United States District Court,
D. 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.

No. CIV.A. 05-12237-WGY

July 3, 2007.

Background: Patentee sought a declaratory judgment that defendant currently infringed or would infringe its patents for erythropoietin (EPO).

Holdings: In construing patent claims, the District Court, Young, J., held that:
(1) patentee, which was a party in a previous case which construed many of the patent claims at issue, and which had a full and fair chance to assert its arguments at that time, was barred from relitigating the claims that were the subject of that previous patent suit;
(2) term "human erythropoietin" meant a protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine; and
(3) "purified from mammalian cells grown in culture" only limited the source from which the EPO was obtained.

Claims construed.

5,441,868, 5,547,933, 5,618,698, 5,756,349, 5,955,422. Construed.

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MEMORANDUM AND ORDER

YOUNG**, District Judge.**

I. INTRODUCTION

Amgen, Inc. ("Amgen") originally brought this action against F. Hoffmann-La Roche Ltd., Roche Diagnostics GMBH, & Hoffmann-La Roche, Inc. (collectively "Roche/Hoffmann") seeking a declaratory judgment that Roche/Hoffmann currently infringes or will infringe Amgen's patents for erythropoietin ("EPO"). Am. Compl. para. 26 [Doc. No. 52]. The patents presently at issue are U.S. Patent Nos. 5,441,868 (the " '868 patent"), 5,547,933 (the " "3 patent"), 5,618,698 (the " '698 patent"), 5,756,349 (the " '349 patent"), and 5,955,422 (the " '422 patent"). Id. para.para. 14, 26.

After this Court decided various preliminary motions, the parties sought claim construction for certain disputed terms. *See* October 20, 2006 Order (denying Ortho Biotech Products, L.P.'s motion to intervene and Roche/Hoffmann's motion to dismiss); March 30, 2007 Order (dismissing some claims and denying other motions). This Court held a Markman hearing on April 17, 2007 to construe the disputed terms. *See* Markman Hearing Transcript ("Tr."). *See generally* Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed.Cir.1995) (*en banc*), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). At the Markman Hearing, this Court construed most of the disputed terms, taking under advisement a single claim construction. This Memorandum and Order summarizes these rulings and sets forth the analysis this Court followed at the Markman hearing.

II. DISCUSSION

A. Precedential Effect of Prior Claim Construction

In this Court's previous Order of March 30, 2007, the Court submitted to the parties some of the problematic issues the parties and the Court must resolve when dealing with an infringement action involving patents previously construed in other litigation. In fact, both this Court and the Federal Circuit have undertaken detailed analyses to construe the terms of the patents here at issue. Thus, two well-settled legal principles come into play: issue preclusion (collateral estoppel) and stare decisis.

In 1996, in Markman v. Westview Instruments, Inc., 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), the Supreme Court addressed the roles played by the judge and jury in patent infringement cases, id. at 371, 116 S.Ct. 1384. That seminal decision foresaw (though it did not expressly decide) the issue before the court today. After thoroughly examining the question whether the construction of a patent's claims ought be reserved entirely for the judge, or whether the Seventh Amendment guarantees that a jury will bear a hand in such determinations, a unanimous Court held that claim construction is a matter for judges. The Supreme Court concluded its opinion as follows:

[W]e see the importance of uniformity in the treatment of a given patent as an independent reason to allocate all issues of construction to the court....

Uniformity would, however, be ill served by submitting issues of document construction to juries. Making them jury issues would not, to be sure, necessarily leave evidentiary questions of meaning wide open in every new court in which a patent might be litigated, for principles of issue preclusion would ordinarily foster uniformity. *Cf.* Blonder-Tongue Laboratories, Inc. v. University of Ill. Foundation, 402 U.S. 313, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971). But whereas issue preclusion could not be asserted against new and independent infringement defendants even within a given jurisdiction, treating interpretive issues as purely legal will promote (though it will not guarantee) intrajurisdictional certainty through the application of *stare decisis* on those questions not yet subject to interjurisdictional uniformity under the authority of the single

appeals court.

Id. at 390-91, 116 S.Ct. 1384.

By mentioning the importance of uniformity in the treatment of patent claim construction, the Supreme Court recognized the implications that construing patent claims as matter of law would have on future litigants. In fact, by specifically noting the principles of issue preclusion and stare decisis, the Supreme Court set forth the framework that guides this court today.

[1] [2] It is important to remember that generally the doctrine of issue preclusion, also called collateral estoppel, bars relitigation by the same parties of matters decided by a judgment on the merits in a suit. Innovad Inc. v. Microsoft Corp., 260 F.3d 1326, 1334 (Fed.Cir.2001) (citing In re Freeman, 30 F.3d 1459, 1465 (Fed.Cir.1994)); Grella v. Salem Five Cent Sav. Bank, 42 F.3d 26, 30 (1st Cir.1994). However, "[i]ssue preclusion operates only if: (1) the issue is identical to one decided in the first action; (2) the issue was actually litigated in the first action; (3) resolution of the issue was essential to a final judgment in the first action; and (4) the party against whom estoppel is invoked had a full and fair opportunity to litigate the issue in the first action." Innovad Inc., 260 F.3d at 1334 (citing Freeman, 30 F.3d at 1465; A.B. Dick Co. v. Burroughs Corp., 713 F.2d 700, 702 (Fed.Cir.1983)); *see also* Grella, 42 F.3d at 30.

