

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS
CORPORATION and NOVARTIS AG,

Plaintiffs,

v.

PAR PHARMACEUTICAL, INC.,

Defendant.

Civil Action No. 14-1494-RGA

Civil Action No. 15-78-RGA

NOVARTIS PHARMACEUTICALS
CORPORATION and NOVARTIS AG,

Plaintiffs,

v.

ROXANE LABORATORIES, INC.,

Defendant.

Civil Action No. 14-1508-RGA

Civil Action No. 15-128-RGA

MEMORANDUM OPINION

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October 16, 2015


ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is the issue of claim construction of a term in U.S. Patent Nos. 7,297,703 (“the ’703 patent”) and 7,741,338 (“the ’338 patent”). Plaintiffs Novartis Pharmaceuticals Corporation and Novartis AG assert claims of the ’703 patent, the ’338 patent, and U.S. Patent No. 5,665,772 against Defendants Par Pharmaceutical, Inc. and Roxane Laboratories, Inc. in the above-captioned cases.¹ The Court has considered the parties’ Joint Claim Construction Brief. (D.I. 72).² The Court heard oral argument on October 14, 2015.

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). 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 and citations 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

¹ The claim terms of U.S. Patent No. 5,665,772 are not at issue in this proceeding.

² Citations to “D.I. ___” are citations to the docket in C.A. No. 14-1494.

question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Id.* at 1312–13 (internal quotation marks and citations 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 (internal citations omitted).

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 (internal quotation marks and citations omitted). 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).

II. CONSTRUCTION OF DISPUTED TERM

The disputed claim term “catalytic amount” appears in claim 1 of the ’703 patent and claim 2 of the ’338 patent. (D.I. 72 at 8). The ’338 patent is a continuation of the ’703 patent and the ’703 and ’338 patents share the same specification. (D.I. 73-1 at 13; D.I. 72 at 8). The

parties agree that the term should be construed to have the same meaning in the claims of the '703 and '338 patents. (D.I. 72 at 8).

1. “catalytic amount”

- a. *Plaintiffs’ proposed construction*: small amount as compared to the amount of the poly-ene macrolide
- b. *Defendants’ proposed construction*: an amount up to 1% based on the weight of the poly-ene macrolide
- c. *Court’s construction*: small amount as compared to the amount of the poly-ene macrolide

The parties agree that the term “catalytic amount” refers to an amount of antioxidant that is relative to the amount of the claimed poly-ene macrolide. (D.I. 72 at 9–10, 26). The dispute concerns how much antioxidant is a “catalytic amount” as that term is used in the asserted claims.

Plaintiffs argue that their construction is proper under principles of claim differentiation, relying on claims 1 and 2 of the '703 patent. (*Id.* at 12). Claims 1 and 2 of the '703 patent read:

1. A solid mixture comprising a poly-ene macrolide and an antioxidant wherein the poly-ene macrolide is selected from the group consisting of rapamycin, a 16-O-substituted rapamycin, and a 40-O-substituted rapamycin and wherein the antioxidant is present in a catalytic amount.
2. A mixture according to claim 1, wherein the antioxidant is present in an amount of up to 1% based on the poly-ene macrolide weight.

('703 patent, col. 8, ll. 37–44). Plaintiffs contend that “catalytic amount” in claim 1 of the '703 patent should be construed to encompass amounts greater than the amount disclosed in dependent claim 2 of that patent, “up to 1% based on the poly-ene macrolide weight,” because the scope of an independent claim is presumed to be different from and broader than the scope of a claim that depends from the independent claim. (D.I. 72 at 12–14). Plaintiffs further contend that a claim term expressed in general descriptive terms typically should “not be limited to a

numerical range that may appear in the written description as referring to a preferred embodiment or in other, narrower claims.” (*Id.* at 14 (quoting *RF Del., Inc. v. Pac. Keystone Techs., Inc.*, 326 F.3d 1255, 1263 (Fed. Cir. 2003) (internal quotation marks omitted))).

Plaintiffs maintain that their construction can be applied to the ’338 patent consistent with the doctrine of claim differentiation. (*Id.* at 15). Claims 1 and 2 of the ’338 patent read:

1. A solid mixture comprising 40-O-(2-hydroxy)ethyl-rapamycin and 2,6-di-tert-butyl-methylphenol (BHT).
2. A mixture according to claim 1, wherein said 2,6-di-tert-butyl-4-methylphenol (BHT) is present in a catalytic amount.

(’338 patent, col. 10, ll. 12–15). Plaintiffs argue that the scope of independent claim 1 of the ’338 patent remains broader than the scope of dependent claim 2 under its proposed construction of “catalytic amount” because the amount of BHT in claim 1 is not limited, while the amount of BHT in claim 2 is limited to a catalytic amount. (D.I. 72 at 15).

