IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 22-615 (MN)
	)	
LUPIN LTD., LAURUS LABS LIMITED, AND CIPLA LIMITED,	)	
	)	
	)	
Defendants.		

MEMORANDUM ORDER

At Wilmington, this 21st day of February 2025:

The Court heard argument about the disputed claim terms of U.S. Patent Nos. 9,708,342 ("the '342 Patent"), 10,385,067 ("the '067 Patent"), and 10,548,846 ("the '846 Patent) on December 18, 2024. (D.I. 273). IT IS HEREBY ORDERED that the claim term of the '342 Patent and the '067 Patent with an agreed-upon construction is construed as follows (*see* D.I. 251 at 1):

1. "therapeutically effective amount" means "An amount of the claimed compound, which when administered to a patient in need thereof, is sufficient to effect treatment for disease-states, conditions, or disorders for which the compounds have utility" ('342 Patent, cls. 11; 12; '067 Patent, cls. 1, 10).

Further, as announced at the hearing on December 18, 2024, IT IS HEREBY ORDERED that the disputed claim terms of the '342 Patent, '067 Patent, and '846 Patent are construed as follows:

1. "about [5.5°, 16.1°, 23.3°] 2-θ ±0.2° 2-θ" means "within 0.2° 2-θ above or below the recited peak, as rounded to the nearest tenth of a degree (0.1°) 2- θ" ('342 Patent, cl. 3; '067 Patent, cls. 1, 10);
2. "A method for treating an HIV infection in a human in need thereof" means "a method for alleviating or eliminating symptoms of an HIV infection and/or reducing HIV viral load in a human in need thereof, which may yield a variety of clinical outcomes, depending on the patient" ('067 Patent, cls. 1, 10); and

3. "a multilayer tablet" means "a tablet with two or more layers in which at least one of the claimed components is in a separate layer, wherein a layer is a section or compartment of components" ('846 Patent, cl. 1).

The parties briefed the issues (D.I. 263) and submitted exhibits containing intrinsic and extrinsic evidence (D.I. 264; D.I. 265). The Court carefully reviewed all submissions in connection with the parties' contentions regarding the disputed claim terms, heard oral argument (D.I. 273), and applied the legal standards below in reaching its decision.

I. LEGAL STANDARDS

A. Claim Construction

"[T]he ultimate question of the proper construction of the patent [is] a question of law," although subsidiary fact-finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325 (2015). "[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 v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (internal citations and quotation marks omitted). Although "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim must also be considered. *Id.* at 1314. "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted).

The patent specification "is always highly relevant to the claim construction analysis . . . [as] it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at

1316. "Even when the specification describes only a single embodiment, [however,] the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence, . . . consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, courts "will need to look beyond the patent's intrinsic evidence and [] consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 574 U.S. at 331. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. Expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Phillips*, 415 F.3d at 1318. Nonetheless, courts must not lose sight of the fact that "expert reports

and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, although extrinsic evidence "may be useful to the court," it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

B. <u>Indefiniteness</u>

"The primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, e.g., competitors of the patent owner, can determine whether or not they infringe." *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28-29 (1997)). Put another way, "[a] patent holder should know what he owns, and the public should know what he does not." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002).

A patent claim is indefinite if, "viewed in light of the specification and prosecution history, [it fails to] inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). A claim may be indefinite if the patent does not convey with reasonable certainty how to measure a claimed feature. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). But "[i]f such an understanding of how to measure the claimed [feature] was within the scope of knowledge possessed by one of ordinary skill in the art, there is no requirement for the specification to identify

a particular measurement technique." *Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312, 1319 (Fed. Cir. 2015).

Like claim construction, definiteness is a question of law, but the Court must sometimes render factual findings based on extrinsic evidence to resolve the ultimate issue of definiteness. *See, e.g.*, *Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1376 (Fed. Cir. 2017); *see also Teva*, 574 U.S. at 334-36. "Any fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence." *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003); *see also Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008).

II. THE COURT'S RULING

The Court's ruling regarding the disputed claim terms of the '342 Patent, '067 Patent, and '846 Patent was announced during the *Markman* hearing on December 18, 2024, as follows:

> At issue, there are three disputed claim terms in three patents.[1] I am prepared to rule on the disputes. I will not be issuing a written opinion, but I will issue an order stating my rulings.
>
> I want to emphasize before I announce my decisions that although I am not issuing a written opinion, we have followed a full and thorough process before making the decisions I am about to state. I have reviewed the patents and all the evidence submitted by the parties. There was joint briefing on each of the disputed terms and we had argument today. All of that has been carefully considered.
>
> As to my rulings, I am not going to read into the record my understanding of claim construction law and indefiniteness. I have a legal standard section that I have included in earlier opinions, including somewhat recently in *REX Computing, Inc. v. Cerebras Systems, Inc.*, Civil Action No. 21-525 (MN). I incorporate that law and adopt it into my ruling today and will also set it out in the order that I issue.

[1] U.S. Patent Nos. 9,708,342, 10,385,067, and 10,548,846.

The first dispute is over the term "[about [5.5°, 16.1°, 23.3°] 2-θ ±0.2° 2-θ]."[2] The disagreement is whether the claim allows for rounding experimental XRPD peak positions to the tenth of a degree to get within the allowed range.[3] Plaintiff argues that the XRPD peak position values should be rounded to the tenth of a degree[4] and proposes construing the term as "[within 0.2° 2-θ above or below the recited peak, as rounded to the nearest tenth of a degree (0.1°) 2-θ]."[5] Defendants argue that no rounding should occur[6] and construe the term as "[within 0.2° 2-θ above or below [5.5°, 16.1°, 23.3°]]."[7] In the alternative, Defendants argue that the term is indefinite.

The crux of this dispute is whether, as Plaintiff argues, the word "about" in the claims applies to allow rounding to occur for the peak position values claimed[8] or, as Defendants posit, to the [±0.2° 2-θ] range, meaning no rounding allowed.[9]

I agree with Plaintiff on this construction. The word "about" immediately precedes the peak position values, indicating that the word is intended to note imprecision in those values. If, as Defendants argue,[10] "about," was meant to describe the recited "[±0.2° 2-θ]" range around the claimed peak positions, there is no dispute that the "plus or minu" portion of the claim would be rendered meaningless. The word "about" and the "plus or minus" have distinct functions in the context of the claim.

This construction is also supported by the specification which states that:

2 This term is found in claim 3 of the '342 Patent and claims 1 and 10 of the '067 Patent.

3 (D.I. 263 at 1-2).

4 (*Id.* at 2).

5 (*Id.* at 1).

6 (*Id.* at 11).

7 (*Id.* at 1).

8 (*Id.* at 15).

9 (D.I. 263 at 9).

10 (*Id.*).

> Those skilled in the art recognize that the measurements of the XRPD peak locations and/or intensity for a given crystalline form of the same compound will vary within a margin of error. The values of degree 28 allow appropriate error margins. Typically, the error margins are represented by "[±]." For example, the degree 28 of about "8.7[±]0.3" denotes a range from about 8.7[+]0.3, i.e., about 9.0, to about 8.7[-]0.3, i.e., about 8.4. Depending on the sample preparation techniques, the calibration techniques applied to the instruments, human operational variation, and etc, those skilled in the art recognize that the appropriate error of margins for a XRPD can be [±0.5; ±0.4; ±0.3; ±0.2; ±0.1; ±0.05]; or less. In certain embodiments of the invention, the XRPD margin of error is [±]0.2.[11]

I do not think that the reference to "about" in column 6, line 34 of the patent changes the analysis or suggests that other parts of the specification do not say what they clearly seem to say.[12]

As to Defendants' assertion that if I do not adopt their construction, the term is indefinite, Defendants have the burden of proving

[11] '342 Patent at 23:49-62. The specification thus applies the word "about" to the peak position values claimed, which includes the ± 0.2.

[12] Defendants supplied the specification's explanation that "[r]eference to 'about' a value or parameter herein includes (and describes) embodiments that are directed to that value or parameter per se. For example, description referring to 'about X' includes description of 'X.,'" ('067 Patent at 6:33-36), as support for their argument. (D.I. 273 at 11). However, this language does little more than make clear that X itself is included in a description "about X." During oral argument, (*id.*), Defendants further cited to Plaintiff's expert's statement that, "The '0.2° 2-θ' range is a commonly used standard of variability that permits skilled persons in the art of XRPD analyses to assess whether two peaks that appear to correspond to the same crystalline form but vary by a small amount are, in fact, the same peak." (D.I. 264-1, Ex. 2, Chyall Decl. at 11). This, too, is insufficient support for Defendants' argument that no rounding should be permitted. It ignores Dr. Chyall's subsequent statement that "[g]iven the uncertainty associated with XRPD peak positions that are measured on laboratory instruments, a skilled person would understand that it is not typically meaningful to consider comparisons of the observed positions of XRPD peaks at a level of precision greater than a tenth of a degree 2θ . . . a skilled person would understand that when reporting XRPD peak positions, the standard procedure is to round these peak positions to the nearest tenth of a degree 2θ, because that is the level of precision that corresponds to a meaningful comparison between experiments." (*Id.* at 12). Defendants did not provide expert rebuttal or opinion for this term.

indefiniteness by clear and convincing evidence. Here, Defendants have not met that burden. I am not going to address the waiver issue that was raised briefly today because I just don't have enough information.