[3] Premised on these principles of fairness, the Supreme Court in Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation, 402 U.S. 313, 333, 91 S.Ct. 1434, 28 L.Ed.2d 788 (1971) expressly extended the scope of collateral estoppel to patent law, id. at 333, 91 S.Ct. 1434. In Blonder-Tongue Laboratories, Inc., the Court held that where a patent has been declared invalid in a proceeding in which the, "patentee has had a full and fair chance to litigate the validity of his patent," the patentee is collaterally estopped from relitigating the validity of the patent. Id. A judgment or decree among parties to a lawsuit, however, resolves issues as among them, but it does not conclude the rights of strangers to those proceedings. *See* Richards v. Jefferson County, Ala., 517 U.S. 793, 798, 116 S.Ct. 1761, 135 L.Ed.2d 76 (1996); Hansberry v. Lee, 311 U.S. 32, 40, 61 S.Ct. 115, 85 L.Ed. 22 (1940).

In the patent context, it is usually the new defendant who invokes collateral estoppel against the patentee who has had a say in previous litigation of its patent. *See* Dynacore Holdings Corp. v. U.S. Philips Corp., 243 F.Supp.2d 31, 35 (S.D.N.Y.2003) *aff'd by* 363 F.3d 1263 (Fed.Cir.2004) (holding that since all elements of collateral estoppel were met, previous claim construction had preclusive effect upon patent owner); Abbott Labs. v. Dey, L.P., 110 F.Supp.2d 667, 669-71 (N.D.Ill.2000) (holding that the doctrine of issue preclusion barred plaintiffs from relitigating claim construction issues decided in an earlier infringement action); TM Patents v. International Bus. Mach. Corp., 72 F.Supp.2d 370, 379 (S.D.N.Y.1999) (holding that where plaintiff had a full and fair opportunity to litigate the meaning of claims at an earlier claim construction, that constructionwas binding on the plaintiff). In all of those cases, since the patent owner had a full and fair chance to assert his claims, all the elements of collateral estoppel were plainly met. There are, however, exceptional cases in which the patent owner, having succeeded on previous litigation of his patent, might want to invoke collateral estoppel against a new defendant. Such was the case in Texas Instruments, Inc. v. Linear Technologies Corp., 182 F.Supp.2d 580 (E.D.Tex.2002), where a plaintiff sought to apply collateral estoppel to bar an unrelated new defendant from arguing the issue of claim construction afresh, id. at 584-85. The court in Texas Instruments, Inc. held that collateral estoppel did not apply to a defendant who was not part of the original litigation since doing so would "cause an injustice of precisely the sort that due process seeks to avoid." Id. at 590.

[4] Here Amgen falls squarely within the ambit of the four elements of collateral estoppel. Specifically, Amgen was a party in a previous case before this Court which construed many of the patent claims at issue here, and it had a full and fair chance to assert its arguments at that time. Thus, Amgen is barred from relitigating the claims that were the subject of that previous patent suit. *See* Dynacore Holdings Corp., 243

F.Supp.2d at 35; Abbott Labs., 110 F.Supp.2d at 669-71; TM Patents, 72 F.Supp.2d at 379. Roche/Hoffmann, on the other hand, was not a party in that case and cannot be precluded from asserting its arguments. *See* Texas Instruments, Inc., 182 F.Supp.2d at 582; Nilssen v. Motorola, 80 F.Supp.2d 921, 924 n. 4 (N.D.Ill.2000); KX Indus., L.P. v. PUR Water Purification Prods., 108 F.Supp.2d 380, 387 (D.Del.2000).

Here, to the extent that this Court has already had the opportunity to construe the language of the claims in the patents at issue and no new arguments have been presented to dispute the previous constructions, fairness requires this court to adhere to the previous constructions. In other words, Roche/Hoffmann has to come forward with some argument that would alter this Court's previous claim construction before this Court will modify its previous decision. To do otherwise would be to create the type of ambiguity and uncertainty that Markman intended to prevent. *See* Markman, 517 U.S. at 391, 116 S.Ct. 1384.

[5] The second principle at issue here is stare decisis. This principle expresses the rule of adherence to judicial precedents. *Black's Law Dictionary* 1443 (8th ed.2004). Under this doctrine, a court is bound to follow a higher court's applicable holding, but need only give consideration and careful analysis to a sister court's decision where applicable to a similar fact pattern. *See* United States v. Rodriguez-Pacheco, 475 F.3d 434, 441 (1st Cir.2007). Where the Federal Circuit has already construed the claims here disputed, then that higher Court's construction is binding, and this Court cannot modify its holding. This is the exact result that the Supreme Court intended in Markman when it held both that claim construction was a matter for the judge and that stare decisis principles should apply in the patent context. Markman, 517 U.S. at 391, 116 S.Ct. 1384.

