IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION, Plaintiff, v. LIQUIDIA TECHNOLOGIES, INC. Defendant.	Civil Action No. 23-975-RGA

MEMORANDUM OPINION

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/s/ Richard G. Andrews
ANDREWS, U.S. DISTRICT JUDGE:

Before me is the issue of claim construction of multiple terms in U.S. Patent No. 11,826,327 ("the '327 patent"). The parties submitted a Joint Claim Construction Brief (D.I. 123) and Appendix (D.I. 124-1). I heard oral argument on September 30, 2024. (Markman Tr.).[1] I received three additional letters after the argument. (D.I. 133; D.I. 134; D.I. 139). I have considered all briefing.

I. BACKGROUND

Plaintiff United Therapeutics Corporation ("UTC") filed a complaint against Defendant Liquidia Technologies ("Liquidia"). (D.I. 1). Plaintiff amended its complaint, alleging infringement of the '327 patent in addition to another patent[2] not currently at issue. (D.I. 8 at 1).[3]

UTC sells products for the treatment of pulmonary hypertension ("PH"), including TYVASO DPI (a dry powder inhaler). (D.I. 26 at 2). In 2009, the FDA approved TYVASO for the treatment of pulmonary arterial hypertension ("PAH"). (*Id.*; *see also* D.I. 52 at 2). In 2021, following a clinical trial named INCREASE, the FDA approved TYVASO for an additional indication: the treatment of pulmonary hypertension associated with interstitial lung disease ("PH-ILD"). (D.I. 26 at 2; *see also* D.I. 52 at 2–3).

[1] Citations to the transcript of the argument, which is not yet docketed, are in the format "Markman Tr. at ___."

[2] U.S. Patent 10,716,793 was invalidated by the PTAB. The PTAB's decision was affirmed by the Federal Circuit on December 20, 2023. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 2023-1805, 2023 WL 8794633 (Fed. Cir. Dec. 20, 2023), *cert. denied*, No. 23-1298, 2024 WL 4427544 (U.S. Oct. 7, 2024).

[3] The FDA initially granted UTC exclusivity through March 31, 2024. (D.I. 26 at 2). In 2022, the FDA approved TYVASO DPI for the treatment of both PAH and PH-ILD. (*Id.*). The FDA recently granted an extension of this exclusivity for the dry powder inhaler through May 2025. (Markman Tr. at 4). Defendant is challenging this extension in the District Court for the District of Columbia, with arguments to occur in December 2024. (*Id.*).

Following the INCREASE clinical trial, the USPTO issued the '327 patent. (D.I. 123 at 1). The '327 patent, entitled "Treatment for Interstitial Lung Disease," "generally relates to methods of treating a disease with prostacyclins and more particularly, to treating a disease with treprostinil." ('327 patent at 1:1–17).

Defendant filed a New Drug Application seeking FDA approval to market a dry powder, treprostinil-based product named YUTREPIA for the PAH indication. (D.I. 26 at 3). In 2023, Defendant amended its application to add a PH-ILD indication. (*Id*.).

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) (cleaned up). "'[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 (cleaned up). "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.' . . . [It 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 omitted). "[T]he 'ordinary meaning' of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id*. at 1321. "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 on 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 AGREED-UPON TERMS

I adopt the following agreed-upon constructions. (D.I. 123 at 5):

Claim Term	**Claims**	**Construction**
"A method of improving exercise capacity in a patient having pulmonary hypertension associated with interstitial lung disease"	'327 patent, Claim 1	This preamble is limiting

IV. CONSTRUCTION OF DISPUTED TERMS

The parties agree that Claims 1, 2, 11, and 14 of the '327 patent are representative for the purpose of claim construction. Those claims state:

> 1. A method of improving exercise capacity in ***a*** patient having pulmonary hypertension associated with interstitial lung disease, comprising administering by inhalation to ***the*** patient having pulmonary hypertension associated with interstitial lung disease an effective amount of at least 15 micrograms up to ***a maximum tolerated dose*** of treprostinil or a pharmaceutically acceptable salt thereof in ***a*** single administration event that comprises at least 6 micrograms per breath.

('327 patent at 54:6–14 (disputed terms bolded and italicized)).

> 2. The method of claim 1, wherein said administering provides a statistically significant increase of a 6 minutes walk distance in ***the*** patient after 8 weeks, 12 weeks, or 16 weeks of ***the*** administering.

('327 patent at 54:15–18 (disputed terms bolded and italicized)).

> 11. The method of claim 1, wherein said administering is performed by a ***pulsed inhalation device***.

('327 patent at 54:50–51 (disputed terms bolded and italicized)).

> 14. The method of claim 11, wherein the ***pulsed inhalation device*** is a dry powder inhaler comprising a dry powder comprising treprostinil or a pharmaceutically acceptable salt thereof.

