

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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November 30, 2016

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 have also considered the parties’ supplemental letters. (D.I. 138; D.I. 144–45). Oral argument was held on September 21, 2016.

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. CONSTRUCTION OF DISPUTED TERMS

The parties dispute various aspects of claim 8, including language in claim 1, which is referenced by claim 8. Claim 8 reads as follows:

8. A composition consisting essentially of two or three erythropoietin isoforms according to claim 1.

('298 Patent, claim 8). Claim 1 in turn reads as follows:

1. An isolated biologically active erythropoietin isoform having a single isoelectric point and having a specific number of sialic acids per molecule, said number selected from the group consisting of 1-14, and said isoform being the product of the expression of an exogenous DNA sequence in a non-human eucaryotic host cell.

('298 Patent, claim 1).

A. “an isolated . . . isoform” ('298 Patent, Claim 1, 8)

Amgen proposes that “an isolated . . . isoform” allows for mixtures of at least one isoform. (*See* D.I. 138).

Hospira proposes that that language allows for mixtures of only one isoform. (*See* D.I. 144).

I begin with the dispute over “an isolated . . . isoform.” “[A]n indefinite article ‘a’ or ‘an’ in patent parlance carries the meaning of ‘one or more’ in open-ended claims containing the transitional phrase ‘comprising.’” *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1342 (Fed. Cir. 2008). “That ‘a’ or ‘an’ can mean ‘one or more’ is best described as a rule, rather than merely as a presumption or even a convention. The exceptions to this rule are extremely limited: a patentee must ‘evince[] a clear intent’ to limit ‘a’ or ‘an’ to ‘one.’” *Id.* “An exception to the general rule that ‘a’ or ‘an’ means more than one only arises where the language of the claims themselves, the specification, or the prosecution history necessitate a departure from the rule.” *Id.* at 1342–43.

Here, the exception applies because the plain language evinces a clear intent to claim only one isoform. The claim language reads “an isolated . . . isoform.” Plaintiff’s reading would render the word “isolated” superfluous. Plaintiff’s reading would equate the phrase “an isolated . . . isoform” with “an isoform.” This violates the principle that “claims are interpreted with an

eye toward giving effect to all terms in the claim.” *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006).

Hospira’s proposal is consistent with the prosecution history. Claim 1 was initially broadly drafted to read “[a]n . . . isoform.” (D.I. 60-4, Exh. 3 at 2). Two rejections were issued to claim 1. Claim 1 was then amended to read “[a]n isolated . . . isoform.” (D.I. 60-4, Exh. 7 at 2). The purpose of the amendment was “to further clarify that an erythropoietin isoform represents a homogeneous preparation.” (*Id.* at 6). Amgen concedes that the word “isolated” is used to clarify that the isoform in claim 1 is a “homogeneous preparation.” (D.I. 138). Consistent with Hospira’s interpretation, Amgen appears to concede that each of lanes two through ten in Figure 1 of the ’298 patent illustrate isolated homogeneous preparations. (*Id.*) Amgen argues that because two lines appear on lane one multiple isoforms may exist in an “isolated” mixture. (*Id.*) Amgen’s argument is in tension with the specification, which explains that degradation of a single isoform could have been the cause. (*See* ’298 Patent, 10:65-67).

Hospira’s proposal is also consistent with what a person of skill in the art would have understood from the prior art. It appears that the prior art disclosed isoform mixtures of more than one isoform. (’298 Patent, Figure 3 & 3:51–4:11). It would thus make sense for the patentee to “clarify” that claim 1 requires only one isoform to avoid the prior art.

Amgen points to language in the specification that “repeatedly and consistently emphasizes both a single isoform and compositions containing two or more isoforms” (D.I. 138) (emphasis removed). For example, Amgen points to column 1, lines 9–15 of the specification, which reads: “The present invention relates to erythropoietin isoforms or mixtures thereof, to the methods for the preparation of specific isoforms or mixtures thereof, to pharmaceutical compositions comprising such isoforms or mixtures thereof, and to methods of

treatment utilizing such isoforms and compositions.” (’298 Patent, 1:9–15). If claim 1 claimed just one isoform, as Hospira argues, I do not find that that reading would be inconsistent with this portion of the specification because the invention teaches the preparation of single isoforms. *See id.* Thus, Amgen’s references to the specification are consistent with Hospira’s proposal.

Thus, I adopt Hospira’s proposal that “an isolated . . . isoform” means only one isoform.

B. “isolated . . . isoform” (’298 Patent, Claim 1, 8)

As to the phrase, “isolated . . . isoform,” Amgen proposes that it means “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. 145).