Other courts agree. Tate Access Floors, Inc. v. Interface Architectural Res., Inc., 185 F.Supp.2d 588, 595 (D.Md.2002); Wang Labs., Inc. v. Oki Elec. Indus. Co., Ltd., 15 F.Supp.2d 166, 175 (D.Mass.1998) (Lindsay, J.); Lamps Plus, Inc. v. Dolan, No. 3:01-CV-1537-K, 2003 WL 22435702, at (N.D.Tex. Aug.26, 2003). For instance, in Wang Laboratories, Inc. v. Oki Electric Industry Co., Ltd., 15 F.Supp.2d 166 (D.Mass.1998), Judge Lindsay faced the issue of what role a prior construction of a patent by a sister court ought play in subsequent decisions, id. at 175. The court first remarked that it was clear that claim construction was matter of law. Id. at 173. It went on to conclude that the Federal Circuit's construction of patent claims "ha[ve] the same weight as any other decision on a question of law." Id. at 176. Accordingly, Judge Lindsay adopted the previous Federal Circuit's constructions and applied them to a subsequent case.

[6] " ' *Stare decisis,* unlike the doctrines of res judicata and collateral estoppel, is not narrowly confined to parties and privies... [T]he doctrine is broad in its impact, reaching strangers to the earlier litigation.' " Id. (quoting E.E.O.C. v. Trabucco, 791 F.2d 1, 2 (1st Cir.1986)) (alteration in original). When construing the claims of a patent, the Federal Circuit is creating legal precedent. In accordance with the principles of stare decisis, this Court is bound to follow the prior constructions of Amgen's patents adopted or affirmed by the Federal Circuit in the earlier Amgen v. HMR/TKT litigation, most specifically the holding in Amgen Inc. v. HMR, 457 F.3d 1293, 1295, 1297 (2006) (recounting procedural history).

B. General guidelines for claim construction

[7] "It 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." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed.Cir.2005) (internal quotation marks and citation omitted). Infringement analysis thus begins with the construction of the patent claims alleged to have been infringed. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed.Cir.1998) (*en banc*). Claim construction is matter of law. Markman, 517 U.S. at 372, 116 S.Ct. 1384. The court will construe only those terms "that are in controversy, and only to the extent necessary to resolve the controversy." Vivid Techs., Inc. v. American Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed.Cir.1999).

The words of a claim " 'are generally given their ordinary and customary meaning,' " Phillips, 415 F.3d at 1312 (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996)), which is the "meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Id. at 1313 (citing Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1116 (Fed.Cir.2004)). To determine what "a person of skill in the art would have understood disputed claim language to mean," the court looks to several sources, including "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." Id. at 1314 (quoting Innova/Pure Water, Inc., 381 F.3d at 1116). In divining a claim's meaning, a court must give more weight, perhaps even dispositive weight, to intrinsic evidence-which includes inferences drawn from the full context of the patent, the specifications, and the prosecution history-rather than to extrinsic evidence. *See* id. at 1313-14, 1317-18.

The "claims 'must be read in view of the specification, of which they are part.' " Id. at 1315 (quoting Markman, 52 F.3d at 979). The "specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.' " Id. (quoting Vitronics Corp., 90 F.3d at 1582). As the purpose of the specification is to enable one skilled in the art to duplicate the invention, *see* Phillips, 415 F.3d at 1323, it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims," id. at 1317. Nonetheless, the Federal Circuit, in Phillips v. AWH Corp., warned of "the danger of reading limitations from the specification into the claim." Id. at 1323. In other words, the Court "must use the written description for enlightenment and not to read a limitation from the specification." Playtex Prods., Inc. v. Procter & Gamble Co., 400 F.3d 901, 906 (Fed.Cir.2005).

Although generally not as useful in construing a claim as the specification, the court may consider the prosecution history if it is in evidence. Like the specifications, the prosecution history "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Phillips, 415 F.3d at 1317 (citing Vitronics, 90 F.3d at 1582-83); *see also* Chimie v. PPG Indus., Inc., 402 F.3d 1371, 1384 (Fed.Cir.2005) ("The purpose of consulting the prosecution history in construing a claim is to exclude any interpretation that was disclaimed during prosecution.") (internal quotations and citation omitted). Trial courts must remember, however, that because the prosecution history "represents an ongoing negotiation between the PTO and the applicant," it is less useful for claim construction purposes. Phillips, 415 F.3d at 1317; Sky Techs., LLC v. Ariba, 491 F.Supp.2d 154, 156 (D.Mass.2007).