('327 patent at 54:57–60 (disputed terms bolded and italicized)).

A. "a"/"the" in the following terms: "a patient," "the patient," "a maximum tolerated dose," "a single administration event," "the administering," and "the single inhalation administration event" (claims 1–5, 8–10, and 15–19)

1. *Plaintiff's proposed construction*: no construction required/plain and ordinary meaning; i.e., one or more unless context clearly dictates otherwise
2. *Defendant's proposed construction*: one and more than one
3. *Court's construction*: one or more

At the hearing on September 30, 2024, I ruled from the bench in favor of Plaintiff's construction. I asked the parties for supplemental letters, however, specifying the meaning of

each disputed "a," "an," or "the," thus fixing the meaning in each "context." (Markman Tr. at 22).

Plaintiff suggests that every disputed "a" and "the" means "one or more." (D.I. 139 at 2). Defendant notes that Claims 2, 4, 6, 7, 8, 9, and 10 "require achieving a 'statistically significant' increase, reduction, or improvement in a specified outcome." (D.I. 134 at 1); *see* '327 patent at 54:5–55:10. Defendant argues, "[C]laims requiring a 'statistically significant' outcome cannot be met by treating a single patient." (D.I. 134 at 1).

Though I agree that finding statistical significance requires data from multiple patients, each individual administration and increase, reduction, or improvement involves a single patient. Therefore, I find that "one or more" is the most appropriate construction for each instance of "a" and "the" at issue. The dispute concerning statistical significance is better left for argument about infringement.

B. "maximum tolerated dose" (Claim 1)

1. *Plaintiff's proposed construction*: not indefinite; plain and ordinary meaning, i.e., the highest dose that does not cause unacceptable adverse events
2. *Defendant's proposed construction*: indefinite; if not indefinite, the highest dose before a patient discontinues administration
3. *Court's construction*: not indefinite; plain and ordinary meaning

At the hearing on September 30, 2024, I found that Defendant had not proven by clear and convincing evidence that the term "maximum tolerated dose" was indefinite. (Markman Tr. at 31). I also ruled that no construction of the term was necessary. (*Id*.).

C. "pulsed inhalation device" (Claims 11 and 14)[4]

1. *Plaintiff's proposed construction*: a device that provides for non-continuous inhaled drug delivery
2. *Defendant's proposed construction*: a device that provides the force for non-continuous inhaled drug delivery
3. *Court's construction*: a device that provides for non-continuous inhaled drug delivery

The parties agree that a pulsed inhalation device provides non-continuous inhaled drug delivery. The parties dispute whether a pulsed inhalation device may be breath-powered or whether the device must provide the force for medication delivery.

Plaintiff argues that Defendant's construction conflicts with the '327 patent specification. Specifically, requiring a "force" limitation would exclude embodiments identified in the patent. (D.I. 123 at 41). Plaintiff points out that the patent states a pulsed inhalation device "may be a dry powder inhaler." (D.I. 123 at 42; '327 patent at 21:6–7). Plaintiff also contends that WO2019/237028 ("Guarneri"), a breath-powered dry powder inhaler, is "incorporated . . . by reference in its entirety." (D.I. 123 at 42; '327 patent at 21:11–14). Similarly, Plaintiff contends that the patent incorporates by reference WO2017/192993 ("Roscigno"), the breath-powered inhaler used by Defendant's accused YUTREPIA product, and depicts a breath-powered dry powder inhaler at Figure 11. (D.I. 123 at 43–44; '327 patent at 15:5–9; 5:66–67). Therefore, Plaintiff argues that requiring a "force" limitation external to a patient's breath "would be inconsistent with the intrinsic evidence." (D.I. 123 at 44–45).

In response to the '327 patent's disclosure of dry powder inhalers—Guarneri and Roscigno—Defendant argues these are not incorporated as pulsed inhalation devices. (*Id*. at 50). Instead, Defendant contends that the patent incorporates Guarneri and Roscigno merely for "dry

[4] The term appears in three claims. The third one, Claim 12, is not asserted. (Markman Tr. at 68).

powder inhalers" and "powder compositions." (Markman Tr. at 47; *compare* '327 patent at 20:51–53 ("[p]ulsed inhalation devices are disclosed"), *with* '327 patent at 21:11–13 ("a dry powder inhaler and a dry powder composition or formulation comprising treprostinil are disclosed")). As Defendant noted at oral argument, "Claim 1 is not limited to a pulsed inhalation device." (Markman Tr. at 48).

Courts "normally do not interpret claim terms in a way that excludes disclosed examples in the specification." *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1305 (Fed. Cir. 2007). The patent discloses metered dose inhalers and nebulizers as examples of pulsed inhalation devices. ('327 patent at 20:51–57). But the patent also states, "In some embodiments, the inhalation device, such as a pulsed inhalation device, may be a dry powder inhaler[.]" ('327 patent at 21:6–7). In the next sentence, the patent discloses Guarneri as "a dry powder inhaler and a dry powder composition or formulation comprising treprostinil." ('327 patent at 21:11–14).

Though I recognize that the language introducing these different inhalation devices is not identical, I do not agree with Defendant's interpretation. Instead, the language of column 21 suggests that Guarneri is an example of a dry powder inhaler, which is an example of a pulsed inhalation device, which is a type of inhalation device. Furthermore, Defendant's expert during preliminary injunction proceedings had never encountered a device that was both a dry powder inhaler and a pulsed inhalation device according to Liquidia's definition. (D.I. 124-1, Ex. 23 at p. 173 (internal page numbering)). Defendant's interpretation of the claim term would leave no example in the specification of a dry powder inhaler that is a pulsed inhalation device. Nor could Plaintiff likely have included one because that device does not exist.

Defendant notes several embodiments described in the '327 patent as "pulsed inhalation devices" that disclose a pulsed nebulizer. (D.I. 123 at 47). A nebulizer "produces a force for non-continuous inhaled drug delivery." (*Id*.). Plaintiff responds that none of these references equates "pulsed" with being self-powered and "pulsed" could be read as non-continuous. (D.I. 123 at 52).

"Even when the specification describes only a single embodiment, 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." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (cleaned up). Though a pulsed nebulizer may be a "pulsed inhalation device," it is only one example of a pulsed inhalation device. The specification discloses metered dose inhalers and dry powder inhalers as other examples of pulsed inhalation devices. ('327 patent at 20:51–53; 21:6–7).

Defendant claims that its construction aligns with the plain and ordinary meaning of the term as a POSA would understand it. (D.I. 123 at 47). Defendant cites a dictionary definition of the word "pulse," defined as "3a: to produce or modulate (something, such as electronic waves) in the form of pulses" or "b: to cause (an apparatus) to produce pulses[.]" (D.I. 124-1 at 282 of 903; *see* D.I. 123 at 47). Defendant also cites PAH literature disclosing externally powered pulsed inhalation devices. (D.I. 123 at 48).

Plaintiff argues, however, that nothing in the intrinsic evidence suggests a "force" requirement, and "the term 'force' is never used in the '327 patent with respect to the disputed term." (D.I. 123 at 45; *see generally* '327 patent).

"Extrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence."

Phillips v. AWH Corp., 415 F.3d 1303, 1319 (Fed. Cir. 2005) (en banc). "Extrinsic evidence is to be used for the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 981 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). "As a general proposition, a limitation that does not exist in a claim should not be read into that claim." *Biovail Corp. Int'l v. Andrx Pharms., Inc.*, 239 F.3d 1297, 1301.

Defendant relies primarily on extrinsic evidence in support of its proposed "force" limitation. Though metered dose inhalers and nebulizers, as disclosed in the patent, do provide external force, these are examples. I agree with Plaintiff that nowhere in the specification or claims does external force appear as an explicit requirement. Claim 14 indicates that at least some dry powder inhalers are pulsed inhalation devices, but no dry powder inhaler in the specification is externally powered. ('327 patent at 54:57–58). A "force" limitation that is absent from the claims and specification should not be read into Claims 11 and 14.

Defendant argues that "pulsed" is not synonymous with "non-continuous." (D.I. 123 at 48–49). Defendant argues that Plaintiff's construction would make all drug inhalation devices, continuous or non-continuous, into "pulsed inhalation devices" if all that is required for delivery of the "pulse" is force from a patient's breath. (*Id*. at 49). Defendant argues that Plaintiff's construction, therefore, renders the word "pulsed" in "pulsed inhalation device" superfluous. (*Id*.). Plaintiff denies this, noting that its expert testified that "pulsed inhalation devices are those that are 'not continuous' and that '[the drug] comes out in one pulse.'" (*Id*. at 56; D.I. 124-1 at 419 of 903). Plaintiff explained at oral argument, "[P]ulsed inhalation just means it delivers a bolus." (Markman Tr. at 60). Both parties agree that dry powder inhalers provide discrete dosages of medication, for example, as a pill or a cartridge. (Markman Tr. at 63–65).

"A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so." *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005). I disagree, however, that Plaintiff's construction renders the term "pulsed" superfluous. An inhalation device that delivers medication continuously through a cannula could appropriately be termed "continuous" or non-pulsed. By contrast, though a dry powder inhaler could deliver medication via the breath of a patient, the delivery is not continuous. Whether the patient is instructed to breathe once or three times, there is a distinct administration of a "bolus" or "pulse" of medication. It follows that "pulsed" differentiates these inhalation devices from continuous inhalation devices and is not superfluous, even if the "pulse" is actuated by a patient's breath. I therefore adopt a construction that encompasses non-continuous administration, but it does not include an external force limitation.

V. CONCLUSION

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