IN THE UNITED STATES DISTRICT COURT
FOR THE 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 12237 WGY

ORAL ARGUMENT SCHEDULED FOR APRIL 17, 2007

LEAVE TO FILE GRANTED ON 3/30/07

DEFENDANTS' REPLY IN OPPOSITION TO AMGEN, INC.'S CLAIMS CONSTRUCTION BRIEF

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March 30, 2007

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

Page(s)

MISCELLANEOUS

Defendants F. Hoffmann-La Roche Ltd, Roche Diagnostics GmbH, and Hoffmann-La Roche, Inc. (collectively "Roche") respectfully submit this reply memorandum in opposition to Amgen, Inc.'s ("Amgen") Response To Defendants' Claims Construction Brief ("Response Brief").

I. INTRODUCTION

By not setting forth its proposed claim construction and arguments for most of the claim terms in dispute until its Response Brief, Amgen has forced Roche to file this Reply in order to meaningfully respond to Amgen's claim construction positions. In Amgen's Opening Brief on Claim Construction ("Opening Brief"), Amgen spent nine pages on irrelevant exaggerated praise about Lin's alleged inventions. Not until page 16 of its Opening Brief did Amgen set forth its first proposed claim constructions and its arguments in support thereof, and then only proceeded to do one other construction, even though, as Amgen admits, Roche had expressly told Amgen that at least 11 claim terms were in dispute. (Pl. Br. at 1 n.1).[1]

Instead, Amgen waited until its Response Brief to explain its claim constructions for the majority of the claim terms in dispute. The reason for Amgen's gamesmanship is obvious. Realizing that its proposed claim constructions and arguments were unfounded, and in many cases had already been rejected by the PTO and the Federal Circuit, Amgen sought to deprive Roche of the opportunity to present these arguments to the Court.

Additionally, in its Response Brief, Amgen accuses Roche of reading in limitations not found in the claims. However, as pointed out in its opposition brief, Roche merely was interpreting the claims in light of the numerous amendments and rejections during the prosecution of the patents-in-suit. Amgen wishes the Court to ignore the intrinsic record,

[1] "Pl. Br. at __" refers to Amgen's Opening Brief (Doc. No. 312-1).

including the prosecution history, so that it can be free to grossly expand the claims to cover Roche's MIRCERA™. As Amgen itself points out, "claims are not construed one way in order to obtain their allowance and in a different way against accused infringers." *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005); (Pl. Resp. at 4).[2] Because this is exactly what Amgen seeks in its proposed construction, the Court should reject Amgen's proposed claim constructions and adopt Roche's proposed claim constructions.

II. AMGEN'S PROPOSED CLAIM CONSTRUCTIONS HAVE NO SUPPORT IN, AND ARE INCONSISTENT WITH, THE INTRINSIC RECORD

Although Amgen's gamesmanship has deprived Roche of a meaningful opposition as to many of the proposed claim terms first set forth in Amgen's Response Brief, for the sake of judicial economy, Roche will only focus on the following four claim terms in dispute in this Reply,[3] as these are illustrative of the overall weaknesses found in all of Amgen's proposed construction, namely that they lack intrinsic support and are improper litigation-based constructions.

A. Amgen Does Not Identify Any Alleged Structure Associated With "Purified From Mammalian Cells Grown In Culture"

While Amgen is correct that source limitations in claims cannot be eliminated wholesale, such limitations will only be given recognition where they "impart novel structure." Pl. Resp. Br. at 9 (emphasis added). Significantly, Amgen has not made any showing that this term imparts structure, much less that such a structure was novel as compared to the prior art. In fact, Amgen never identifies any structure that this claim term defines. Not surprisingly, there is no

[2] "Pl. Resp. at __" refers to Amgen's Response Brief (Doc. No. 323-1).

[3] (1) "purified from mammalian cells grown in culture," (2) "pharmaceutical composition comprising....diluent, adjuvant, or carrier," (3) "CHO" cells, and (4) "cells transformed or transfected with an isolated DNA."