Additionally, extrinsic evidence, such as dictionaries, treatises, and expert testimony, may provide guidance in certain circumstances, but these sources ought be used with some degree of caution. Specifically, technical dictionaries are helpful to the extent that they assist a court to " 'better understand the underlying technology' and the way in which one of skill in the art might use the claim terms." Phillips, 415 F.3d at 1318 (quoting Vitronics, 90 F.3d at 1584 n. 6). Recourse may also be had, when necessary, to expert testimony. Neither dictionaries nor expert testimony, however, are entirely reliable sources for claim construction for a variety of reasons. The Federal Circuit held in Phillips, for example, that expert testimony, which is "generated at the time of and for the purpose of litigation," is "less reliable" than the patent itself in defining claim terms. Id. Therefore, expert testimony ought be rejected when it "is clearly at odds with the claim construction mandated by the claims themselves." Id. (quoting Key Pharms. v. Hercon Labs. Corp., 161 F.3d 709, 716 (Fed.Cir.1999)).

Ultimately, there is no magic formula for conducting claim construction when the ordinary meaning of the disputed terms as understood by a person of skill in the art is not readily apparent. Id. at 1324. The Court ought concentrate on giving appropriate weight to each "source in light of the statutes and policies that

inform patent law." Id. This equates to attaching the most significance to the claims and the specification, followed by the prosecution history, and finally by extrinsic sources. Id. at 1315-19.

C. Disputed claims

The parties narrowed the disputed claims to a limited number of terms. This Memorandum and Order will address each one of them. The discussion of each term is introduced by a chart setting forth each party's proposed construction as well a this or the Federal Circuit's construction, where applicable, in the course of the earlier Amgen/HMR/TKT litigation. Then, for most of the terms, there is a brief summary of the parties' arguments and this Court's rulings. Since the Court took one of the terms under advisement, that term is discussed in detail.

1. "Human erythropoietin" ('422 claim 1)

Amgen	Roche/Hoffmann	This Court (earlier case)
A protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine	A glycoprotein having the amino acid sequence of erythropoietin isolated from human urine having the structure that would be produced in mammalian cells as of the invention date	Did not address

[8] The Court adopted Amgen's construction of the term "human erythropoietin." Fundamentally, the difference between the parties' constructions of this term is that Roche/Hoffmann sought to include 1) a glycosanation process and 2)a description of the structure of erythropoietin. Tr. 9:5-40:6. The Court declined to work these two limitations into the construction because such a construction would render this claim inconsistent with the other claims, the patent specification, and the prosecution history.

First, the specification itself describes human erythropoietin as a polypeptide having a certain structure. *See* "3 Patent 10 :9-15, 13 :50-53. The specification does not define "erythropoietin" by reference to the presence or absence of any attached molecules, such as the carbohydrate that can be attached to EPO proteins for glycosylated EPO. "3 Patent 10 :28-33. In fact, the specification expressly contemplates that additional molecules ***may*** be attached to "human erythropoietin." By implication, therefore, those additional molecules are not part of the amino acid structure that comprises the claimed product. *Id*.

Second, this Court does not think it ought alter the open construction of the term "human erythropoietin" found in the patent. The patent itself is silent as to the presence or absence of any structural characteristic beyond the required amino acid sequence. Reading, as Roche/Hoffmann proposes, all the characteristics of "erythropoietin isolated from human urine ... produced in mammalian cells as of the invention date" would unnecessarily narrow the claims.

As to this last point, at oral argument the Court expressed its concern about interpreting claims of inventions that at the time of filing were considered "seminal" or "ground braking." Tr. 17:20-19:14. Essentially, the Court was troubled by the fact that since those patents are generally broad on their face, later products or inventions would find it hard to differentiate themselves from the sweep of such general claims. Upon much reflection, however, the Court gives weight to Amgen's argument that as much as an inventor has reasons to claim broadly (to exclude as many future competitors as possible), there are also reasons to claim narrowly. By claiming narrowly, the first inventor not only avoids anticipation but also delimits the essential requirements that an accused embodiment must have in order to infringe. Tr. 26:1-20. Regardless of an inventor's assumed motivation, a district court must interpret the claims as having the "meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1312-13.

Therefore, following the Federal's Circuit mandate on claim construction, the Court adopts the following construction:

Human erythropoietin: A protein having the amino acid sequence of human EPO, such as the amino acid sequence of EPO isolated from human urine

2. "Purified from mammalian cells grown in culture" ('422 claim 1)

Amgen	Roche/Hoffmann	This Court (earlier case)
Wherein the protein is obtained in substantially homogeneous form from mammalian cells grown in culture, such that it originates in mammalian cells, but need not be taken directly out of the interior of the cells	Obtained in substantially homogeneous form from mammalian cells, using the word "from" in the sense that it originates in mammalian cells, without limitation to it only taking it directly out of the interior of the cells, which have been grown in the in vitro culture	"obtained in substantially homogeneous form from the mammalian cells, using the word from in the sense that it originates in the mammalian cells, without limitation to it only taking it directly out of the interior of the cells, which have been grown in the in vitro culture". *Amgen, Inc*. v. *Hoechst Marion Roussel, Inc*., 126 F.Supp.2d 69, 89 (D.Mass.2001), *aff'd in part, rev. in part* 457 F.3d 1293 (Fed.Cir.2006).

