

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC., AMGEN
MANUFACTURING, LIMITED,

Plaintiffs,

v.

HOSPIRA, INC.,

Defendant.

Civil Action No. 15-839-RGA

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Presently before me is the issue of claim construction of multiple terms in U.S. Patent No. 5,856,298 (“the ’298 patent”). The ’298 patent generally relates to erythropoietin (“EPO”) isoforms. I have considered the parties’ Joint Claim Construction Brief. (D.I. 104). I held a *Markman* hearing on September 21, 2016. I have also considered the parties’ supplemental letters submitted after the *Markman*. (D.I. 138; D.I. 144–45). On November 30, 2016, I resolved several threshold issues and invited the parties to submit additional letters if issues remained. (D.I. 162). On December 14, 2016, the parties submitted a lengthy joint letter detailing remaining issues with respect to claim construction. (D.I. 164).

I. LEGAL STANDARD

“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) (en banc) (internal quotation marks omitted). “[T]here is no magic formula or catechism for conducting claim construction.’ Instead, the court is free to attach the appropriate weight to appropriate sources ‘in light of the statutes and policies that inform patent law.’” *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996). Of these sources, “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.” *Phillips*, 415 F.3d at 1315 (internal quotation marks omitted).

“[T]he words of a claim are generally given their ordinary and customary meaning. . . . [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 1312–13 (citations and internal quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). “In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court’s construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Phillips*, 415 F.3d at 1317–19. Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

“A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct interpretation.” *Osram GMBH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation omitted).

II. BACKGROUND

In my previous opinion (D.I. 162), I construed “an isolated . . . isoform” and “isolated . . . isoform.” In particular, I construed “isolated . . . isoform” as “a group of molecules that has a single isoelectric focusing point and a specific number of sialic acids per molecule, and appears as a single band on an isoelectric focusing gel (an example of which is shown in Figure 1 of the ’298 patent).” I implicitly construed “an isolated . . . isoform” as “one and only one isolated . . . isoform.” I did not separately construe “isoform.” In rejecting Plaintiff’s proposal, I commented, “Plaintiff’s reading would equate the phrase ‘an isolated . . . isoform’ with ‘an isoform.’” The present disputes require that I clarify my earlier constructions.

“An isoform” is “a group of molecules that has a single isoelectric focusing point and a specific number of sialic acids per molecule, and appears as a single band on an isoelectric focusing gel (an example of which is shown in Figure 1 of the ’298 patent).”

“An isolated . . . isoform” is “one and only one isoform,” meaning that only erythropoietin isoforms, all with the same isoelectric focusing point and the same number of sialic acids per molecule and which appear as a single band on an isoelectric focusing gel, are claimed. Erythropoietin isoforms with different isoelectric focusing points and different numbers of sialic acids per molecule and which appear at other bands on an isoelectric focusing gel are excluded.

Separately, I also found claim 8 invalid because it did not properly depend from claim 1. (D.I. 162 at 7–9). Claim 1 required one and only one isoform. Because claim 8 claimed compositions consisting essentially of two or three isoforms, it contradicted a limitation of claim 1 and thus improperly narrowed claim 1. (*Id.* at 8).

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III. CONSTRUCTION OF DISPUTED TERMS

A. “erythropoietin molecules having a predetermined number of sialic acids per molecule” (’298 Patent, Claim 24)

The parties dispute whether claim 24 claims one and only one isoform. (D.I. 164 at 3–5, 13–14).

Claim 24 is an independent claim. The complete language of claim 24 is as follows:

24. A method of preparing erythropoietin molecules having a predetermined number of sialic acids per molecule said number selected from the group consisting of 1-14, comprising applying material containing erythropoietin to an ion exchange column and selectively eluting said molecules from the column.

(’298 patent, claim 24).

The language in claim 24 of “erythropoietin molecules having a predetermined number of sialic acids per molecule said number selected from the group consisting of 1-14” essentially describes “an isoform.” “An isoform” is “a group of molecules that has a single isoelectric focusing point and a specific number of sialic acids per molecule, and appears as a single band on an isoelectric focusing gel (an example of which is shown in Figure 1 of the ’298 patent).” (D.I. 162 at 6–7). The language of claim 24 is another way of describing the same concept of “an isoform.” Thus, I understand claim 24 basically to read: “A method of preparing an isoform”

Hospira’s argument is that claim 24 requires one and only one isoform. (See D.I. 164 at 13–14). The language of claim 24, however, does not “evince[] a clear intent” to claim a method of preparing one and only one isoform. See *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008). No language in claim 24 would be rendered superfluous by my construction. See *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) (“claims are interpreted with an eye toward giving effect to all terms in the claim”).