disclosure in the specification or claims of any structure defined by this claim term. Amgen's citation to papers from the prosecution of the patents, (Pl. Rep. at 9 n.29), does not provide any evidence of what structure is imparted by the above claim term, and, in fact, supports Roche's argument that these merely indicate the source of the human EPO. The first citation states "[t]his phrase ["purified from mammalian cells grown in culture"] is intended to include any EPO that is produced by mammalian cells (human, CHO, COS, etc.) that are grown in culture, which means in vitro." (Amgen's Ex. 8 at AM-ITC-00899474). Nothing is stated as to the alleged structure that this term imparts, but only its source. The next paragraph then states "[i]n contrast to [claim 1 of the '422 patent], newly added claim [2 of the '422 patent] does not limit the source of the EPO . . . " thus suggesting that "purified from mammalian cells grown in culture" simply limits the source. (*Id.*) (emphasis added). This is consistent with the Federal Circuit's determination that this phrase "limit[s] only the source from which the EPO is obtained, not the method by which it is produced." *Amgen v. Hoechst Marion Roussel*, 314 F.3d 1313, 1330 n. 5 (Fed. Cir. 2003).[4]

Courts have held that if the structural limitations due to process steps are not taught in the specification or the claims, then they should not be considered for purposes of prior art. *See SmithKline Beecham Corp. v. Geneva Pharms., Inc.*, 2002 U.S. Dist. LEXIS 25275, *20-21 (E.D. Pa. Dec. 20, 2002)[5] ("We conclude that the product of the '944 Patent cannot be

[4] Regarding alleged glycosylation differences this court has previously found that that it is impossible to determine whether a form of EPO differs from urinary EPO. *Amgen v. Hoechst Marion Roussel*, 126 F. Supp. 2d 69, 155 (D. Mass. 2001) ("making comparisons between the glycosylation of recombinant EPO and that of human urinary EPO is virtually impossible."); *see also Amgen v. Chugai* 1989 WL 169006, *84 (D. Mass, 1989) ("Amgen argues that uEPO is a different product than the rEPO. . . However, the overwhelming evidence, including Amgen's own admissions, establishes that uEPO and rEPO are the same product.").

[5] The Federal Circuit did not squarely address this issue because it determined that it had been waived on appeal. *See SmithKline Beecham Corp. v. Apotex Corp*, 439 F.3d 1312 (Fed. Cir. 2006).

distinguished from the paroxetine tablets in the prior art based on these characteristics. Moreover, we decline to recognize product properties that are not required by the patent claims or specification.") If the limitation "purified from mammalian cells grown in culture" were to impart structural limitations on the claimed human erythropoietin, it should have been made evident in the Lin specification or claims. Critically, the Lin specification provides no working example of erythropoietin being purified from mammalian cells grown in culture. (Ex. A at col. 29, ll. 63–66) (Mammalian cell expression products ***may be*** readily recovered in substantially purified form from culture") (emphasis added). Further the structural characteristics of the crude CHO cell produced EPO disclosed in the patent have been now shown to be false. **(**Roche Opening Brief at 12-13 citing *Lin v. Fristch*); *compare* Ex. A at col. 29, l. 67 - col. 30, l. 8 (SDS-PAGE indicate CHO cell produced material has higher molecular weight than pooled source human urinary extract) with Ex. RR at 217-218 ("purified rHuEPO migrates identically to human urinary EPO with an apparent molecular weight of approximately 36,000 daltons"). Additionally, this Court has already found based on Amgen's PLA to the FDA that "all 'physical tests performed on both r-HuEPO and u-HuEPO . . . show these proteins to be indistinguishable'; and that r-HuEPO and uHuEPO are 'indistinguishable' in their biological and immunological properties." *Amgen v. Chugai*, 1989 WL 169006, 84 (D. Mass 1989).

Because Amgen has failed to present any evidence as to any structure imparted by this term, the Court should reject Amgen's proposed claim construction.[6]

[6] Moreover, Amgen's attempts to rely on post-filing technology to read in limitations that are not in the claim or disclosed in the specification are unavailing. During prosecution, Amgen submitted a declaration of its scientists Dr. Thomas W. Strickland in an attempt to demonstrate differences between recombinant EPO and EPO isolated from human urine. (Ex. SS) The recombinant EPO that Dr. Strickland used was purified by a method not disclosed in the Lin Patents, but was subsequently patented in 1985 by Dr. Strickland and another Amgen scientist, Dr. Por H. Lai. (*Id.* at paragraph 6). Dr. Lin is not an inventor of the purification method. *Id.* Any conclusions regarding alleged differences between recombinant and urinary EPO are limited to recombinant material produced from CHO cells and purified by the later patented method.

B. Amgen's Argument That A "Diluent, Adjuvant, Or Carrier" Does Not Have To Be A Distinct Ingredient Is Belied By The Claims And Is Legally Incorrect

Contrary to the plain meaning of the claims and the law of claim interpretation, Amgen argues, for the first time in its Response Brief, that "diluent, adjuvant or carrier"[7] does not have to be distinct from the active ingredient such that the active ingredient could be counted simultaneously as both the active ingredient and as a diluent, adjuvant or carrier. (Pl. Resp. at 12-14). As shown below, such construction has no merit.