[9] This Court previously interpreted "purified from mammalian cells grown in culture" to mean purified to substantial homogeneity. Amgen, Inc. v. Hoechst Marion Roussel, Inc., 126 F.Supp.2d 69, 89 (D.Mass.2001), *aff'd in part, rev. in part* 457 F.3d 1293 (Fed.Cir.2006). Further, the Federal Circuit stated: "the [district] court read the phrase 'mammalian cells grown in culture' as a whole to encompass purification techniques from the cells or the cell culture medium." Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1347-48 (Fed.Cir.2003) (citing Amgen, Inc., 126 F.Supp.2d at 88-89). In fact,

As to the '422 patent, the limitation "purified from mammalian cells grown in culture" in claim 1 clearly limits the source of the EPO used in the claimed "pharmaceutical composition." The limitation only speaks to the source of the EPO and does not limit the process by which the EPO is expressed. Rather, the claim is broadly drawn to a "pharmaceutical composition" having certain elements, one of those being EPO "purified from mammalian cells in culture." This reading is in line with the district court's construction ....

Id. at 1329-30. The Federal Circuit further explained, "[w]e do not hold that these limitations lack meaning, only that they mean just what they say. Accordingly, they limit only the source from which the EPO is obtained, not the method by which it is produced." Id. at 1330 n. 5.

Taking as a starting point this settled construction, that the claim only limits the source from which the EPO is obtained, Roche/Hoffmann asks this Court to revise its previous interpretation. The argument is based on SmithKline Beecham Corp. v. Apotex Corp., 439 F.3d 1312 (Fed.Cir.2006), where the Federal Circuit affirmed the invalidation of a patent to a pharmaceutical composition that recited process steps as the only distinguishing feature over a prior art tablet, id. at 1321. The Federal Circuit stated:

It makes no difference here whether the "4 patent's product-by-process claims are construed broadly to cover the product made by any process or narrowly to cover only the product made by a dry admixing process. Either way, anticipation by an earlier product disclosure (which disclosed the product itself) cannot be avoided. While the process set forth in the product-by-process claim may be new, that novelty can only be captured by obtaining a process claim. We agree with the district court's conclusion that the '723 patent disclosure anticipated the identical product claimed by the "4 patent even though that product was produced

by an allegedly novel process.

Id. at 1318-19.

As Amgen correctly states, however, and as has long been recognized by the Federal Circuit, source or process limitations can and do serve to define the structure of a claimed product where such limitations are the best means to distinguish a claimed product over prior art. In re Luck, 476 F.2d 650, 653 (Cust. & Pat.App.1973) ("[P]roduct claims may include process steps to wholly or partially define the claimed product .... To the extent that these process limitations distinguish the *product* over the prior art, they must be given the same consideration as traditional product characteristics.") (internal citation omitted). In this context, Roche/Hoffmann's citation to SmithKline Beecham Corp. is misplaced since it omits the next passage, which recognizes that process limitations may impart novel structure to a product claim: "If those product-by-process claims produced a different product than that disclosed by the '723 patent, there would be an argument that the '723 patent disclosure did not anticipate." SmithKline Beecham Corp., 439 F.3d at 1319 (citing In re Luck, 476 F.2d at 653).

In this case, Dr. Lin has testified that at the time, "the only way [to] characterize [his claimed] product is by the way they were making ..." Def.'s Mem. Opp'n Amgen's Claim Construction. [Doc. 322] at 11-12 (citing Trial Transcript at 965:8-14, Amgen Inc. v. Hoechst Marion Roussel, Inc., 457 F.3d 1293 (Fed.Cir.2006)). Accordingly, the Court deems it appropriate to include the "source limitation" in a product claim. Thus, Roche/Hoffmann's petition that the Court change the previous construction is denied. This Court's construction will stand as follows:

Purified from mammalian cells grown in culture: obtained in substantially homogeneous form from the mammalian cells, using the word from in the sense that it originates in the mammalian cells, without limitation to it only taking it directly out of the interior of the cells, which have been grown in the in vitro culture.

3. "a pharmaceutical composition comprising... a pharmaceutically acceptable diluent, adjuvant or carrier" ('422 claim 1, "3 claims 9 and 12).

Amgen	Roche/Hoffmann	This Court (earlier case)
A composition suitable for administration to humans containing at least a diluent, adjuvant or carrier	A mixture having in addition to the active ingredient (as defined in the claim), an additional distinct and separate ingredient that acts as a diluent, an adjuvant or a carrier	Did not consider

[10] Basically the discussion on this construction centers around Roche/Hoffmann's intention to (1) distinguish the "diluent, adjuvant or carrier" from the active ingredient with (2) the understanding that the word "comprising" requires *either* a diluent and adjuvant, or a carrier. Tr. 63:6-76:23.

Roche/Hoffmann relies on the claim and two cases. Def.'s Brief [Doc. No. 311] at 7-8. The disputed claim limitation is found in claims 9 and 12 of the "3 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.

Roche/Hoffmann relies on Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553 (Fed.Cir.1995) and Northern Telecom Ltd. v. Samsung Elecs. Co., 215 F.3d 1281 (Fed.Cir.2000). In both of those cases the Federal Circuit taught that in order to prove infringement the plaintiff would have to prove that the defendants used "each of the claimed recipe ingredients in the amounts specifically claimed". Exxon Chem. Patents, Inc., 64 F.3d at 1558. Therefore, Roche/Hoffmann argues that the use of the term "and" implies that the active ingredient must be "distinct" from the diluent, adjuvant or carrier. Def.'s Brief at 7-8.

The Court concedes that from a plain reading of the claims it seems that the active ingredient could well be different from the diluent, adjuvant, or carrier. There is no evidence either in the claims, the specification, or the prosecution history that the ingredients could ***not*** be the same. Thus, adding the limitation that the active ingredient needs to be different from the diluent, adjuvant, or carrier is to read something into the claim that it does not state. Therefore, the better construction is to omit the "additional, distinct and separate" language and allow for potential coincidence or distinction between the active ingredient and the diluent, adjuvant, or carrier.

The same argument works for the second part of the construction. The claim reads: a "diluent, adjuvant or carrier." There is no reason to determine now if that means all three need to be present or that just one suffices. It is better just to construe the claim terms giving them "their ordinary and customary meaning." Phillips, 415 F.3d at 1312-13.

Furthermore, the Court is reluctant to read in limitations that do not necessarily flow from the patent claims and specifications, which is one of "the cardinal sins" of claim construction. Id. at 1320. Accordingly, this Court adopted and now confirms the following construction:

"a pharmaceutical composition comprising ... a pharmaceutically acceptable diluent, adjuvant or carrier": a composition suitable for administration to humans, containing a diluent, adjuvant or carrier.

4. "wherein said cells are CHO cells"('868 Claim 2, "3 claim 8)

Amgen	Roche/Hoffmann	This Court (earlier case)
A cell derived from the ovary of a Chinese hamster.	A cell from the ovary of a Chinese hamster.	Did not address

[11] Here the dispute revolves around the term "derived." Tr. 77:4-79:10. The Court holds that Roche/Hoffmann's construction is more appropriate. The addition of "derived" as modifying "from" is unacceptable and inconsistent with this Court's previous constructions and the plain meaning of the terms.

The relevant claims language states "said host cells are CHO cells" and the "non-human mammalian cell is a CHO cell." Therefore, the plain interpretation of the claim is to assume that the cells in question "are" CHO cells, not that the cells in question "derive from" CHO cells. The Court will not read in limitations where none exist and hereby adopts the following construction:

"wherein said cells are CHO cells": A cell from the ovary of a Chinese hamster.

5. "therapeutically effective amount"

Amgen	Roche/Hoffmann	This Court (earlier case)

Amgen adopts the Federal Circuit's construction	A therapeutically effective amount is one that elicits any one or all of the effects often associated with in vivo biological activity of natural EPO, such as those listed in the specification, column 33, lines 16 through 22, stimulation of reticulocyte response, development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), erythrocyte mass changes, stimulation of hemoglobin C synthesis and, as indicated in Example 10, increasing hematocrit levels in mammals	The Federal Circuit has adopted Roche/Hoffmann's construction. *Amgen, Inc.*, 457 F.3d at 1303.

[12] In view of the Federal Ciruit's construction of this term in Amgen Inc., 457 F.3d at 1303, Amgen agrees that it has no choice but to submit to that construction here. Accordingly, this Court likewise adopts the Federal Circuit's construction:

"therapeutically effective amount": A therapeutically effective amount is one that elicits any one or all of the effects often associated with in vivo biological activity of natural EPO, such as those listed in the specification, column 33, lines 16 through 22, stimulation of reticulocyte response, development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), erythrocyte mass changes, stimulation of hemoglobin C synthesis and, as indicated in Example 10, increasing hematocrit levels in mammals

6. "effective amount of a glycoprotein product effective for erythropoietin therapy**" ("3 Claims 9 and 10)**

Amgen	**Roche/Hoffmann**	**This Court (earlier case)**
A quantity of a glycoprotein product according to claim 1, 2, 3, 4, 5 or 6 that produces a result that in and of itself helps to heal or cure a patient in the class of patients listed in the specification, column 33 lines 31 through 36: patients generally requiring blood transfusions and including trauma victims, surgical patients, renal disease patients including dialysis patients, and patients with a variety of blood composition affecting disorders, such as hemophilia, sickle cell disease, physiologic anemias, and the like	A therapeutically effective amount is one that elicits any one or all of the effects often associated with in vivo biological activity of natural EPO, such as those listed in the specification, column 33, lines 16 through 22, stimulation of reticulocyte response, development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), erythrocyte mass changes, stimulation of hemoglobin C synthesis and, as indicated in Example 10, increasing hematocrit levels in mammals	Adopted Amgen's construction. The Federal Circuit has adopted Roche/Hoffmann's construction. *Amgen, Inc.*, 457 F.3d at 1303.