Hospira argues that the *Markush* group language of claim 24 shows that claim 24 seeks to claim one and only one isoform. (D.I. 164 at 13–14). While an isoform of claim 24 must be an isoform with the number of sialic acids per molecule being selected from the *Markush* group of 1-14, it does not necessarily follow that claim 24 prohibits mixtures of such isoforms. *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1353–54, 1362–63 (Fed. Cir. 2016), is inapposite because that case dealt with whether a component could contain combinations of *Markush* members. Here, the component is the isoform which, by my definition, can only have one member of the *Markush* group. If the isoform had more than one member of the *Markush* group, it would no longer appear as a single band on an isoelectric focusing gel and it would no longer be an “isoform” by definition. Thus, *Multilayer* is not on point. The real issue is whether mixtures of isoforms, where each isoform has one member of the *Markush* group, are allowed, not whether an isoform could be comprised of more than one member of the *Markush* group. *Multilayer* does not speak to this.

Furthermore, the prosecution history does not evince a clear disclaimer of mixtures of isoforms from claim 24. *See Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1095 (Fed. Cir. 2013) (“clear and unmistakable disavowal during prosecution overcomes the heavy presumption that claim terms carry their full ordinary and customary meaning” (internal quotations omitted)). Hospira puts forth evidence that the present language does not encompass mixtures because the original claim language, which expressly provided for mixtures, was eliminated. (D.I. 60-3, Exh. 3 at p. 44; D.I. 60-6, Exh. 9 at p. 4).¹ Amgen puts forth evidence suggesting that the elimination of the original mixture language was not intended to disclaim all

¹ Application claim 30 became issued claim 24. (D.I. 164 at 4, 13).

mixtures, just mixtures generated by techniques of the prior art. (D.I. 60-6, Exh. 9 at p. 10–11). The prior art mixtures were derived from the single-step process of subjecting material containing erythropoietin to ion exchange chromatography. (*Id.*). The present invention derives mixtures through a two-step process of applying material containing erythropoietin to an ion exchange column and selectively eluting the desired isoforms. (*Id.*). The drafting history shows that the patentee intended to disclaim only mixtures derived by prior art techniques and not of mixtures derived from, for example, the “two-step process.” Thus, the prosecution history does not clearly disclaim all mixtures.

I therefore reject Hospira’s argument, and construe claim 24 to claim methods of preparing one or more “isoforms.”

B. “selectively eluting said molecules from the column” (’298 Patent, Claim 24)

The parties initially disputed this phrase. (D.I. 104 at pp. 65–66). In my previous opinion, I requested the parties to inform me if this phrase was still a remaining dispute. (D.I. 162 at 9). Since this phrase was not disputed in the joint letter (D.I. 164), I assume that this phrase is resolved without the need for any construction.

C. “erythropoietin molecules according to claim 13 having two or three specific numbers of sialic acids per erythropoietin molecule” (’298 Patent, Claim 19)

Claim 13 is an independent claim. It provides:

13. Erythropoietin consisting essentially of erythropoietin molecules having a single specific number of sialic acids per molecule, said number selected from the group consisting of 1-14, and said molecules being the product of the expression of an exogenous DNA sequence in a non-human eucaryotic host cell.

(’298 patent, claim 13). Claim 19 depends from claim 13. Claim 19 provides:

19. A composition consisting essentially of erythropoietin molecules according to claim 13 having two or three specific numbers of sialic acids per erythropoietin molecule.

(*Id.*, claim 19).