Hospira proposes that the language refers to “EPO molecules having a specific number of sialic acids per molecule characterized by a single isoelectric point as defined by a single band when EPO is subjected to isoelectric focusing (an example of which is shown in Figure 1 of the ’298 patent).” (D.I. 145).

The parties agree that an “isolated . . . isoform” refers to the “single band” that appears on an isoelectric focusing gel, an example of which is reflected by Figure 1 of the ’298 patent. The parties agree that this “single band” would reflect molecules with a “single isoelectric point” that have a “specific number of sialic acids per molecule.” It appears that Hospira’s only objection to Amgen’s proposal is that Hospira views Amgen’s proposal as an “attempt to eliminate one of the central disputes between the parties[:] whether claim 1 requires an isolated isoform as expressly recited by the claim.” (D.I. 145).

Having resolved Hospira’s objection above, I adopt Amgen’s proposal to construe “isolated . . . isoform,” as referred to in claim 1, 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).”

C. Validity of Claim 8

The parties further dispute whether claim 8 is valid. Here, claim 8 depends on claim 1. ('298 Patent, claim 8). To be valid, claim 8 must properly depend on claim 1.

Section 112 provides, in relevant part:

[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.

35 U.S.C. § 112, ¶ 4. “[A] violation of § 112, ¶ 4 renders a patent invalid just as violations of other paragraphs of § 112 would.” *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1292 (Fed. Cir. 2006). A dependent claim that does not properly narrow the scope of the claim from which it depended is invalid under 35 U.S.C. § 112, ¶ 4. *See id.* (“[R]eading an additional limitation from a dependent claim into an independent claim would not only make that additional limitation superfluous, it might render the dependent claim invalid’ for failing to add a limitation to those recited in the independent claim, as required by 35 U.S.C. § 112, ¶ 4.”). Although “claims should be construed to sustain their validity,” “if the only claim construction that is consistent with the claim's language and the written description renders the claim invalid, then the axiom does not apply and the claim is simply invalid.” *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999). Courts “should not rewrite claims to preserve validity.” *Id.* (noting that “claim 6 could have been properly drafted either as dependent from claim 1 or as an independent claim,” but declining to do so and holding claim 6 invalid).

Here, claim 1 requires only one isoform. Claim 8 contradicts claim 1's limitation that the isoform is "isolated" by requiring a mixture "consisting essentially of two or three" isoforms. Claim 8 thus improperly narrows claim 1.

Let me illustrate.¹ For example, claim 1 is analogous to a claim that claims "a composition having only one of the substances A, B, C, D, or E." Claim 8 is analogous to a claim of "a composition consisting of two or three of the substances of claim 1." If I had a composition that contained only substances A and B, it might meet the limitations of claim 8, but it would logically fail to meet the limitations of claim 1. In other words, the limitations of claim 8 must contradict and override the limitations of claim 1 in order for claim 8 to work. Where a limitation of a dependent claim is logically inconsistent with that of the independent claim, that is a 35 U.S.C. § 112, ¶ 4 problem.²

In contrast, if Claim 8 instead said "a composition of only one of the substances of claim 1, where substance X is present," that might be a proper narrowing. A composition that contained only substances A and X, would meet all the limitations of claim 8. It would also meet the limitations of claim 1, since it could not have any B, C, D, or E, and the presence of X is neither prohibited nor required by claim 1. No limitation in claim 8 needs to contradict or override a limitation of claim 1 in order for claim 8 to work. The dependent claim would be logically consistent with that of the independent claim.

¹ Among other things, I am not a patent draftsman. The example in the text is for the purpose of explaining my analysis. It is not meant as an example of superior claim drafting.

² A different way to identify the problem here is that something that infringes a dependent claim necessarily infringes the independent claim from which the dependent claim depends. See *Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312, 1316 n.1 (Fed. Cir. 2006). When that is not true, there is something wrong with the claim drafting.

Perhaps claim 8 could have been drafted as an independent claim, but the fact is that it was not. *See Pfizer*, 457 F.3d at 1292. I decline to rewrite claim 8 to preserve its validity. *See id.* Claim 8 is thus invalid because it contradicts a limitation of claim 1.

III. CONCLUSION

I understand that the disposition of these issues resolves the remaining *Markman* disputes between the parties. (D.I. 134). To the extent that this is not the case, I request that the parties submit a joint letter laying out the remaining disputes with each parties' respective proposals and rationales within fourteen days.³ If there are no remaining disputes, the parties are to submit a proposed order consistent with this Memorandum Opinion within fourteen days.


United States District Judge

³ I believe this disposition also resolves the “consisting essentially of” dispute. To the extent that is not the case and without prejudice to either side, I was leaning towards adopting the Federal Circuit’s construction.