[13] Certainly this construction was the most interesting one taking place at the hearing. Roche/Hoffmann basically adopts the Federal Circuit's recent determination on "therapeutically effective amount" as having the same meaning than "effective for erythropoietin therapy." Tr. 4:1-9:4; Def.'s Brief at 14. Amgen, on the other hand argues that the terms are not identical and that "effective for erythropoietin therapy" ought be

interpreted as to require the therapy to heal or cure a class of patients. Tr. 4:1-9:4.

This Court's original construction of "therapeutically effective amount" favored Amgen's current argument, but the Federal Circuit has re-written this Court's construction of that phrase *as matter of law*. *See* Amgen, 457 F.3d at 1303. Roche/Hoffmann simply submits the Federal Circuit's construction here and Amgen fails to point to any distinction in the intrinsic record that would point toward a different construction. Therefore, this Court can see no reasoned difference and construes the term as has the Federal Circuit construed "therapeutically effective amount."

"effective amount of a glycoprotein product effective for erythropoiaetin therapy": A therapeutically effective amount is one that elicits any one or all of the effects often associated with in vivo biological activity of natural EPO, such as those listed in the specification, column 33, lines 16 through 22, stimulation of reticulocyte response, development of ferrokinetic effects (such as plasma iron turnover effects and marrow transit time effects), erythrocyte mass changes, stimulation of hemoglobin C synthesis and, as indicated in Example 10, increasing hematocrit levels in mammals.

7. "process for the production of a glycosylated erythropoietin polypeptide ... comprising the steps of" ('868 claims 1 and 2, '698 claims 4-9) and "process for producing erythropoietin comprising the step of" ('349 claim 7).

Amgen	Roche/Hoffmann	This Court (earlier case)
"process for the production of a glycosylated erythropoietin polypeptide ... comprising the steps of"		-Did not address.
A process for the production of an erythropoietin polypeptide having one or more carbohydrate groups attached to the polypeptide ... containing at least the following steps	Process for the production of a glycosylated erythropoietin polypeptide having the amino acid sequence and carbohydrate modifications obtainable through process steps (a) and (b) of these claims	-The Federal Circuit, however, has here construed "comprising" as "a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim." *Amgen, Inc*., 314 F.3d at 1344-45.
"process for producing erythropoietin comprising the step of"		
A process for producing erythropoietin containing at least the step ...	Process for producing a glycoprotein having the amino acid sequence and glycosylation structure of a naturally occurring hormone that is produced in a cell and secreted from that cell, and that controls the formation of red blood cells in bone marrow	

[14] The dispute here centers on the construction of the word "comprising." Tr. 79:10-91:23. Amgen asks the Court to construe the term "comprising" as meaning "containing at least." Further, Amgen argues that its interpretation would mean that any additional steps would be included in the claim. Roche/Hoffmann, on the other hand, wants the Court to construe the term "comprising the steps of" as meaning that any other additional step is outside the claim. It therefore argues that only the two mentioned steps are included in these claims.

The grounds for the disagreement are already reasonably clear. Apparently, Roche/Hoffmann's product includes the addition of a step or more in the process of making the accused composition. Therefore, if the Court construes the claim narrowly, it will potentially prevail on its 35 U.S.C. s. 271(g)(1) argument that its product does not infringe because it is "materially changed by subsequent processes." Amgen, of course,

benefits from the opposite argument. Should the Court construe "comprising" to mean "containing at least," other products that are obtained by the same plus additional elements could potentially fall within the ambit of these patent claims.

There are two important points to make. First, at this point, the Court is only construing the claims, not ruling on infringement. *See* Amgen, 126 F.Supp.2d at 80-81. Second, as the Court made clear at oral argument, construing the term "comprising" as "containing" leaves open for later the discussion and argument to determine whether the additional steps Roche/Hoffmann apparently uses "materially change" the accused product. *See* Biotech Biologische Naturverpackungen GmbH v. Biocorp, Inc., 249 F.3d 1341, 1351-52 (Fed.Cir.2001) ("Whether a change in a product is material is a factual determination, and is properly for the trier of fact.").

Therefore, following the common understanding of the words, the Court determines that "comprising" means "containing the named elements."

8. "cells transformed or transfected with an isolated DNA sequence encoding human erythropoitein" ('868 claims 1 and 2) and "isolating said glycosylated erythropoietin polypeptide expressed by said cells/therefrom" ('868 claims 1 and 2, '698 claims 4-9).

At the Markman hearing the parties suggested to the court the possibility of reaching an agreement as to the construction of these two phrases. Tr. 99:20-103:21. The Court gladly deferred to the parties on this matter since, in case of agreement, there would be no case or controversy and no need for judicial resolution. *See* Vivid Techs., Inc., 200 F.3d at 803 ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy."). FN1 While the parties have made substantial progress, a narrow dispute still remains. The present dispute centers on the phrase "and purified," as set forth below: FN2

FN1. Where the parties agree upon claim construction, that construction properly governs the course of subsequent proceedings just as would a stipulation of fact. Agreed upon claim constructions, however, ought not grow into interpretations enjoying stare decisis effect because it is only the judiciary-not the parties-that declares what the law is. Such agreements, of course, may, where appropriate, implicate judicial estoppel and, where a final judgment occurs, the doctrine of issue preclusion.

