UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SEBELA INTERNATIONAL LIMITED, Plaintiff, -against- TARO PHARMACEUTICALS U.S.A., *et al.*, Defendants.	15cv3720 OPINION & ORDER

WILLIAM H. PAULEY, United States District Judge:

Sebela International Limited ("Sebela")[1] and Taro Pharmaceuticals U.S.A. et al., ("Taro") seek to construe a disputed claim in the underlying patents-in-suit. For the reasons that follow, Sebela's proposed construction is granted in part and denied in part, and Taro's proposed construction is denied.

BACKGROUND

This patent infringement action arises from Taro's attempt to manufacture and sell a generic version of the topical antifungal medication, NAFTIN 2% Gel ("Naftin"). Sebela owns the rights, title, and interest in two patents-in-suit related to Naftin. Both Naftin and its generic version contain naftifine, a synthetic agent proven to be highly "active" against various fungi. Naftin is commonly used to treat athlete's foot.

The two patents-in-suit—U.S. Patent 8,778,365 (the "365 Patent") and U.S. Patent 9,161,914 (the "914 Patent") (collectively, the "Patents")—are directed to topical

[1] Sebela replaced the original plaintiffs in this action—Merz Pharmaceuticals LLC, and Merz North America (together, "Merz")—after purchasing certain of Merz's assets, including the patents-in-suit, in November 2016. (See ECF No. 80.)

compositions containing naftifine. The Patents, both titled "Topical Compositions and Methods for Making and Using the Same," claim related inventions. The 365 Patent is directed to "gel composition[s] for topical administration" (i.e., applied to the skin of the patient) while the 914 Patent is directed to "method[s] of treating fungal infection in a patient in need thereof, comprising administering to the patient a gel composition" containing naftifine or a pharmaceutically acceptable salt of naftifine. (See Declaration of Tara C. Stuart, ECF No. 50, 365 Patent, Ex. 1; 914 Patent, Ex. 2, Parts 1 and 2.) The claimed compositions in both Patents have improved delivery of the active agent compared to prior art compositions, resulting in less frequent dosing, a shorter course of treatment, and reduced irritation when the topical gel is applied to the skin. (365 and 914 Patents, Col. 1, ll. 43–48.)

The parties' sole dispute for purposes of this claim construction proceeding boils down to the meaning of the term "about," as it is used in the phrase "about 0.17 wt % trolamine." That phrase is found in Claim 17 of the 365 Patent and Claim 21 of the 914 Patent, both of which state the following:

> The gel composition of Claim 1, consisting essentially of 2.0 wt % naftifine hydrochloride, about 20 wt % propylene glycol, about 19 wt % ethanol, about 5 wt % Polysorbate 20, about 1.75 wt % hydroxyethyl cellulose, about 1.0 wt % benzyl alcohol, **about 0.17 wt % trolamine**, about 0.02 wt % ethylenediaminetetracetic acid or a salt thereof, water, and optionally one or more of a coloring agent and a fragrance.

(365 Patent, Claim 17; 914 Patent, Claim 21 (emphasis added).) Both Claims 17 and 21 of the Patents depend from Claim 1, which describes a gel composition consisting of the following ingredients:

> (i) naftifine or a pharmaceutically acceptable salt thereof, present in an amount of from about 0.5 wt % to about 4 wt %;
> (ii) a first solvent which is a glycol solvent, present in an amount of from about 10 wt % to about 25 wt %;

> (iii) a second solvent which is an alkyl alcohol solvent, present in an amount of from about 10 wt % to about 25 wt %;
> (iv) a non-carbomer rheology modifier selected from hydroxyl cellulose, present in an amount of from about 0.75 wt % to about 2.25 wt %;
> (v) a polysorbate solubilizing agent present in an amount of from about 3 wt % to about 8 wt %;
> (vi) **a pH adjuster selected from an amine base**; and optionally one or more of: water, a preservative, a chelating agent, a coloring agent, and a fragrance,
>
> wherein the gel composition has a pH of about 4.5 to about 6.0.