The claim language makes clear that, at the very least, an active ingredient is required (*i.e.* "effective amount a glycoprotein product") **and** a separate "diluent, adjuvant or carrier" is required.[8] The disputed claim limitation is found in claims 9 and 12 of the '933 patent and claim 1 of the '422 patent. Claim 9 states:

> 9. 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.

Likewise, 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.

Under the plain meaning of the claim which Amgen has not disputed, the use of additive preposition "and" indicates that the active ingredient and the "diluent, adjuvant or carrier" terms are separate and distinct elements and that both must be present in order to infringe this claim.

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[7] In the claim term "pharmaceutical composition comprising [an effective amount of glycoprotein product] … and a pharmaceutically acceptable diluent, adjuvant or carrier"

[8] *See* Defendants' Opening Memorandum In Support Of their Proposed Claim Construction ("Def. Br.") at 7-8 (Doc. No. 311).

In contrast to the plain meaning of the words of the claims, the only support that Amgen could muster is extrinsic evidence in the form of an expert affidavit accompanying its Response Brief. (Pl. Resp. at 14 n. 47). No citation to the claim language (which, as shown above, contradicts Amgen's position) or to the specification or the prosecution history is provided. Additionally, the extrinsic evidence cited does not support Amgen's position. Amgen's expert makes no distinction among various forces, *i.e.* whether they are strong or weak, and makes no distinction between transient complexes and situations where the two entities combine to form a separate molecular entity. (Pl. Resp. Ex. 2 at ¶¶ 33, 35). The absurdity of Amgen's argument is seen by the fact that under Amgen's argument, anything and everything would be considered diluents, adjuvants, or carriers. Such construction should be rejected.

Amgen's position is contrary to the law of claim construction. For example, *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553 (Fed. Cir. 1995) rejects Amgen's position. In *Exxon*, the claim at issue comprised (1) lubricating oil, (2) ashless dispersant, (3) ZDDP, (4) copper; and (5) a detergent additive. *Id.* at 1556. Lubrizol provided evidence that when one mixes the ingredients together the copper releases zinc from the ZDDP, and this released zinc combines with the ashless dispersant to make it non-ashless. *Id.* at 1559. Specifically, Lubrizol proved "the reactions are immediate and the bond formed between the dispersant and zinc is firm, and as a result, its product lacks the ashless dispersant specified as a necessary ingredient in Exxon's claims." *Id.* The Federal Circuit agreed stating "[i]n order to prevail under properly interpreted claims, Exxon was obliged to prove both the presence of ashless dispersant and presence of the required quantity." *Id.* at 1560. It was not enough for Exxon to try to prove infringement by showing that Lubrizol's product was made by mixing these same five ingredients. Rather, "[u]nder the proper charge, the jury would not have been asked if Lubrizol

used Exxon's starting ingredients. Instead, the jury would have been asked to find whether Exxon had proved by a preponderance of the evidence that Lubrizol's products at some time contained each of the claimed recipe ingredients in the amounts specifically claimed." *Id.* at 1558 (emphasis added).

Likewise, *Northern Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281 (Fed. Cir. 2000) dictates a similar result. In *Northern Telecom,* the claim at issue was to "[a] process for gaseous etching of aluminum and aluminum oxide, including an initial step of plasma etching in the presence of a gaseous trihalide comprising at least in part, a boron trihalide." *Id.* at 1283. The district court defined "aluminum and aluminum oxide" "to refer solely to pure aluminum and its native layer of aluminum oxide, and not to alloys such as aluminum silicon." *Id.* at 1285. Samsung argued that:

> [T]he district court's construction of "aluminum" as "pure" aluminum renders the "aluminum oxide" limitation superfluous. That is, Samsung suggests that because aluminum oxide also includes "aluminum" as defined by the district court, the district court has effectively negated the "aluminum oxide" limitation.

Id. at 1291. The Federal Circuit rejected Samsung's argument stating:

> The "aluminum oxide" limitation is an additional limitation in claim 1. That is, to infringe claim 1, both aluminum and aluminum oxide must be etched. Or, to state it differently, both elemental aluminum and the molecular combination of aluminum and oxygen must be etched. Any accused process that fails to etch either aluminum or the molecular combination of aluminum and oxygen (i.e., "aluminum oxide") will not infringe.