Beginning with claim 13, I interpret the entire phrase, “Erythropoietin consisting essentially of erythropoietin molecules having a single specific number of sialic acids per molecule,” to refer to the concept of “one and only one isoform.” I accord the words “consisting essentially of” the meaning usually given to this patent-drafting term of art. It is a phrase where “the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention.” *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). “A ‘consisting essentially of’ claim occupies a middle ground between closed claims that are written in a ‘consisting of’ format and fully open claims that are drafted in a ‘comprising’ format.” *Id.*

Here, Claim 13 claims one and only one isoform. The natural reading, i.e., its plain and ordinary meaning, of the claim suggests that claim 13 is claiming a pure composition of erythropoietin consisting essentially of erythropoietin molecules having a single specific number of sialic acids per molecule. *See Phillips*, 415 F.3d at 1312–13. The first word, erythropoietin, is not further modified to suggest that mixtures of erythropoietin are being claimed. Absent such language, the claim language naturally suggests that it is claiming pure compositions of erythropoietin, or in other words, one and only one isoform. *See id.* at 1314.

With that understanding of claim 13’s scope, claim 19 improperly narrows claim 13 because claim 13 permits compositions of one and only one isoform. Claim 19 contradicts a limitation of claim 13 by permitting compositions consisting essentially of two or three isoforms. Thus, for the reasons provided in my previous opinion as to claim 8 (D.I. 162 at 7–9), claim 19 is invalid. *See Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1292 (Fed. Cir. 2006).

D. “mixture of two or more erythropoietin isoforms of Claim 1” (’298 Patent, Claim 27)

Claim 27 provides:

27. A method for obtaining an erythropoietin composition having a predetermined in vivo specific activity comprising preparing a mixture of two or more erythropoietin isoforms of claim 1.

(’298 patent, claim 27).

The parties dispute whether claim 27 is an independent claim. “To establish whether a claim is dependent upon another,” I examine whether “the new claim both refers to an earlier claim and further limits that referent.” *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1357 (Fed. Cir. 2007). “A claim’s status as dependent or independent depends on the substance of the claim in light of the language of § 112, ¶ 4, and not the form alone.” *Id.*² In *Monsanto*, where both claims were method claims, where the prosecution history showed that one of the claims “was incontestably a dependent claim,” the Federal Circuit held that one claim depended from the other. *See id.* at 1357–58.

While the form of claim 27 suggests that it depends from claim 1, the substance of claim 27 does not. First, claim 27 is a method claim, while claim 1 is a composition claim. (’298 patent, claims 1 and 27). This is unlike in *Monsanto*, where both claims were method claims. *See id.* at 1357. Second, the prosecution history tends to show that claim 27 was treated as an independent claim during prosecution. Issued claim 27 corresponded to application claim 35. (D.I. 164 at 8). Application claims 35, 37, and 39 all referred to application claim 1. In the Examiner’s Action dated April 29, 1995 (D.I. 60-8, Exh. 12), application claim 1 was rejected

² 35 U.S.C. § 112, ¶ 4 provides: “[A] claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.”

(*Id.* at p. 4) and the Examiner objected to application claims 37 and 39 because they were “dependent upon a rejected base claim” (referring to application claim 1) (*Id.* at p. 10). The Examiner did not object to application claim 35 on the same basis as claims 37 and 39, which logically suggests that the Examiner regarded application claim 35 as an independent claim.³ (*Id.* at pp. 4, 10). Unlike in *Monsanto*, here the prosecution of claim 27 does not show that claim 27 “was incontestably a dependent claim.” *See* 503 F.3d at 1358. For these reasons, claim 27 is an independent claim.

Hospira argues that because claim 1 requires one and only one isoform, claim 27, in referring to claim 1, improperly narrows claim 1 because claim 27 teaches mixtures of two or more isoforms. (D.I. 164 at 15). I disagree. Unlike with claim 8, claim 27 is an independent claim. Claim 27 does not have to properly narrow claim 1. Thus, claim 27 can properly claim methods of mixing two or more of the isolated isoforms of claim 1.

Hospira correctly notes that Amgen has materially changed its positions from arguing that claim 27 depended from claim 1 (D.I. 104 at 72) to claim 27 is independent of claim 1 (D.I. 164 at 7–8). More generally, Hospira also correctly notes that Amgen has made statements that could be interpreted as representing that the resolution of terms related to claim 1 and claim 8 would resolve the issues with the other claims (D.I. 164 at 10–11). Hospira’s frustrations are reasonable. In the interest of resolution on the merits, however, I decline to hold this against Amgen in connection with claim construction.

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³ At the time of the April 29, 1996 Action, application claim 35 had the same language as issued claim 27. (*See* D.I. 60-6, Exh. 9 at 4).

IV. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion.