consisting of' in claiming a Markush group." *In re Harnish*, 631 F.2d at 723; *see also* Suh Decl. to Roche Motion, Ex. I (MPEP § 2173.05(h)(I)). The claim language itself contradicts a construction that includes Roche's closed-end Markush group.

b. *Abbott Labs* does not preclude infringement by a composition comprising two members of a Markush group

Amgen clearly disputes that the claims at issue are limited to a Markush group. However, even if the claims are viewed as including a Markush group, nothing in the case Roche so heavily relies on, *Abbott Labs*, allows Roche to avoid infringement by including two members of the alleged Markush group in its composition, rather than one.

A careful reading of *Abbott Labs* shows that the case does not exclude compositions that include more than one member of a Markush group. The claims in *Abbott Labs* contain a standard Markush group with a functional limitation. For example, claim 1 read as follows:

An anesthetic composition comprising:

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[4] The claims in *Abbott Labs* use the typical form for a Markush group: "a member selected from the group consisting of …" Specifically, the claims in *Abbot Labs* recite "a Lewis acid inhibitor in an amount effective to prevent degradation by a Lewis acid …, said Lewis acid inhibitor selected from the group consisting of …" The term "said Lewis acid inhibitor selected from …" is an alternative form of "wherein the Lewis acid inhibitor is selected from …".

> 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.[5]

Abbott Labs, 334 F.3d at 1276-1277 (emphasis added). Defendant Baxter's sevoflurane composition used a combination of two Lewis acid inhibitors, neither present in an effective amount individually, but when combined capable of effectively inhibiting sevoflurane degradation by Lewis acids. *Id.* at 1282. To prove literal infringement, Abbott had to show that Baxter's sevoflurane composition contained a species selected from the members of the recited Markush group that was present in an amount effective to function as a Lewis acid inhibitor. *Id.* Abbott therefore argued that "a" Lewis acid inhibitor in the claims was understood to mean that "more than one inhibitor would still fall within the claim boundaries." *Id*. at 1280. The court disagreed, stating:

> "the plain meaning of [the claims] limits them to a single Lewis acid inhibitor selected from the recited Markush group, and present in an amount effective to prevent degradation of sevoflurane by Lewis acids."

Id. at 1281. The *Abbott Labs* court determined that the claims required a single Lewis acid present in an effective amount.

Abbott Labs does not stand for the meaning Roche imposes upon it, *i.e.*, that only one member of a Markush may be present in a composition, and that the addition of another member of a Markush group places the accused product outside the scope of the claims. Roche Mem. at 5-6. Such an interpretation conflicts with the holdings of the *Abbott Labs* case as well as the law related to additional, unrecited elements: (1) the transitional term "comprising" does not exclude additional, unrecited elements; and (2) merely adding elements does not avoid infringement if

[5] Claim 1 in *Abbott Labs* is addressed to a composition and recites "in an amount effective to prevent degradation by a Lewis acid." The other two claims at issue are method claims and recite "in an amount sufficient to prevent degradation by a Lewis acid." *Abbott Labs,* 334 F.3d at 1276-1277. The differences between the composition claim and the method claims is not relevant to this analysis. The court addressed both limitations in terms of "effective amount." *Id.* at 1277-1278.

each element recited in the claims is found in the accused product. *See Crystal Semiconductor*, 246 F.3d at 1347; *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 703 (Fed. Cir. 1983) (It is fundamental that one cannot avoid infringement merely by adding elements if each element recited in the claims is found in the accused product.); *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1372 (Fed. Cir. 2005) (addition of elements not recited in the claim cannot defeat infringement); *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1482 (Fed. Cir. 1984) (infringement is not avoided merely by adding an additional element). By the plain language of the claims at issue, even if the Court interprets the claims to contain a Markush group, the pharmaceutical composition claimed may contain more than one of the recited elements (diluent, adjuvant, or carrier) so long as it contains at least one of the recited elements.

3. Surrender of Claim Scope Requires Express, Explicit Disclaimer by the Patentee

a. The specification does not manifestly exclude or explicitly disclaim coverage of pharmaceutical compositions comprising more than a single diluent or adjuvant or carrier

Roche directs the Court to one phrase in the patent specification common to the '422 and '933 patents as evidence that "Amgen chose to claim the pharmaceutical formulations through a closed Markush group." Roche Mem. at 6. Specifically, Roche argues that because the specification refers to "suitable diluents, adjuvants, and/or carriers" and the claims recite "a pharmaceutically acceptable diluent, adjuvant, or carrier," Amgen "clearly intended" to claim only a closed Markush group. *Id.* The language in the specification and claims pointed out by Roche does not even approach being the "words or expressions of manifest exclusion or explicit disclaimers" that are necessary to disavow claim scope covering more than a single diluent or carrier or adjuvant. *See Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1374 (Fed. Cir. 2005); *Kumar v. Ovonic Battery Co., Inc.*, 351 F.3d 1364, 1371 (Fed. Cir. 2003); *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1326 (Fed. Cir. 2003).

At the onset, unstated limitations are not to be read into the claim language. *Northern Telecom v. Samsung*, 215 F.3d 1281, 1290 (Fed. Cir. 2000) ("This court has repeatedly and

clearly held that it will not read unstated limitations into claim language." (citations omitted)). Words or expressions of manifest exclusion or explicit disclaimers in the specification are necessary to disavow claim scope. *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1374 (Fed. Cir. 2005).