Id. at 1291-92 (emphasis added).

Amgen also advocates a claim construction not limited to only one of the three types of additives, *i.e.* "a pharmaceutically acceptable diluent, additive, or carrier." In patent law, when a closed ended list of alternative claim elements[9] is preceded by "a," the claim is properly

[9] *See* Def. Br. at 8; Ex. R.

construed to allow for one and only one of the listed alternatives. If applicants wish to claim combinations of the listed alternatives, they must use express language such as "or mixtures thereof." *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1281 (Fed. Cir. 2003) ("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. *See Meeting Held to Promote Uniform Practice In Chemical Divisions, supra*, at 852 (citing examples of qualifying language such as: 'and mixtures thereof' and 'at least one member of the group.')").[10]

Moreover, as set forth in detail in the accompanying declaration of Dr. Patrick P. DeLuca, one of skill in the art in 1984, reading the Lin specification, would have considered adjuvants, carriers, and diluents to be separate and distinct from the active ingredient. Chemical bonding with these elements would have created completely new molecules different from the active ingredient. In the case of albumin, Dr. DeLuca explains that while this element is capable of being chemically bonded to certain enzymes through a complicated process, this process is nowhere described in the Lin patents. Moreover, this complex process results in a new chemical entity. In 1984, adding albumin to a pharmaceutical formulation containing a protein was routine, but its purpose was not to covalently bond with the active ingredient. Instead, albumin acted as a distinct stabilizing agent for increased shelf life by minimizing the intramolecular association of the protein, *i.e.* interaction with itself and the resultant aggregation, and thus preventing precipitation and loss of activity.

[10] 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).

C. Amgen's Proposed Construction For "CHO Cells" Incorrectly Imports Language Not Suggested By The Claims And Is Inconsistent With The Court's Construction Of "Mammalian Cells" And "Vertebrate Cells"

Amgen's construction of CHO cell, "A cell **derived** from the ovary of a Chinese hamster", is not in accordance with the Court's past claim constructions or the intrinsic evidence. This *post hoc* construction should be rejected.

The addition of "derived" as modifying "from" is inconsistent with the Court's construction of "mammalian cells" (and "vertebrate cells"). Of the asserted claims, "CHO cells" is found only in dependent claims: claim 2 of the '868 patent and claim 8 of the '933 patent. As is clear from the claim language, the term "CHO cell" limits the genus term "mammalian cell" in the prior '868 and '933 patent claims. The term "mammalian cells" has been previously construed by this Court as "cells from a warm-blooded animal, whose young are fed by milk secreted from mammary glands" *Amgen*, 126 F. Supp. 2d at 86 (D. Mass. 2001). Amgen is bound under doctrine of issue preclusion from contesting this construction. Noticeably absent from the construction of "mammalian cells" is the word "derived" modifying "from."[11]

Amgen accuses Roche of trying to "read unstated limitations into Lin's claimed use of Chinese Hamster Ovary cells to produce EPO" (Pl. Resp. Br. at 14) while it tries to slip in "derived" to the construction of CHO cells. However, the plain meaning of the claim clearly does not include "derived".

The relevant claim language states "said host cells are CHO cells" and "the non-human mammalian cell is a CHO cell." The use of "are" and "is" identifies the cells as equaling "CHO

[11] Similarly, this Court has also previously construed "vertebrate cells" in the context of their use as host cells as "cells from an animal having a backbone" *Amgen*, 126 F. Supp. 2d at 85. Again, absent from the construction is the word "derived."

cells."[12] Tellingly, the claim language does not state "are derived from CHO cells" or "is derived from a CHO cell." "Derived" is absent from the claims and, so should it be absent from the proper construction of this claim term.

Not only is the addition of the word "derived" against the claim language, but its addition would render the scope of the claim indefinite. The word "derived" is ambiguous and could cover a few changes or an infinite number of changes made to a cell taken from the ovary of a Chinese hamster ovary. It could even include any cell that contained even a chromosome taken from a CHO cell.

In contrast to Amgen's proposed construction, Roche's construction of "CHO cells" ("a cell from the ovary of a Chinese hamster") parallels the Court's prior uncontestable construction of the terms with which CHO cells replaces. Thus, for this additional reason, the Court should adopt Roche's proposed construction.

D. Transformed Or Transfected With An Isolated DNA Sequence Encoding Human Erythropoietin

Amgen's arguments regarding "cells transformed and transfected with an isolated DNA sequence encoding human erythropoietin" are without merit.

