

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

VERTEX PHARMACEUTICALS  
INCORPORATED,

Plaintiff,

v.

LUPIN LIMITED and  
LUPIN PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. 22-966-RGA

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Before me is the issue of claim construction of one term in U.S. Patent No. 11,752,106 (“the ’106 patent”) (D.I. 86-1 at 2–110, Ex. A). Plaintiff Vertex Pharmaceuticals and Defendants Lupin Limited and Lupin Pharmaceuticals (collectively “Lupin”) submitted a Joint Claim Construction Brief. (D.I. 85). I heard oral argument on November 20, 2024. (D.I. 101). I have considered the briefing and oral argument.

### **I. BACKGROUND**

This case is part of a consolidated action for patent infringement under the Hatch-Waxman Act involving six of Vertex’s patents.<sup>1</sup> (D.I. 85 at 1, 5–6).

Vertex sells several drugs for the treatment of cystic fibrosis containing active ingredient ivacaftor.<sup>2</sup> (D.I. 85 at 5). One of these drugs is Kalydeco. (D.I. 85 at 5). Lupin submitted Abbreviated New Drug Application No. 217431 to the FDA, seeking approval to market a generic version of Vertex’s Kalydeco oral granules prior to the expiration of patents that cover Kalydeco and its use. (D.I. 1 at 1; D.I. 85 at 8). Vertex filed a complaint against Lupin for infringement of U.S. Patent Nos. 8,883,206 (“the ’206 patent”); 10,272,046 (“the ’046 patent”); 10,646,481 (“the ’481 patent”); and 11,147,770 (“the ’770 patent”). (D.I. 1 at 1). Lupin amended their ANDA to include Paragraph IV certifications for U.S. Patent Nos. 11,564,916 (“the ’916 patent”) and 11,752,106 (“the ’106 patent”). (D.I. 85 at 9). In response, Vertex filed two more complaints asserting patent infringement of the ’916 and ’106 patents. (D.I. 85 at 10); Complaint, *Vertex Pharms. Inc. v. Lupin Ltd.*, No. 23-cv-00583 (D. Del. May 26, 2023);

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<sup>1</sup> U.S. Patent Nos. 10,646,481 and 11,564,916 belong to the same patent family. The ’106 patent and U.S. Patent Nos. 8,883,206; 10,272,046; and 11,147,770 belong to another patent family. (D.I. 85 at 5–6).

<sup>2</sup> “Ivacaftor” refers to the same chemical as “Compound 1” in the ’106 patent. (See D.I. 85 at 7; ’106 patent at 190:39–47).

Complaint, *Vertex Pharms. Inc. v. Lupin Ltd.*, No. 24-cv-00458, (D. Del. Apr. 11, 2024). The three actions have been consolidated. (D.I. 85 at 9).

The pharmaceutical compositions claimed in the '106 patent comprise a solid dispersion that includes, along with other excipients, N-[2,4-bis(1,1-dimethylethyl)-5-hydroxyphenyl]-1,4-dihydro-4-oxoquinoline-3-carboxamide (“Compound 1” or “ivacaftor”); hydroxypropylmethylcellulose acetate succinate (“HPMCAS”); and sodium lauryl sulfate (“SLS”). (D.I. 85 at 7; '106 patent at 190:36–47). Three of the other asserted patents are members of the same patent family as the '106 patent. The other family members likewise address pharmaceutical compositions containing a solid dispersion of ivacaftor, including formulations of the solid dispersion into granules, pellets, particles, and mini-tablets. (D.I. 85 at 6). The '106 patent itself is directed to various “formulations of the solid dispersions,” “methods for manufacturing and processing,” and “methods for treating cystic fibrosis employing the pharmaceutical composition.” ('106 patent at 1:14–21). The priority date of the '106 patent appears to be February 27, 2012. ('106 patent at 1:7).

## II. 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) (alteration in original) (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 omitted). “While claim terms are understood in light of the specification, a claim construction must not import limitations from the specification into the claims.” *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1354 (Fed. Cir. 2012) (citing *Phillips*, 415 F.3d at 1323).

“[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.” *Phillips*, 415 F.3d 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 Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331 (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 (quoting *Markman*, 52 F.3d at 980). 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.*

### III. CONSTRUCTION OF DISPUTED TERMS

The parties agree that Claim 1 is representative for the purpose of claim construction.<sup>3</sup>

That claim states:

1. A pharmaceutical composition in a unit dose form comprising one or a plurality of granules, pellets, particles or mini-tablets, wherein the composition comprises:
  - (a) a solid dispersion in an amount from 30 to 40 percent by weight of the composition, wherein the solid dispersion comprises:
    - (i) ***about 80 wt % of substantially amorphous or amorphous N-[2,4-bis(1,1-dimethylethyl)-5-hydroxyphenyl]-1,4-dihydro-4-oxoquinoline-3-carboxamide (Compound 1) by weight of the dispersion,***
    - (ii) ***about 19.5 wt % of hydroxypropylmethylcellulose acetate succinate (HPMCAS) by weight of the dispersion, and***
    - (iii) ***about 0.5 wt % sodium lauryl sulfate (SLS) by weight of the dispersion;***
  - (b) a binary filler, wherein the binary filler comprises mannitol and lactose in a ratio of about 1:3 mannitol to lactose;
  - (c) a sweetener, wherein the sweetener is sucralose;
  - (d) a disintegrant;
  - (e) a glidant; and
  - (f) a lubricant;wherein the unit dose form comprises at least about 5 mg of substantially amorphous or amorphous Compound 1, and wherein substantially amorphous Compound 1 has less than 15% crystallinity.

(‘106 patent at 190:32–58 (disputed terms bolded and italicized)).

The only disputed term is the word “about.”<sup>4</sup>

1. *Plaintiff’s proposed construction:* No construction necessary.
2. *Defendant’s proposed construction:*

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<sup>3</sup> All other claims are dependent on claim 1. (‘106 patent at 190:59–192:24).

<sup>4</sup> The word “about” appears several other places in the claims, but the parties only dispute the meaning when it is describing the make-up of the solid dispersion. (D.I. 85 at 13–14).

- (a)(i) “79.5 wt % to 80.4 wt % of substantially amorphous or amorphous N-[2,4-bis(1,1-dimethylethyl)-5-hydroxyphenyl]-1,4-dihydro-4-oxoquinoline-3-carboxamide (Compound 1) by weight of the dispersion”
- (a)(ii) “19.45 wt % to 19.54 wt % of hydroxypropyl-methylcellulose acetate succinate (HPMCAS) by weight of the dispersion”
- (a)(iii) “0.45 wt% to 0.54 wt % sodium lauryl sulfate (SLS) by weight of the dispersion”

Alternatively, indefinite.

3. *Court’s construction*: no construction necessary; not indefinite.

The parties dispute whether the term “about” in these three instances should be constrained to encompass rounding principles, or whether it should have a broader meaning. The parties also dispute whether the claim becomes indefinite absent a construction employing rounding principles.

Defendants have the burden to prove indefiniteness by clear and convincing evidence. 35 U.S.C. § 282(a); *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 912 n.10 (2014) (citing *Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91, 95 (2011)). “A patent is invalid for indefiniteness if its claims, read in light of the specification . . . and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Id.* at 901. “Claim language employing terms of degree [i.e. ‘about’] has long been found definite where it provided enough certainty to one of skill in the art when read in context of the invention.” *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014); *see, e.g., Transcend Med., Inc. v. Glaukos Corp.*, 2015 WL 5546988, at \*8 (D. Del. Sept. 18, 2015) (“less than about 1 mm” not indefinite).

The ’106 patent’s specification and claims contain values expressed with relative precision despite uses of ranges and the word “about.” Defendants provide largely conclusory statements regarding indefiniteness. (D.I. 85 at 27–28, 43–44). Therefore, I find that Defendants

have not provided sufficient evidence to meet their burden to show that use of the term “about” renders the claims indefinite.

Plaintiff argues that “about” is “clear and readily understandable,” and therefore no construction is necessary. (D.I. 85 at 14). Though other courts have adopted “approximately” as the plain and ordinary meaning for “about,” Plaintiff argues it is unnecessary to define “about” with a synonym. (D.I. 85 at 15).

Plaintiff points out that Defendants do not seek construction of “about” for other occurrences of the term in the ’106 patent claims and did not seek construction of “about” in the claims of the other asserted patents. (D.I. 85 at 14). Plaintiff notes that the specification “repeatedly and consistently uses the word ‘about’ without reference to a specific parameter or particular range of values” and argues that courts have declined to constrain “about” to the rounding range without specific support in the intrinsic evidence. (D.I. 85 at 17). Plaintiff states, “There is no limiting or definitional language for ‘about’” and “[t]he specific ranges proposed by Lupin . . . do not appear anywhere in the specification.” (D.I. 85 at 18–19).

Plaintiff argues that, absent inclusion of the word “about,” the stated values would already encompass the rounding range. Accordingly, limiting “about” to the rounding range would read the term out of the claim language. (D.I. 101 at 11, 26; D.I. 85 at 17 (citing Order Regarding Claim Construction, *Lipocine Inc. v. Clarus Therapeutics, Inc.*, No. 19-cv-00622 (D. Del. Mar. 20, 2020), D.I. 119 at 44–45)).

Defendants argue that “about” must indicate rounding ranges because the ’106 patent uses the term “about” to identify quantities recited to varying degrees of precision and uses ranges of values when it means to indicate ranges. (D.I. 85 at 21–23; *see* D.I. 85 at 38–39). Defendants argue that the proposed ranges are the broadest possible ranges because broader

ranges “would run contrary to the patentee’s differentiation between whole numbers and fractions.” (D.I. 85 at 24).

Defendants argue that the prosecution history of U.S. Patent Application No. 12/583,066 (“the ’066 application”)—an abandoned application in a different patent family—is relevant evidence, because the publication for the ’066 application—U.S. Publication No. 2010/0074949 (“the ’949 publication”)—appears in the References Cited section of the ’106 patent. (D.I. 85 at 41; *see* D.I. 86-1 at 212 of 280, Ex. H; ’106 patent at p. 4). The ’949 publication also appears in the information disclosure statement (D.I. 86-1 at 260 of 280, Ex. I) and is incorporated by reference in the patent. (’106 patent at 48:52–58). Defendants contend that Plaintiff represented to the PTO during prosecution of the ’066 application “that the ‘specific’ excipients and ‘specific’ amounts of excipients and [active pharmaceutical ingredient] in the formulation distinguished it from the formulations of the prior art.” (D.I. 85 at 24–25; *see* D.I. 86-1 at 187–88 of 280, Ex. E). Therefore, Defendant argues that this surrendered claim scope should be relevant to claim construction in the ’106 patent, which discloses the same values preceded by the word “about.” (*See* D.I. 85 at 25).

I agree with Plaintiff’s position that the term “about” in these three instances requires no construction. It is also unnecessary for Plaintiff to use a synonym to define a simple word like “about” when it is used in its common sense as a term of approximation.

“Generally claim terms should be construed consistently with their ordinary and customary meanings, as determined by those of ordinary skill in the art.” *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1369–70, 1372 (Fed. Cir. 2005) (holding “about” should be given its ordinary meaning of “approximately”). The term “about” may be given its ordinary meaning when it is “not defined either explicitly or by implication by the specification.” *See*

*Ferring B.V. v. Watson Labs., Inc.-Fla*, 764 F.3d 1382, 1389 (Fed. Cir. 2014). “[T]he statement in the specification must have sufficient clarity to put one reasonably skilled in the art on notice that the inventor intended to redefine the claim term.” *Merck*, 395 F.3d at 1370.

