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

Michael J. Flynn, MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE; William C. Jackson, Katherine Cheng, Eric Levi, GOODWIN PROCTER LLP, Washington, DC; Eric T. Romeo, Louis L. Lobel, GOODWIN PROCTER LLP, Boston, MA; Adam Horowitz, GOODWIN PROCTER LLP, New York, NY; Douglas H. Carsten, Art Dykhuis, Katherine Pappas, MCDERMOTT WILL & EMERY LLP, San Diego CA; Adam W. Burrowbridge, Courtney Seams, Lillian Spetrino, MCDERMOTT WILL & EMERY LLP, Washington, DC; Kyle Sorenson, MCDERMOTT WILL & EMERY LLP, Austin, TX;

Attorneys for Plaintiff.

Karen E. Keller, Nathan R. Hoeschen, SHAW KELLER LLP, Wilmington, DE; Sanya Sukduang, Jonathan Davies, Adam Pivovar, Phillip E. Morton, Rachel Preston, John A. Habibi, Rosalynd D. Upton, COOLEY LLP, Washington, DC; Daniel Knauss, Lauren Strosnick, Kyung Taeck Minn, COOLEY LLP, Palo Alto, CA; Thomas Touchie, COOLEY LLP, New York, NY; Annie Beveridge, COOLEY LLP, San Diego, CA,

Attorneys for Defendant.

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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. 11,826,327 ("the '327 patent"). I held a pre-trial conference on May 30, 2025. At this conference, it became apparent that there was a claim construction issue to resolve before a trial beginning on June 23, 2025. I have considered the parties' letters. (D.I. 374, 375, 378, 379).

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[1] not currently at issue. (D.I. 8 at 1).

In 2009, the FDA approved UTC's drug, TYVASO, for the treatment of pulmonary arterial hypertension ("PAH"). (*Id.* at 4). 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).

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).

In 2020, 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.*).

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[1] 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.*, 2023 WL 8794633 (Fed. Cir. Dec. 20, 2023), *cert. denied*, 145 S. Ct. 352 (2024).

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." *Id.* 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 TERM

The disputed term appears in claim 1. Claims 2 through 19 depend from claim 1. I previously construed the preamble as limiting, as agreed to by the parties. (D.I. 149 at 4; D.I. 155). Claim 1 reads:

> 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, 54:6–14 (disputed term bolded and italicized)).

"pulmonary hypertension associated with interstitial lung disease" (claim 1)

> *Plaintiff's proposed construction*: plain and ordinary meaning, or "pulmonary hypertension due to a patient's interstitial lung disease"

Defendant's proposed construction: "pulmonary hypertension and interstitial lung disease"
Court's construction: "pulmonary hypertension due, at least in part, to a patient's interstitial lung disease"

For a patient having "pulmonary hypertension associated with interstitial lung disease," the parties dispute whether the interstitial lung disease ("ILD") must be the cause of that patient's pulmonary hypertension ("PH"), or whether the two conditions must merely be "concomitant." (*See* D.I. 380 at 32–35).[2]

A. Claim Language

Defendant argues that the plain language of "associated with" in claim 1 only requires a patient to have both pulmonary hypertension and interstitial lung disease. (D.I. 374 at 3). Defendant argues that nothing in the claims supports a requirement of causation, severity, or relative proportionality concerning either disease component of PH-ILD. (*Id.* at 4). Plaintiff argues that a POSA would understand the claim language "associated with" to "require a relationship between the patient's PH and ILD." (D.I. 375 at 1). Plaintiff argues that Defendant's proposed construction of "and" does not capture this relationship and that the conditions must be more than "concomitant." (*Id.* at 1–2).

B. Specification

Defendant argues that the patent specification contains no support for a requirement of a causal relationship between PH and ILD. (D.I. 374 at 5). Defendant notes that the specification includes both phrases "associated with interstitial lung disease" and "due to interstitial lung disease." (*Id.* at 4; *see, e.g.*, '327 patent at 1:48–53, 13: 11–13, 27:7–8). Defendant argues that

[2] I asked the parties to submit letters on claim construction. (D.I. 380 at 36–37 of 99). I address that issue and do not address Liquidia's non-infringement arguments (D.I. 374 at 12–14) or UTC's contention that Liquidia is bound by the position it stated in its pleadings (D.I. 375 at 7).

the '327 patent's use of different language indicates that the phrases have different meanings. Accordingly, Defendant argues that "associated with" in claim 1 cannot be synonymous with "due to." (D.I. 374 at 4–5). Defendant also contends that INCREASE study, as described in Example 3, simply required that patients had both conditions. (*Id.* at 5; '327 patent at 26:38–41).