(365 and 914 Patents, Claim 1 (emphasis added).) Trolamine is a "pH adjuster selected from an amine base."

The parties offer competing interpretations of the disputed claim term. On one hand, Sebela contends that "about 0.17 wt % trolamine" should be construed to mean "approximately 0.17 wt % trolamine," which includes at least 0.15 wt % trolamine. While Sebela does not believe the term should be defined by a numerical boundary, it proposes a variance of +/- 10% if one is required. (Sebela Opening Brief ("Sebela Opening Br."), ECF No. 49, at 11.) On the other hand, Taro construes the disputed claim more narrowly as: "0.17 wt % trolamine wherein the degree of variance is +/- 0.005 wt %." (Taro Opening Brief ("Taro Opening Br."), ECF No. 47, at 2.)

DISCUSSION

I. Standard

Claim construction is a matter of law decided by courts. Markman v. Westview Instruments, Inc., 517 U.S. 370, 384–85 (1996). Claim construction allows a determination to be made "whether the allegedly infringing product in fact infringes the patent, as construed, and/or whether the patent itself is valid." Loftex USA LLC v. Trident Ltd., 957 F. Supp. 2d 375, 377 (S.D.N.Y. 2013).

Claim terms are "generally given their ordinary and customary meaning," which is the meaning they would have to a person of ordinary skill in the art at the time of invention. Ortho–McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd., 476 F.3d 1321, 1326 (Fed. Cir. 2007). The disputed claim must be interpreted in a "manner consistent with the scientific and technical context in which it is used in the patent," unless the intrinsic record suggests that the inventor used a term with a special meaning. AFG Indus. Inc. v. Cardinal JG Co., 239 F.3d 1239, 1248 (Fed. Cir. 2001). "Absent intrinsic evidence to the contrary, imprecise terms are construed to have their ordinary meaning." Au New Haven, LLC v. YKK Corp., 2016 WL 6879263, at *6 (S.D.N.Y. Nov. 22, 2016).

In construing a claim, the court should look to the intrinsic evidence of record, which "includes the claims themselves, portions of the specification, drawings, and the prosecution history." AT&T Corp. v. Microsoft Corp., 2003 WL 21459573, at *2 (S.D.N.Y. June 24, 2003); Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). "The court must first review the words of the claims themselves, both asserted and nonasserted." Unigene Labs., Inc. v. Apotex Inc., 2008 WL 3992294, at *3 (S.D.N.Y. Aug. 28, 2008); AT&T, 2003 WL 21459573, at *2. If the answer is not clear from the text of the claim, "it is always necessary to review the specification[,] which acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Olaf Soot Design, LLC v. Daktronics, Inc., 220 F. Supp. 3d 458, 464 (S.D.N.Y. 2016); Markman, 52 F.3d 967, 979 (Fed. Cir. 1995) ("Claims must be read in view of the specification, of which they are a part."). The specification is "the single best guide to the meaning of a disputed term." Vitronics, 90 F.3d at 1582.

In addition to the claim and specification, a court may examine the "prosecution history of the patent, which contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims." Unigene Labs., 2008 WL 3992294, at *4. The patent applicant's statements "regarding the meaning of a claim term are relevant to the interpretation of that term in every claim of the patent absent a clear indication to the contrary." CVI/Beta Ventures, Inc. v. Tura LP, 112 F.3d 1146, 1155 (Fed. Cir. 1997).

Finally, consideration of extrinsic evidence is proper if the intrinsic evidence does not resolve the ambiguity in a disputed claim term. McNeil–PPC, Inc. v. Perrigo Co., 2007 WL 104513, at *3 (S.D.N.Y. Jan. 17, 2007); Vitronics, 90 F.3d at 1583. "The policy behind this limitation is that the patent, specification, and file history constitute the public record on which competitors are entitled to rely in ascertaining the scope of the patentee's claimed invention and designing around the claimed invention." Unigene Labs., 2008 WL 3992294, at *4 (internal alterations and citations omitted). Extrinsic evidence includes expert testimony, inventor testimony, dictionaries, and learned treatises. Unigene Labs., 2008 WL 3992294, at *4.

II. Analysis

A. Person of Ordinary Skill in the Art

As an initial matter, the "person of ordinary skill in the art" standard from which the disputed claim term should be assessed is a pharmaceutical scientist with experience in topical drug formulation. (See Sebela Responsive Br. at 1–2; Taro Opening Br. at 4.) While the parties propose varying qualifications, they both acknowledge that the most critical trait for purposes of this claim construction is that the person is a "scientist with some experience in topical drug formulation." (Claim Construction Transcript ("Tr.") at 9:22–23; see also Tr. at

37:23–38:1 (“Taro agrees that the differences in the definitions should not make a difference in how this particular claim term is construed and that both definitions of a person of ordinary skill in the art have a very high level of skill.”).)

B. Construing “About”

The question presented here is how a pharmaceutical scientist with experience in topical drug formulation would construe the term “about” in the phrase, “about 0.17 wt % trolamine,” The Federal Circuit has held that the term “about” avoids a “strict numerical boundary to the specified parameter” and that its range “must be interpreted in its technological and stylistic context.” Central Admixture Pharmacy Serv., Inc. v. Advanced Cardiac Solutions, P.C., 482 F.3d 1347, 1355–56 (Fed. Cir. 2007).

In this case, the patentee deliberately used—and chose not to use—the word “about” to qualify the values of certain ingredients. Claim 17 in the 365 Patent, for example, assigns a strict numerical value to one ingredient—2.0 wt % naftifine hydrochloride—while qualifying the values of all other ingredients with the word “about,” underscoring the patentee’s intent to impart some range in the use of that word. (365 Patent, Claim 17, Col. 78, ll. 34–35.) A person of ordinary skill in the art, in reviewing the deliberate use or non-use of the word “about,” would understand that ingredients whose weight percentages are qualified by the word “about” are not defined by a strict numerical limitation. See Unigene Labs., Inc. v. Apotext Inc., 2008 WL 3992294, at *6 (“The inventor’s selective use of distinct figures . . . leads to a conclusion that one of ordinary skill in the art would understand the inventor[ ] intended a range when [he] claimed one and something more precise when [he] did not.”). The word “about” must impart some range in order to “give meaning to all words in [the Patents’] claims.” Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 1557 (Fed. Cir. 1995); Merck & Co. v.

Teva Pharms. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all terms of the claim is preferred over one that does not do so.").

The Patents do not expressly define the word "about," and nothing in the claim or specification suggests that the word should be given anything other than its ordinary meaning of "approximately." Merck, 395 F.3d at 1369. Nor is there anything in the intrinsic evidence that reflects the patentee's intent to redefine "about" differently from its ordinary meaning. Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc., 214 F.3d 1302, 1307 (Fed. Cir. 2000) ("Absent an express intent to impart a novel meaning, claim terms take on their ordinary meaning."). Thus, the disputed claim term "about 0.17 wt % trolamine" may be read as "approximately 0.17 wt % trolamine."

C. Numerical Boundaries

Each of the parties offer constructions that contain a numerical range on the disputed claim term. Sebela contends that "about 0.17 wt % trolamine" should include 0.15 wt % trolamine and, if necessary, a 10% variance (resulting in an approximate range of 0.15 to 0.19 wt %).[2] Taro opposes that definition, claiming instead that "about" imparts a narrower variance of 0.005 wt % with a range of 0.165 wt % to 0.175 wt % trolamine.

To the extent that the claim term of "about 0.17 wt % trolamine" imparts a numeric range, that range must be narrow. Most of the ingredients in the claim are assigned a weight percentage value anywhere from a whole number to a tenth of a decimal. By contrast, trolamine is one of three elements that is quantified to a hundredth of a decimal. Thus, the "dichotomy between the specific [amount of trolamine] . . . and the broader [ ] ranges of the other claims points to a narrow scope" for the disputed claim term. Ortho-McNeil, 476 F.3d at

[2] The range is calculated as follows: 10% of 0.17, or 0.017, is subtracted from and added to 0.17, resulting in a range of 0.153 and 0.187. Rounding to the hundredth of a decimal, the range rounds to 0.15 to 0.19.

1328. In this regard, the patentee's attention to detail, and the deliberate and intentional "use of varying decimal places" suggests that it "expected a certain range of accuracy." Sta-Rite Indus., LLC. V. ITT Corp., 682 F. Supp. 2d 738, 746 (E.D. Tex. 2010).

However, both Sebela and Taro's proposed constructions miss the mark. Taro offers the narrower construction of the two, but adopting its proposal would vitiate the meaning of the word "about." Taro's proposed variance of +/- 0.005 wt % would create a range of 0.165 wt % and 0.175 wt %, essentially amounting to nothing more than "an extended range that numerically rounds to the claimed quantity." Sta-Rite Indus., 682 F. Supp. 2d at 745 (noting that a construction of 0.145 is "equivalent to 0.15 due to numerical rounding principles."). Because every measured value has an inherent range associated with it, a person of ordinary skill in the art would understand that it is "just basic scientific knowledge" to round a value up or down based on that range. (Declaration of Tara C. Stuart, ECF No. 56, Ex. 2, Deposition Transcript of Bozena Michniak-Kohn at 63:18–25.) Put another way, Taro's proposed variance is already built into the value of 0.17 wt % and does nothing to draw the boundaries added by the term "about."

Taro's proposed variance is derived from a section in the specification addressing pH adjusters. It states, in relevant part: "pH adjusters can be present in various numerical ranges and amounts, including 'from about 0.15 wt % to about 0.2 wt %; from about 0.16 wt % to about 0.19 wt %; from about 0.16 wt % to about 0.18 wt %; from about 0.165 wt % to about 0.175 wt %; about 0.16 wt %; about 0.17 wt %; or about 0.18 wt %." (Taro Opening Br. at 6–7 (citing 365 Patent and 914 Patent, Col. 13, ll. 49–64).) According to Taro, because some pH adjusters are quantified in distinct amounts rather than as ranges—e.g., those that have only "about 0.16

wt %; about 0.17 wt %; and about 0.18 wt %"—a person with ordinary skill in the art would understand that those amounts "would not overlap with one another." (Taro Opening Br. at 7.)

Taro's approach is flawed. First, the range resulting from Taro's variance—0.165 wt % to 0.175 wt %—already appears as one of the ranges expressly contemplated in that section. (See, e.g., 365 Patent, Col. 13, ll. 62–63.) Given that the range is already accounted for in the specification, applying this variance to the claim term "about 0.17 wt % trolamine" would render that portion redundant. Additionally, Taro's proposal actually introduces the overlap that it originally sought to eliminate in its variance. The upper boundary of the range—0.175 wt %—rounds up to 0.18 wt %, a distinct amount that is already (and separately) accounted for in the specification. Thus, Taro's variance would result in an overlap between 0.17 wt % and 0.18 wt %.

Moreover, in formulating its variance, Taro relies on a section that generally addresses weight percentage ranges of "pH adjusters," which includes trolamine but also applies to other pH adjusters like hydroxide or carbonate. (Patent 365, col. 13, ll. 37, 43.) It ignores a section of the specification that addresses weight percentage ranges of trolamine, which a person of ordinary skill in the art would likely consult, or accord greater weight, in the context of determining what range, if any, is imparted by the disputed term. More critically, that trolamine-specific section quantifies trolamine as a distinct amount only once—as "about 0.17 wt %"—while listing all other embodiments of the gel compositions in weight percent ranges. (See, e.g., 365 Patent, col. 13, ll. 20–36.) In the absence of any distinct amounts, save one, Taro's rationale supporting its proposed variance—i.e., to avoid overlap between distinct amounts—sheds any persuasive force.

Taro's other arguments fare no better. While the Patents' specifications list examples describing gel compositions containing exactly 0.17 wt % trolamine, they are just that, and do not describe the appropriate numeric range associated with the word "about." See Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988) ("What is patented is not restricted to the examples [in a specification], but is defined by the words in the claims if those claims are supported by the specification."). Indeed, if the examples using an exact amount of trolamine were dispositive of the issue, the word "about" would be meaningless.

For similar reasons, Taro's contention that the prosecution history underlying these Patents—wherein a gel formulation consisting of exactly 0.17 wt % trolamine prevailed over the examiner's prior rejections—somehow lends credence to its narrow construction of the claim term is not compelling. There is nothing in the file history suggesting that the precise weight percentage of trolamine was the defining feature in Sebela's ability to obtain an allowance of claims over the prior art. The Notice of Allowability merely states that "unexpected results . . . showed that the instant inventive formulation" comprising a number of ingredients, including 0.17 wt % trolamine, "provided a more [sic] clear gel whereas the formulations of closest prior art provided cloudy or solidified composition." (Declaration of Bozena Michniak-Kohn, Ph.D., ECF No. 48, Ex. D, 365 Patent File History, at TARO0033428–29.)

Sebela's construction also suffers from defects. As a threshold matter, it is arbitrary. Sebela includes 0.15 wt % in its construction of "about 0.17 wt % trolamine" on the basis that "a composition containing 0.15 wt % trolamine, like 0.17 wt % trolamine, would be expected to achieve a composition within the claimed pH range of 4.5 to about 6.0." (Pl. Expert Report, ¶ 32.) At first blush, tying trolamine to the prescribed pH range seems like a sensible

approach given that trolamine is a pH adjuster. But while 0.15 wt % trolamine may achieve a pH level that falls into the pH range prescribed by the claim, Sebela's approach overlooks the myriad possibilities that other weight percentages of trolamine—like 0.155 wt %, 0.16 wt %, or any figure between 0.15 wt % and 0.17 wt %—could achieve a pH level in the same range.

This 0.15 wt % amount becomes all the more arbitrary in view of Sebela's litigation objectives. Sebela's construction, if adopted, would ultimately capture Taro's proposed naftifine gel product. Offering a claim construction on this basis is improper. SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1118 (Fed. Cir. 1985) ("A claim is construed in light of the [intrinsic evidence] . . . not in light of the accused device.") (emphasis original); Ferring B.V. v. Barr Labs., Inc., 2005 WL 437981, at *13 (S.D.N.Y. Feb. 7, 2005) ("The claims of the patent cannot be construed in light of the accused product.").

Sebela further justifies the inclusion of 0.15 wt % based on its position that a +/- 10% variance is appropriate. Sebela manufactures that variance from the trolamine-specific section of the specification. (365 Patent, col. 13, ll. 25–34.) Several ranges of weight percentages quantifying trolamine are listed, varying between "about 0.12 wt % to about 0.23 wt % trolamine"; "about 0.14 wt % to about 0.21 wt %"; "about 0.15 wt % to about 0.20 wt %"; and "about 0.16 wt % to about 0.19 wt %." According to Sebela's expert, "these ranges generally decrease in size in approximate steps of 10%, which is the degree of variance [Sebela] propose[s] to modify the term 'about 0.17 wt % trolamine,' to the extent a numerical range is deemed appropriate." (Pl. Expert Report, at ¶ 37.) In other words, the lower boundaries of each range appear to increase by 10% while the upper bounds of each range appear to decrease by 10%.