Neither party here could point to a place in the specification that clearly defined “about” or disclaimed claim scope. (D.I. 101 at 8, 10–11, 22). The patent contains no explicit reference to a specific parameter or range of values that would constrain the meaning of “about” to rounding based on significant figures. Defendants make various arguments for a definition by implication based on the number of significant figures, trailing zeroes, and the ’106 patent’s use of value ranges elsewhere to support their contention that a rounding range is the only reasonable interpretation of “about.” (See D.I. 85 at 22–23, 38–40). But a POSITA could interpret “about” to mean different things. See, e.g., *Abbott Labs. v. Lupin Ltd.*, 753 F. Supp. 2d 382, 418, 420 (D. Del. 2010) (finding “about” to have different definitions based on context, including “within the range of scientifically acceptable error” and “to require consultation” of a professional standard). Absent clear intrinsic or extrinsic evidence to the contrary, I cannot find that a POSITA would interpret the plain and ordinary meaning of “about” to be the rounding range.

Intrinsic evidence includes “the patent itself” and its prosecution history. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citing *Markman*, 52 F.3d at 979). “An [information disclosure statement] is part of the prosecution history[.]” *Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1303 (Fed. Cir. 1997). The ’949 publication is intrinsic evidence as it appears on the face of the ’106 patent and in the information disclosure statement. See *V-Formation, Inc. v. Benetton Group SpA*, 401 F.3d 1307, 1311 (Fed. Cir. 2005) (noting that prior art references on the face of a patent are intrinsic evidence). But intrinsic evidence is not endlessly recursive like a never-ending Russian nesting doll. A statement to a patent examiner

during prosecution of the '066 patent application is intrinsic evidence to the '066 patent application and '949 publication, but intrinsic evidence from another patent family does not disclaim claim scope in the '106 patent. “[W]hile extrinsic evidence can shed useful light on the relevant art . . . it is less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Phillips*, 415 F.3d at 1317 (internal citation omitted).

Even if I take the statement to the patent examiner into account, “[t]he claim term ‘about’ cannot be eliminated by the prosecution history . . . [without] ‘a clear and unmistakable disavowal of scope during prosecution.” *Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1370 (Fed. Cir. 2008). “A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.” *Merck*, 395 F.3d at 1372.

When the applicant of the '066 patent application referred to “specific weight percentages of each of API and the excipients” and “specific amounts of that API and those excipients” required by the claims (D.I. 86-1 at 186 of 280, Ex. E), it appears the “specific weight percentages” are in fact the weight percentages recited in amended claims 147–156 and 182, which all include the word “about.” (D.I. 86-1 at 182–84 of 280, Ex. E). That is to say, “about 80 wt%,” “about 19.5 wt%,” and “0.5 wt %” are described by the applicant as “specific weight percentages of each of API and the excipients.” (D.I. 86-1 at 183–84, Ex. E).

Furthermore, unlike in the '481 and '916 patents, the term “about” does appear in the claims of the '106 patent. (See D.I. 86-1 at 175, Ex. C ('481 patent at 63:1–10); D.I. 86-2 at 45 of 46, Ex. J ('916 patent at 63:60–64:2); *c.f. Cohesive Techs.*, 543 F.3d at 1370 (noting that, despite prosecution history including statements of “30  $\mu$ m particles” without “about,” the term still appeared in the claims, suggesting no clear disavowal during prosecution). “[T]he deliberate

imprecision inherent in the word ‘about’ makes it impossible to ‘capture the essence’ of the claimed invention in strict numeric terms.” *Cohesive Techs.*, 543 F.3d at 1370 (citation omitted).

Therefore, I find that the term “about” in claim 1 is construed according to its plain and ordinary meaning and the term does not render the claims indefinite. I reject Lupin’s attempt to limit “about” to a rounding range.

#### **IV. CONCLUSION**

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