FN2. The substantial agreement in interpretation of these terms was communicated to the Court by a joint letter from the parties. Letter from Lloyd R. Day, Jr., Attorney for Amgen Inc., Leora Ben-Ami, Attorney for Roche, & Lee Carl Bromberg, Attorney for Roche to the Hon. William G. Young, United States District Court Judge for the District of Massachusetts (June 12, 2007).

"cells transformed or transfected with an isolated DNA sequence encoding human erythropoitein" '868 claims 1 and 2

Amgen	Roche/Hoffmann	This Court (earlier case)
Cells that have been genetically modified with isolated DNA containing genetic instructions for human erythropoietin or later generations of these cells that have inherited those instructions	Cells that have been genetically modified with isolated *and purified* DNA containing genetic instructions for human erythropoietin or later generations of these cells that have inherited those instructions	Did not discuss, but defined "purified" in another context as "recovering in pure form" and "isolating" as not requiring "in pure form." Tr. 93:15-98:14

[15] Roche/Hoffman seeks to add this limitation by drawing upon references to the prosecution history. As explained in Sky Technologies, Inc. v. Ariba, 491 F.Supp.2d 154 (D.Mass.2007), however, to import into a claim at the Markman stage a limitation found in the prosecution history requires clear and unequivocal admissions by the patent holder, id. at 157. This is, after all, an exercise leading to determination as matter of law. Markman, 517 U.S. at 391, 116 S.Ct. 1384. There is no such compelling evidence here. Accordingly, this Court, construing the language of the claim itself and according the language its plain and ordinary meaning, adopts Amgen's position.

"cells transformed or transfected with an isolated DNA sequence encoding human erythropoitein": cells that have been genetically modified with isolated DNA containing genetic instructions for human erythropoietin or later generationsof these cells that have inherited those instructions.

9. "a non-naturally occurring glycoprotein product of the expression in a mammalian host cell of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin" ("3 claims 3,7-9,11-12 and 14).

Amgen	Roche/Hoffmann	Federal Circuit
A glycoprotein product not occurring in nature that is expressed in a mammalian cell from a DNA sequence that does not originate in the genome of the host and comprises a DNA sequence encoding human erythropoietin	A protein that is the expression product of the mammalian host cell having the amino acid sequence of human erythropoietin which is glycosylated naturally by the host cell at specific amino acids	"Non-naturally occurring" means not occurring in nature. *Amgen*, 314 F.3d at 1329

The main difference between the parties constructions for this claim is that Roche/Hoffmann's construction defines the recited "non-naturally occurring" glycoprotein product as "having": (a) the amino acid sequence of human EPO and glycosylation (b) added by the host cell, (c) only at specified amino acid residues. Amgen's construction, on the other hand, refers only to the first one of these three limitations. Tr. 40:16-62:25.

From reading the actual specification the Court is aware that while the claim includes the limitation that the glycoprotein incorporates a DNA encoding human EPO, it does not expressly state such glycoprotein product must be glycosylated or that glycosylation must occur at a specified amino acid residue.

[16] The Court is bound to read the terms of a claim giving them their ordinary and customary meaning as understood by "a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1312-13. In Phillips, the Federal Circuit not only explained how a court must give more weight to intrinsic, rather than to extrinsic evidence but also cautioned against improper importation of unintended limitations from the written description into the claims. Id.

[17] At oral argument, the parties argued extensively over the meaning of "product of expression," its distinction from secretion, and its implications. Tr. 40:16-62:25. At the moment, however, the Court need not discuss matters implicating prior art or infringement arguments. The Court only must rely heavily in the written description in order to give the terms their ordinary meaning at the time of the invention. Phillips, 415 F.3d at 1323. Accordingly, the Court now adopts the following construction:

"a non-naturally occurring glycoprotein product of the expression in a mammalian host cell of an exogenous DNA sequence comprising a DNA sequence encoding human erythropoietin": a glycoprotein (not occurring in nature) that is the product of the expression FN3 in a mammalian host cell of a DNA sequence that does not originate in the genome of the host, and which contains the genetic

instructions (or a DNA sequence) encoding human erythropoietin.

FN3. Wherein expression means that the glycoprotein was produced in a cell and recovered from the cell culture. Tr. 60: 17-19.

III. CONCLUSION

This Court has followed the Markman mandate to construe the disputed terms of the patent. As expressed to the parties at the hearing, the Court puts forward these constructions as a starting point from which to work. If later in the proceedings the Court considers it helpful to modify these constructions better to explain the terms to the jury or ratify the parties agreement to any aspect of those constructions,FN4 it will immediately do so.

FN4. *See supra* note 1.

SO ORDERED.

D.Mass.,2007.
Amgen, Inc. v. F. Hoffmann-La Roche Ltd.