But the math does not support Sebela's theory because the lower and upper boundaries in each successive range are not separated by 10%. The upward or downward

incremental movements actually vary from as low as roughly 5% to as high as roughly 15%. Take, for example, the percentage increase between the lower boundary of the first range, about 0.12 wt %, to a lower boundary of the next range, about 0.14 wt %, which is roughly 15% after rounding. (See Declaration of Daniel Bucks, Ph.D. ("Bucks Decl."), ECF No. 51, ¶ 38.) And a percentage decrease between the upper boundary of the first range, about 0.23 wt %, to the upper boundary of the next range, about 0.21 wt %, is roughly 9% after rounding. While Sebela's expert opines that "the increase in the lower bounds of ranges disclosed, and the decreases in the upper bounds disclosed are generally in increments of around 10%," the inconsistency between just the first and second ranges underscores the imprecision and arbitrariness associated with the Sebela's variance. (Bucks Decl., ¶ 38 (emphasis added).) Accordingly, this Court rejects Sebela's expert testimony on this issue because "the selection of a variation of +/- 10% . . . appears to be an unsupported opinion." Unigene Labs., 2008 WL 3992284, at *8.

D. Final Construction

While the intrinsic evidence suggests that the term "about" means "approximately," it says nothing about "what numerical range is meant" by that word. Shire LLC v. Sandoz Inc., 2012 WL 5494944, at *6 (D. Colo. Nov. 13, 2012); Biopolymer Eng'g Inc. v. Immuno Corp., 2007 WL 4562592, at *10 (D. Minn. Dec. 21, 2007). Nor is the extrinsic evidence particularly helpful in illuminating the boundaries inherent to the word "about."[3] The parties' expert reports merely recite their respective interpretations of the intrinsic evidence without citing to any other authority.

[3] That includes the parties' dueling letters detailing an intervening development regarding a separate patent application—the "232 Application"—which, while relevant extrinsic evidence, is ultimately not persuasive or dispositive of the issues here. In short, although the 232 Application is characterized as a continuation of the 914 Patent, Taro relies too heavily on the omission of trolamine in seeking to draw an inference against Sebela. Trolamine's omission as a distinct pH adjuster from the 232 Application does nothing to undermine Sebela's valid arguments in reading, analyzing, and interpreting patents here that have actually made such distinctions.

Thus, this Court gives the word "about" its ordinary meaning of "approximately," which at least one court has "defined as 'nearly correct or exact,' or 'located close together,'" without construing the claim term any further. Unigene Labs., 2008 WL 3992294, at *8–9; Biopolymer, 2007 WL 4562592, at *27–31. That definition—consistent with what this Court can glean from the intrinsic evidence—suggests a narrow construction. But while the claim is not as narrow as the construction advanced by Taro, it is certainly not as broad as Sebela's attempt to include 0.15 wt %.

At the claim construction hearing, Taro urged this Court to assign a numeric range to the claim term. (See, e.g., Tr. at 26:10–12.) While claims are "often drafted using terminology that is not as precise or specific," that "does not mean, however, that a court, under the rubric of claim construction, may give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product." PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1355 (Fed. Cir. 1998) (citations omitted). Rather, "after the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact." PPG Indus., 156 F.3d at 1355. Notably, a "sound claim construction need not always purge every shred of ambiguity." Acumed LLC v. Stryker Corp., 483 F.3d 800, 806 (Fed. Cir. 2007); see also Abbott Labs. v. Baxter Pharm. Prods., Inc., 471 F.3d 1363, 1368 (Fed. Cir. 2006) ("[W]e need not construe [the disputed] phrase with numerical exactitude."). "The resolution of some line-drawing problems . . . is properly left to the trier of fact." Stryker, 483 F.3d at 806.

CONCLUSION

Accordingly, because neither party offers specific evidence from which a numeric range could be inferred, this Court construes the claim term "about 0.17 wt % trolamine" in Claim 17 of the 365 Patent and Claim 21 of the 914 Patent to be "approximately 0.17 wt % trolamine."

Dated: September 19, 2017
New York, New York

SO ORDERED:

WILLIAM H. PAULEY III
U.S.D.J.