Defendants argue that the specification defines the disputed term and that that definition must govern construction of the claim term in spite of Plaintiffs’ claim differentiation arguments. (*Id.* at 28, 30). Defendants maintain that the term “catalytic amount” is defined in the specification language that follows:

According to the invention, there is provided

1. A process for stabilizing a poly-ene macrolide comprising adding an antioxidant to the purified macrolide, preferably at the commencement of its isolation step. This process is particularly useful for the production of a stabilized poly-ene macrolide in bulk. The *amount of antioxidant may conveniently be up to 1%*, more preferably from 0.01 to 0.5% (based on the weight of the macrolide). Such a small amount *is referred to hereinafter as a catalytic amount.*

(’703 and ’338 patents, col. 1, ll. 27–36 (emphasis added); D.I. 72 at 28). Relying on *Sinorgchem Co., Shandong v. International Trade Commission*, 511 F.3d 1132, 1136 (Fed. Cir.

2007), Defendants argue that the presence of the words “is referred to” indicates that the patentees acted as their own lexicographers and that the term “catalytic amount” is defined in the specification as an amount up to 1% based on weight of the macrolide. (D.I. 72 at 28).

Plaintiffs respond that the specification does not limit the claim term “catalytic amount” to the specific numeric ranges disclosed because the specification makes clear that the numeric ranges are merely “convenient” and “preferable” examples of catalytic amounts. (*Id.* at 17–18). Plaintiffs also respond that, to control construction of a claim term, a definition in the specification must be set forth with “reasonable clarity, deliberateness, and precision.” (D.I. 72 at 41 (quoting *Abbott Labs. v. Syntron Bioresearch, Inc.*, 334 F.3d 1343, 1354 (Fed. Cir. 2003))). Plaintiffs argue that the specification does not clearly express an intent to define the term “catalytic amount” because the specification does not state that “catalytic amount” “is” or “refers to” a certain amount and the claim term is not set off in quotation marks. (*Id.* at 41–42).

Regarding extrinsic evidence, Plaintiffs argue that the term “catalytic amount” is used by persons having ordinary skill in the art to encompass small amounts relative to the weight of reactants, which is a broader meaning than “up to 1%” of the weight of reactants. (*Id.* at 21–25). Defendants argue that Plaintiffs’ reliance on extrinsic evidence is unavailing because: (1) extrinsic evidence is irrelevant when an analysis of intrinsic evidence alone resolves the ambiguity in a claim term; (2) the prior art on which Plaintiffs rely is inapposite; and (3) Plaintiffs’ expert’s declaration improperly argues legal issues. (*Id.* at 33–35).

Defendants also contend that Plaintiffs’ proposed construction frustrates the purpose of claim construction because it does not clarify the meaning of the claim term and itself requires construction. (*Id.* at 36). Plaintiffs respond that a proper construction can be provided in descriptive terms and need not set forth an exact numeric bound. (*Id.* at 49–50). Plaintiffs

maintain that their construction does not introduce additional vagueness into the claim term. (*Id.* at 49).

Here, the patentee did not “clearly set forth a definition of the disputed claim term[] and clearly express an intent to define the term.” *GE Lighting Solutions, LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014) (internal quotation marks omitted). The language identified by Defendants does not express an intent to define “catalytic amount” as an amount of antioxidant “up to 1%” for several reasons. First, the numerical percentage recited in the specification is preceded by the non-limiting phrase “may conveniently be,” which weighs against adopting a claim construction that is limited to what follows the phrase. *See Glaxo Group LTD v. Teva Pharm. USA, Inc.*, 2009 WL 1220544, at *3 (D. Del. Apr. 30, 2009). Second, although the presence of the phrase “is referred to” is one factor that may indicate that the patentee acted as his own lexicographer, *see In re Imes*, 778 F.3d 1250, 1252–53 (Fed. Cir. 2015), *Linear Tech. Corp. v. Int’l Trade Comm’n*, 566 F.3d 1049, 1054 (Fed. Cir. 2009), here the phrase does not connect the term and its alleged definition. Rather, it connects the term with an intervening phrase, “[s]uch a small amount,” which, in turn, refers to the previous sentence containing Defendants’ proposed construction. Third, there are no quotation marks around “catalytic amount.” Although the absence of quotation marks around a supposedly defined term does not necessarily mean that the patentee did not act as his own lexicographer, it is one factor tending to show that the description is not definitional. *See France Telecom, S.A. v. Marvell Semiconductor, Inc.*, 2014 WL 1007449, at *4 (N.D. Cal. Mar. 12, 2014).

Analysis of Plaintiffs’ extrinsic evidence is unnecessary because the intrinsic evidence resolves the dispute. *See Vitronics Corp. v. Conceptoronic Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). Because I conclude that the specification does not define the term “catalytic amount,” I

construe the term as Plaintiffs propose, in accordance with the doctrine of claim differentiation. This construction does not introduce additional vagueness by failing to import a numerical limitation.

III. CONCLUSION

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