Plaintiff counters that the specification contains no "reference or example where PH associated with ILD involves the PH and the ILD being merely 'concomitant' with one another, without any causal link." (D.I. 375 at 4). Plaintiff argues that the specification describes the claimed invention as "treating [pulmonary hypertension] that is due to chronic lung disease, including ILD." (*Id.* at 2). Plaintiff points to the title of the INCREASE study: "Inhaled Treprostinil in Pulmonary Hypertension Due to Interstitial Lung Disease." (*Id.* (citing '327 patent at 26:28–29)). Plaintiff notes that the specification incorporates the Simonneau 2019[3] reference in its entirety. (*Id.*; '327 patent at 27:11–16, 45:23). Plaintiff argues that Simonneau 2019 "provides updates to the WHO clinical classifications of pulmonary hypertension" and "expressly classifies group 3 pulmonary hypertension as pulmonary hypertension due to" lung diseases or hypoxia. (D.I. 375 at 2–3). The specification provides ILD as an example of "chronic lung disease." ('327 patent at 2:9). Plaintiff argues that the "express incorporation of Simonneau 2019 . . . makes clear that claim 1's reference to 'pulmonary hypertension associated with interstitial lung disease' involves PH that is due to ILD." (D.I. 375 at 3–4).

Defendant agrees that the WHO classification and Simonneau 2019 use "due to." (D.I. 378 at 2). However, Defendant counters that neither equates "due to" and "associated with" when defining PH-ILD, and Plaintiff chose not to use the term "due to" in the claims. Defendant

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[3] Gérald Simonneau, et al., *Haemodynamic Definitions and Updated Clinical Classification of Pulmonary Hypertension*, 53 Eur. Respiratory J. 1801913 (2019) [http://doi.org/10.1183/13993003.01913-2018]. (D.I. 375-1 at 61–73 of 166, Ex. 3).

argues, therefore, that neither the WHO classification nor Simonneau 2019 can "provide the definition of 'pulmonary hypertension associated with interstitial lung disease.'" (*Id.*).

C. Prosecution History

Defendant argues that the original claim 1 included the "due to" language and Plaintiff amended it to "associated with" to overcome rejections by the PTO. (D.I. 374 at 6). The original as-filed claims 1, 3 and 4 read:

> 1. A method of treating a pulmonary hypertension due to a condition which is selected from a chronic lung disease, hypoxia and a combination thereof, comprising administering to a subject having the pulmonary hypertension due to the condition selected from a chronic lung disease, hypoxia and a combination thereof an effective amount of treprostinil, a prodrug thereof or a pharmaceutically acceptable salt thereof.
>
> 3. The method of claim 1, wherein the chronic lung disease comprises chronic obstructive pulmonary disease, emphysema, interstitial lung disease, pulmonary fibrosis and a combination thereof.
>
> 4. The method of claim 1, wherein the pulmonary hypertension is pulmonary hypertension associated with interstitial lung disease.

(D.I. 374-2 at 79 of 112, Ex. 2).

The PTO rejected all pending claims as anticipated by prior art references, stating that the prior art "discloses methods for treating pulmonary hypertension due to a condition which is selected from a chronic lung disease, hypoxia and a combination thereof with treprostinil." (D.I. 374-2 at 100–02 of 112, Ex. 2). In response, Plaintiff amended claim 1 in several ways, including changing the language describing the patient's condition to "pulmonary hypertension associated with interstitial lung disease." (D.I. 374-2 at 105 of 112, Ex. 2). Plaintiff also canceled claims 3 and 4. (*Id.*).

Defendant argues that, because Plaintiff "both deleted the 'due to' language and relied on its amended 'associated with' limitation to distinguish prior art during prosecution,"[4] Plaintiff cannot "recapture the 'due to' claim language it gave up during prosecution." (D.I. 374 at 8; D.I. 378 at 1).

Plaintiff notes that original claim 4 included the language "associated with interstitial lung disease," and original claim 4 was a dependent claim of original claim 1, which contained the language "due to . . . chronic lung disease." (D.I. 375 at 4). Because original claim 4 was a dependent claim, Plaintiff argues that the scope of original claim 4 was narrower than original claim 1. (D.I. 379 at 1). Accordingly, Plaintiff contends that the inventors considered pulmonary hypertension "associated with" ILD to be a "subset" of pulmonary hypertension "due to . . . chronic lung disease." (D.I. 375 at 4). Plaintiff argues that a POSA would understand the amendment to claim 1—which takes the "associated with" language from original claim 4—to retain the "due to" requirement of original claim 1. (D.I. 379 at 2).