Amgen believes that Roche's construction "requires: (1) that the DNA introduced into the cell 'must be isolated and not be introduced with other genetic material;' and (2) that the step of transforming a cell with EPO DNA is a process step that limits Dr. Lin's '868 process claims." (Pl. Resp. at 18-19).

As to the first objection, Amgen misinterprets Roche's proposed claim construction. As seen by the Roche's reference to "vector pSVgHUEPR" (Def. Br. at 18), a plasmid containing

[12] "Are" and "is" are verb tenses for "be" which is defined as "5a. To equal in meaning : be identical with..." Ex. TT at 63.

EPO DNA and regulatory DNA, Roche's proposed definition never meant to exclude other isolated DNA. Roche's construction (to which Amgen agrees) was to impart the proper meaning to the word "isolated" in the claims. *See, e.g., Innova/Pure Water, Inc. v. Safari Water Filtration Sys.*, 381 F.3d 1111, 1119 (Fed. Cir. 2004) ("all claims terms are presumed to have meaning in a claim").

Of course, it should be uncontested that for "isolated" to have any meaning, the claim term must exclude processes where the EPO containing vector is not isolated from the cell in which the vector was produced. Thus, Amgen's objection is unfounded, and the construction of the above limitation should properly take into account the word "isolated" so as to exclude the introduction of other material from the vector producing cell.

As to the second objection, Amgen itself believed that transforming a cell with EPO DNA was an action step, as is evidenced by Amgen's use of "receiving," the active present verb tense of "receive," in its proposed claim construction ("cells receiving purified genetic instructions for human erythropoietin"). Amgen has been pushing the claim construction relying on the active present verb tense "receiving" since its Response To Roche's First Set Of Interrogatories. Only now, after taking discovery from Roche, Amgen wants to change its own previously expounded claim construction to exclude this step as requiring some action. The Court should not allow Amgen to do so at this late date.[13]

For the above reasons, Amgen's proposed construction of "cells transformed or transfected with an isolated DNA sequence encoding human erythropoietin" should be rejected.

[13] Additionally, by suggesting a motive for Roche's claim construction (Pl. Resp. at 19 n.65), Amgen again improperly invites the Court to interpret the claims in light of the Roche's product and process and not in light of the intrinsic evidence. This is not proper.

III. ROCHE'S PROPOSED CLAIM CONSTRUCTIONS ARE BASED ON AMGEN'S STATEMENTS AND CONDUCT BEFORE THE PTO

It is quite incongruous that Amgen admits that disavowals and disclaimers can limit claim scope (Pl. Resp. at 2-5), but then proceeds to completely ignore the long and contentious prosecution of the patents-in-suit in which the PTO over and over again required Amgen to whittle down the scope of the asserted patents. Instead, Amgen (1) seeks to construe the claim terms expansively as if it were writing on a blank slate and (2) seeks to require that the Court construe the claims in light of Roche's product. Both of these gambits invite error and thus do a disservice to the Court.

"It is a rule of patent construction consistently observed that a claim in a patent as allowed must be read and interpreted with reference to claims that have been cancelled or rejected and the claims allowed cannot by construction be read to cover what was thus eliminated from the patent." *Schriber-Schroth Co. v. Cleveland Trust Co.*, 311 U.S. 211, 220-21 (1940); *see also Omega Eng'g Co. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003) ("The doctrine of prosecution disclaimer [precludes] . . . patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution.").

In its opposition brief,[14] Roche pointed out in great detail how in response to multiple PTO rejections, Amgen successively narrowed its claims, including, *inter alia*, disclaiming analogs it now seeks to re-capture through the guise of claim construction. (Def. Opp. at 5-10). The Court should see through this veiled attempt to expand the scope of their monopoly, in the same way that Amgen has improperly sought to extend its monopoly temporarily, and construe the disputed terms in light of the specification and prosecution history. *Chimie*, 402 F.3d at 1384

[14] Defendants' Memorandum In Opposition To Amgen, Inc.'s Claim Construction Brief ("Def. Opp.") [Doc. No. 322].

("Such a use of the prosecution history ensures that the claims are not construed one way in order to obtain allowance and a different way against accused infringers."). Once that is done, it is clear that Roche's proposed claim constructions result directly from the intrinsic evidence while Amgen's are disconnected to the intrinsic evidence.

IV. CONCLUSION

Based on the foregoing, Roche respectfully requests that the Court adopt Roche's proposed construction of the claim terms discussed above and in Roche's opening and opposition briefs.

Dated: March 30, 2007
Boston, Massachusetts

Respectfully submitted,

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