UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMGEN INC.,	)	
	)	
Plaintiff,	)	
v.	)	Civil Action No.: 05 Civ. 12237 WGY
	)	
F. HOFFMANN-LA ROCHE LTD, ROCHE DIAGNOSTICS GmbH, and HOFFMANN-LA ROCHE INC.,	)	
Defendants.	)	

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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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

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

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche Inc. (collectively "Roche") submit this memorandum of law in support of their motion for summary judgment that claim 1 of U.S. Patent No. 5,955,422 (the '422 patent) and claims 9 and 12 of U.S. Patent No. 5,547,933 (the '933 patent) are not infringed by Roche's importation and sale of the product MIRCERA®.

I. PRELIMINARY STATEMENT

Roche is entitled to summary judgment of non-infringement of claim 1 of the '422 patent and claims 9 and 12 of the '933 patent because Roche's product MIRCERA, at a minimum, does not meet the limitation "[a] pharmaceutical composition comprising . . . a pharmaceutically acceptable diluent, adjuvant or carrier."[1]

As explained herein, infringement of these claims can be disposed of on summary judgment by looking at the single limitation, "A pharmaceutical composition comprising . . . a pharmaceutically acceptable diluent, adjuvant or carrier." This Court has construed this phrase to mean "a composition suitable for administration to humans containing a diluent, adjuvant or carrier." Under the Federal Circuit's holding in *Abbott Labs. v. Baxter Pharm. Prods., Inc*., 334 F.3d 1274, 1281 (Fed. Cir. 2003), the limitation embraces a Markush group that is "closed, i.e., it

[1] In filing this motion, Roche does not concede that its product MIRCERA meets any of the other limitations of the claims at issue. Indeed, MIRCERA, *inter alia*, (i) is not, and does not contain "human erythropoietin" or its equivalent, (ii) does not contain a "therapeutically effective amount of human erythropoietin" (iii) is not "purified from mammalian cells grown in culture," and (iv) does not contain a "glycoprotein product of the expression in a mammalian host cell of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin." However, for the purposes of this motion it is not necessary to consider whether MIRCERA meets any of these limitations.

must be characterized with the transition phrase 'consisting of,' rather than 'comprising' or 'including.'" *Id.* Therefore, this claim covers *only* pharmaceutical compositions containing one and only one of the specified alternatives, i.e., one diluent **or** one adjuvant **or** one carrier, and not, for example, a combination of a diluent **and** a carrier.

The undisputed evidence in this case establishes that MIRCERA cannot be a pharmaceutical composition in accordance with the asserted claims. Dr. Lodish, Amgen's own expert, states that MIRCERA is a pharmaceutical composition that is formulated by adding "a diluent ***and*** carrier." Consequently, there are no issues of fact, and summary judgment of non-infringement with respect to claim 1 of the '422 patent and claims 9 and 12 of the '933 patent should be granted.

II. STATEMENT OF FACTS

Amgen alleges that Roche infringes claim 1 of the '422 patent (Suh Decl.,[2] Ex. A)[3] and claims 9[4] and 12[5] of the '933 patent (*see id.* Ex. D at p.3). All the claims at issue share the

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[2] "Suh Decl." refers to the Declaration of Howard S. Suh 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.

[3] Claim 1 of the '422 patent states:
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. (*Id.* Ex. A, claim 1).

[4] Claim 9 of the '933 patent states:
9. A pharmaceutical composition comprising an effective amount of a glycoprotein product effective for erythropoietin therapy according to claims 1, 2, 3, 4, 5 or 6 and a pharmaceutically acceptable diluent, adjuvant or carrier. (*Id.* Ex. B, claim 9).

[5] Claim 12 of the '933 patent states:
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. (*Id.* Ex. B, claim 12).

common limitation "[a] pharmaceutical composition comprising . . . a pharmaceutically acceptable diluent, adjuvant or carrier."

This Court has construed this phrase to mean "a composition suitable for administration to humans containing a diluent, adjuvant or carrier." (Suh Decl. Ex. C at 77:1-3). As discussed in more detail below, Amgen elected to claim pharmaceutical formulations through a Markush group without certain qualifying language that would prevent this group from being closed. As a result, the claims cover only pharmaceutical compositions containing one and only one of the specified alternatives.

Dr. Lodish's expert report, submitted in support of Amgen's infringement allegations, unequivocally states that Roche formulates the active ingredient "into a pharmaceutical composition by adding a diluent ***and*** carrier, and fills it into vials or syringes." (Suh Decl. Ex. F ¶ 92) (emphasis added).

III. ARGUMENT

A. The Summary Judgment Standard

Pursuant to Fed. R. Civ. P. 56(c), summary judgment "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." As this Court has stated, "if there are no genuine issues of material fact, summary judgment is appropriate in a patent infringement case as in any other." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 93 (D. Mass. 2001) ("*Amgen I*").

A determination of infringement requires a two step analysis. *Amgen I*, 126 F. Supp.2d at 93. "First, the court determines the scope and meaning of the patent claims asserted . . . [and second] the properly construed claims are compared to the allegedly infringing device." *Cybor*

Corp., v. FAS Techs., Inc. 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc) (internal citation omitted). The second step of the infringement analysis, comparison of the claim to the accused device, requires a determination that every claim limitation, or its equivalent, be found in the accused device. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997).

"Since the ultimate burden of proving infringement rests with the patentee, an accused infringer seeking summary judgment of non-infringement may meet its initial responsibility either by providing evidence that would preclude a finding of infringement, or by showing that the evidence on file fails to establish a material issue of fact essential to the patentee's case." *Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1046 (Fed. Cir. 2001); *see also Exigent Tech., Inc. v. Atrana Solutions, Inc.*, 442 F.3d 1301, 1308-09 (Fed. Cir. 2006).

B. The Claim Limitation "Containing a Diluent, Adjuvant, or Carrier" is A Closed Markush Group

"A Markush group is a listing of specified alternatives of a group typically expressed in the form: "a member selected from the group consisting of A, B, and C." *Abbott Labs.*, 334 F.3d at 1280. However, as *Abbott Labs.* also makes clear, claim language in the format "A, B, C, or D" is equally acceptable for Markush claiming. *Id.* This is also supported by the Manual of Patent Examining Procedure ("MPEP") which states that:

> 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. For example, 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."

MPEP §2173.05(h), Suh Decl., Ex. I; *see also 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 the regular Markush form.").

Moreover, as discussed *infra*, unless there is certain qualifying language, a Markush group should be "closed" in the sense that no additional elements can be added to the listed group of alternatives. As the Federal Circuit stated in *Abbott Labs*,

> 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." ' [internal citations omitted]. Thus, "members of the Markush group are used ***singly***." [internal citations omitted]

Abbott Labs., 334 F.3d at 1281 (emphasis added). Here, the claim language construed by this Court, "containing a diluent, adjuvant, or carrier" is thus a closed Markush group in the form "A, B, or C."

C. A Closed Markush Group Can Contain One And Only One Member Of The Group And Not Combinations

Abbott Labs. also requires that when a specified list of alternative claim elements is not modified by qualifying language to include mixtures or combinations of the members of the Markush group, the claim is properly construed to allow for one and only one of the listed alternatives.

> If a patentee desires mixtures or combinations of the members of the Markush group, the patentee would need to add qualifying language while drafting the claim . . . such as: 'and mixtures thereof' and 'at least one member of the group.')") (citations omitted). "[W]ithout expressly indicating the selection of multiple members of a Markush grouping, a patentee does not claim anything other than the plain reading of the closed claim language.

Abbott Labs., 334 F.3d at 1281.