Moreover, the specification discloses a preferred method for administering the compositions that requires more than a single diluent or adjuvant or carrier: "a preferred method" for administering the polypeptide products of the invention "would ordinarily include therapeutically effective amounts of product in combination with acceptable diluents, carriers and/or adjuvants." Suh Decl. to Roche Motion, Ex. A, col. 33, ln. 41-46. The use of plural "diluents, carriers and/or adjuvants" conveys that the preferred method requires at least two or more of a diluent, adjuvant or carrier. A construction that excludes a preferred embodiment in the specification from coverage by the claims "is rarely, if ever, correct and would require highly persuasive evidentiary support." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996); *see also Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1581 (Fed. Cir. 1996) ("We share the district court's view that it is unlikely that an inventor would define the invention in a way that excluded the preferred embodiment, or that persons of skill in this field would read the specification in such a way."). Roche has no evidentiary support, much less the necessary "highly persuasive evidentiary support" required, to limit the claims so as to exclude the preferred method.

b. Neither patents' prosecution history expressly and explicitly limits the claims to only one diluent or one adjuvant or one carrier

Consideration of the prosecution history in informing the meaning of a disputed claim term "is limited to arguments or disavowals made during prosecution regarding the meaning of the disputed claim term." *Sky Tech., LLC v. Ariba, Inc.*, 2007 U.S. Dist. LEXIS 43100, at *9 (D. Mass. June 14, 2007). Claim terms are given their ordinary meaning "unless the patentee unequivocally imparted a novel meaning to those terms or expressly relinquished claim scope during prosecution." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d at 1323; *see also Kumar*, 351

F.3d at 1371 (ambiguous statements in prosecution history are not sufficient to surrender claim scope). For prosecution disclaimer to attach, the alleged disavowing actions or statements made during prosecution are required to be deliberate, unambiguous, and explicit. *Sky Tech.*, 2007 U.S. Dist. LEXIS 43100, at *10 (citing *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985)); *see also Omega Eng'g*, 3343 F.3d at 1325-1326 (prosecution disclaimer attaches only where the alleged disavowing actions or statements are both clear and unmistakable).

The only portion of either patent's prosecution history to which Roche points to justify its self-serving interpretation relates to an interference count proposed during prosecution of the application leading to the '422 patent. The proposed count, which never resulted in a declared interference, read as follows: "An erythropoietin preparation containing ***one or more*** selected from the group consisting of bovine serum albumin, human serum albumin and gelatin" (emphasis added). Suh Decl. to Roche Motion, Ex. J at 3-4; Gaede Decl., ¶ 5. First, the proposed count does not even address "a pharmaceutical composition comprising … a pharmaceutically acceptable diluent, adjuvant, or carrier." Second, far from demonstrating a "clear and unmistakable" statement that the disputed claim term is limited to Roche's interpretation, 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"); they unambiguously chose ***not*** to do so in drafting claim 1 of the '422 patent. Third, the proposed count is consistent with Amgen's position that the claims at issue extend to "***one or more***" diluent, adjuvant, or carrier. Finally, the request for interference and proposed interference count, and therefore the alleged disavowal, are not contained in the prosecution history of the '933 patent. Gaede Decl., ¶ 6.

c. Roche's proposed construction of the claims at issue would exclude coverage of Amgen's product EPOGEN®

Amgen's erythropoietin product EPOGEN® contains Epoetin alfa, saline, and human serum albumin, as well as other components. Gaede Decl., Ex. 1. The common specification of

the '422 and '933 patents states that "[s]tandard diluents such as human serum albumin are contemplated for pharmaceutical compositions of the invention, as are standard carriers such as saline." Suh Decl., Ex. A, col. 33, ln. 41-46; Ex. B, col. 33, ln. 50-55. Thus EPOGEN® comprises at least one diluent ***and*** at least one carrier. Under Roche's proposed claim construction EPOGEN® would fall outside the scope of the claims at issue. It strains credulity to propose that the claims at issue were expressly, explicitly, and unambiguously drafted so that they do not cover Amgen's own product.

V. CONCLUSION

Roche's motion for summary judgment of non-infringement hinges on a claim construction that goes against the rules of claim construction and imposes improper limitations on the claims at issue. The unambiguous, straightforward construction of "a pharmaceutical composition ***comprising*** … a pharmaceutically acceptable diluent, adjuvant or carrier" permits the presence of more than a single diluent, adjuvant or carrier in the composition. Such a claim construction covers Roche's peg-EPO product, which comprises EPO, a diluent, and a carrier.[6]

Roche has cited ***no evidence*** to dispute that its peg-EPO is a pharmaceutical composition comprising at least each of the elements of each of the claims at issue in its motion for summary judgment. Roche's motion for summary judgment of non-infringement of claim 1 of the '422 patent and claims 9 and 12 of the '933 patent must be denied.

[6] Roche's motion for summary judgment of non-infringement does not raise the issue of non-infringement under the Doctrine of Equivalents and presents no evidence to support such a finding. The burden of production imposed by Rule 56 requires Roche to make a *prima facie* showing that it is entitled to summary judgment if it requests summary judgment of on this issue. *Celotex Corp. v. Catrett*, 477 U.S. 317, 331 (1986). It has not done so. Although Amgen need not present evidence that Roche infringes claim 1 of the '422 patent and claims 9 and 12 of the '933 patent under the Doctrine of Equivalents, if the Court finds the claims are not literally infringed, for at least the reasons articulated in Amgen's motion for summary judgment of infringement of '422 claim 1, '933 claim 3, and '698 claim 3, the Court should deny Roche's motion with respect to infringement under the Doctrine of Equivalents.

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Respectfully Submitted,

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