And with that, I will adopt Plaintiff's proposal and construe "about [[5.5°, 16.1°, 23.3°] 2-θ ±0.2° 2-θ]" as "within [0.2° 2-θ above or below the recited peak, as rounded to the nearest tenth of a degree (0.1°) 2- θ]."

The second term is "A method for treating an HIV infection in a human in need thereof"[13] in the preamble. During the hearing, some of the parties came to an agreement on the meaning of this term, which I read into the record. [On December 19, 2024, remaining Defendant, Lupin Ltd., confirmed acceptance of the construction agreed upon during the hearing. (D.I. 272). Thus, the term "a method for treating an HIV infection in a human in need thereof" will be construed by agreement as "a method for alleviating or eliminating symptoms of an HIV infection and/or reducing HIV viral load in a human in need thereof, which may yield a variety of clinical outcomes, depending on the patient." (D.I. 273 at 21).]

The third and final disputed term is "a multilayer tablet."[14] The parties agree that the preamble is limiting. Plaintiff's proposed construction is "a tablet with two or more layers, in which at least one of the claimed components is in a separate layer, wherein a layer is a section or compartment of components."[15] Defendants offer the construction "at least a bilayer tablet in which at least one of the claimed components is in one of the separate layers of the at least a bilayer tablet."[16]

I agree with Plaintiff's construction of this term. Plaintiff disagrees with Defendants' use of "bilayer" in their proposed construction.[17] This is because "bilayer" in the context of the patent is a specific embodiment described in the specification as a two-layer tablet in which the first and second layers are ordered and oriented in a

13 This term appears in claims 1 and 10 of the '067 Patent.

14 This term is found in claim 1 of the '846 Patent.

15 (D.I. 263 at 47).

16 (*Id.*).

17 (*Id.* at 51).

horizontal, striped fashion.[18] Because a "bilayer tablet" has a defined meaning within the patent, including the term in this construction would unduly narrow the claim scope.

Defendants focus on the meaning of "layer" and offer their expert's declaration that, within the context of tablet formulation techniques, a layer must be at least a continuous mass, "one thickness course or fold," lying over another continuous mass and containing at least one of the claimed components.[19] Defendants' expert's understanding, however, is not more instructive than the patent itself, which refers to "layer" as "a section or compartment."[20]

[The specification, however,] says: "Unless otherwise specified, the terms 'first layer,' 'second layer,' 'third layer' and so forth do not specify a particular order or orientation of the multilayer tablet formulations disclosed herein. Rather, these terms are used to distinguish the sections of the composition from each other and to specify the characteristics or components of each section or compartment."[21]

Ultimately, I think Defendants' proposed construction introduces unnecessary confusion, and I think that Plaintiff's construction is more consistent with the specification. Thus, I will construe "a multilayer tablet" as "a tablet with two or more layers in which at least one of the claimed components is in a separate layer, wherein a layer is a section or compartment of components." And I will

18 *See, e.g.,* '846 Patent at 58:10-60; 67:41-62.

19 (D.I. 265-1, Ex. 13, Muzzio Decl. ¶¶ 31–32, 65–66, 70). To further substantiate their argument and construction, Defendants assert that the prosecution history informs that the bilayer tablet configuration was the primary reason for the examiner's decision to allow the claims. (D.I. 263 at 61). Even if this were true, it would not provide adequate support for narrowing the formulation technique to a bilayer formulation, which is mentioned by the patent only as a "certain embodiment." *See, e.g.*, '846 Patent at 50:14-18.

20 '846 Patent at 12:12-18.

21 Defendants' definition of "layer" as being "at least a continuous mass" lying over another continuous mass is inconsistent with the intrinsic evidence. The specification contemplates configurations in which "the additional layer or layers are located on either side of the first and/or second layer, such that they are an outside layer of the table[t] and/or are disposed between the first and/or second layer and a coating layer. [And,] [i]n some embodiments, the additional layer or layers encapsulate the first and second layers" as types of multilayer tablets. ('846 Patent at 32:57-62). These configurations would not comport with Defendants' idea of a layer simply being one mass lying on top of another.

reserve for trial the issue of whether any particular configuration meets this limitation.

The Honorable Maryellen Noreika
United States District Judge