Here, like in *Abbott Labs*., there is no qualifying language to indicate that applicant Lin intended to claim a selection of multiple members from the Markush group. Under *Abbott Labs*, the claim limitation "containing a diluent, adjuvant, or carrier" means that the pharmaceutical composition must contain one and only one member of the group to be selected as part of the

claimed invention. The claimed invention can cover a pharmaceutical composition with a diluent, or one with an adjuvant, or one with a carrier; but it cannot cover a pharmaceutical composition with a ***combination*** of a diluent ***and*** an adjuvant.[6]

Critically, Amgen chose to claim the pharmaceutical formulations through a closed Markush group rather than employing open language found in the patent specification. The common specification of the '422 and '933 patent states that "[a]lso comprehended by the invention are pharmaceutical compositions comprising effective amounts of polypeptide products of the invention together with suitable diluents, adjuvants ***and/or*** carriers. . . ." (S*ee e.g.* Suh Decl., Ex. A at col. 12, ln. 5-8; Ex. B. at col. 12 ln. 1-4.) (emphasis added). Nonetheless, Amgen opted to claim only "[a] pharmaceutical composition comprising . . . a pharmaceutically acceptable diluent, adjuvant ***or*** carrier." (*Id.* Ex. A at claim 1) (emphasis added). Therefore, by its selection of language, Amgen clearly intended for the Markush group to be closed, rather than allow for a pharmaceutical composition that contained, for example, a diluent and a carrier.

Moreover, when Applicant Lin wanted to claim more than one member of a selected group, he explicitly chose to do so, such as when he used the language "containing ***one or more*** selected from" during the prosecution of the '422 patent. In attempting to provoke an

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[6] The Federal Circuit in *Gillette Company v. Energizer Holdings*, 405 F.3d 1367 (Fed. Cir. 2005) does not compel a different result. First, it is not even clear from *Gillette* whether the Court even interpreted the claim at issue as a Markush group. *See Maxma v. ConocoPhillips, Inc.*, 2005 WL 1690611, n. 2 (E. D. Tex. 2005) (referring to *Gillette*, "That case did not address a Markush group claim, even considering the alternative drafting language ('group consisting of') suggested by the court. . . . The decision is therefore off the mark."). But more importantly, *Gillette* addressed the issue of whether a claim to a "group of first, second, and third blades" can have more than one second blade. *Gillette,* 405 F.3d at 1372. Thus, this is irrelevant to the current issue of whether Amgen's claims can cover a pharmaceutical composition with a combination of diluent and an adjuvant and a carrier.

interference with another party based on what eventually became claim 2 of the '422 patent, Lin's counsel proposed the count: "An erythropoietin preparation containing one or more selected from the group consisting of bovine serum albumin, human serum albumin and gelatin." (Ex. J at 4; *see also* Ex. K; Ex. L) (emphasis added)). Nevertheless, Amgen subsequently chose to prosecute claim 1 of the '422 patent to state that only one of the members of the specified list, "diluent, adjuvant or carrier," must be used.

Thus, Amgen could have claimed a pharmaceutical composition that contained a combination of a diluent and an adjuvant and a carrier, as described in the patent specification, but Amgen deliberately chose not to do so. As a result, by failing to claim an alternate embodiment discussed and contemplated in the patent specification, that unclaimed embodiment has been dedicated to the public and cannot form the basis of patent infringement, either literally, or under the doctrine of equivalents. *See Johnson & Johnston v. R.E. Service Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2003) ("a patentee cannot narrowly claim an invention to avoid prosecution scrutiny by the PTO, and then, after patent issuance, use the doctrine of equivalents to establish infringement because the specification discloses equivalents.").

D. Amgen's Assertions Regarding the Composition of MIRCERA Establish that it Cannot Meet the Limitation of Claim 1 of the '422 Patent and Claims 9 and 12 of the '933 Patent

After reviewing information provided by Roche concerning the composition of MIRCERA, Amgen's expert witness Dr. Lodish has stated in his expert report that MIRCERA is formulated "into a pharmaceutical composition by adding a diluent *and* carrier." (Suh Decl. Ex. Ex. F ¶ 92) (emphasis added). Based on Dr. Lodish's contention, Amgen cannot dispute that MIRCERA is not a pharmaceutical composition within the scope of asserted claim 1 of the '422 patent and asserted claims 9 and 12 of the '933 patent. Based on the Court's claim construction,

and Federal Circuit precedent under *Abbott Labs.*, these claims cover a closed Markush group, and thus cannot cover a pharmaceutical composition containing both a diluent and a carrier.

IV. CONCLUSION

For all the foregoing reasons, this Court should grant 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.

DATED: Boston, Massachusetts
June 11, 2007

Respectfully submitted,

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