Plaintiff denies that it relinquished or disclaimed the "due to" requirement because it "distinguished the prior art using other limitations."[5] (*Id.*). Plaintiff argues that nothing in its arguments to the PTO "read out the causation requirement." (*Id.*).

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[4] Defendant contends that "UTC argued that the Morgans, Wang, and Bosc prior art references did not anticipate because they do not teach the 'associated with interstitial lung disease' term in amended claim 1." (D.I. 374 at 8).

It is true that "associated with interstitial lung disease" is underlined in each of Plaintiff's remarks concerning amendments to avoid anticipation based on these three prior art references. (D.I. 374-2 at 109–11 of 112, Ex. 2). But that underlining does not exist alone. In each, the relevant limitation is described as, "improv[es] exercise capacity in a patient having pulmonary hypertension associated with interstitial lung disease." (*Id.*) (brackets and underlining in original). Plaintiff argued that each reference was not anticipatory because each "teaches nothing regarding improving exercise capacity in any patient." (*Id.*). Plaintiff did not comment on the "associated with interstitial lung disease" language to avoid anticipation.

[5] Other narrowing amendments to claim 1: changing "a method of treating" to "a method of improving exercise capacity," adding a limitation of administration "by inhalation," adding a

Defendant counters that original claims 1 and 4 were never issued and Plaintiff's argument "wrongly assumes original claim 4 was a proper dependent claim."[6] (D.I. 378 at 1). Defendant argues that the use of both "associated with" and "due to" in original claims 1 and 4 further indicates that the two terms are not synonymous. (*Id.* at 2).

D. Discussion

"[T]he words of a claim are generally given their ordinary and customary meaning." *Phillips*, 415 F.3d at 1312 (internal quotation marks and citations omitted). "[T]he ordinary and customary meaning of a claim term 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." *Id.* at 1313. "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." *Id.* at 1314. I agree with Plaintiff that "associated" by its plain meaning implies a relationship[7]—if a patient has two unrelated, concomitant conditions, neither a POSA nor a lay judge would understand those diseases to be "associated." For this reason, and other reasons explained below, I reject Defendant's construction that "associated with" simply means "and." The question is whether, as Plaintiff proposes, "associated with" is synonymous with "due to."

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dosage requirement of "at least 15 micrograms up to a maximum tolerated dose," and adding a limitation that the treprostinil be administered "in a single administration event that comprises at least 6 micrograms per breath." *Compare* ('327 patent at 54:6–14) *with* (D.I. 374-2 at 79, 105 of 112, Ex. 2).

[6] Defendant does not provide any reason for why original claim 4 was not a proper dependent claim. (D.I. 378 at 1). Contrary to this assertion, original claim 4 appears to be in the proper form: it narrows PH to PH-ILD.

[7] The first definition of "associated" in the Merriam-Webster dictionary is "joined together often in a working relationship." The second definition is "related, connected, or combined together." *Associated*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/associated (last visited June 17, 2025).

The canon of claim differentiation dictates that different words used in patent claims are generally presumed to carry different meanings. *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998). Some courts have applied this principle to language in the specification as well. *See, e.g.*, *BTL Indus., Inc. v. Rejuva Fresh LLC*, 2025 WL 1333524, at *6 (D. Me. May 7, 2025) ("Different words in different portions of a patent's specification are presumed to have different meanings."). However, this inference is "not conclusive" and "different words [may] be used to express similar concepts, even though it may be poor drafting practice." *Bancorp Servs., L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1373 (Fed. Cir. 2004). The specification's use of "due to" in some places and "associated with" in others does not prevent "pulmonary hypertension associated with interstitial lung disease" from indicating causation or other relationship between the two conditions.

In fact, though issued claim 1 is no longer a dependent claim, the specification supports an interpretation that aligns with the relationship between original claims 1 and 4. The specification states: "The present disclosure also provides a method of treating a pulmonary hypertension due to . . . a chronic lung disease[.]" ('327 patent at 17:54–56). The specification then provides "interstitial lung disease" as an example of one such "chronic lung disease" that may occur alone or in combination with other conditions. ('327 at 17:64–18:5). The use of "due to" in the INCREASE trial and updated WHO classifications in Simonneau 2019 likewise indicate that a POSA would read "associated with interstitial lung disease" to imply a relationship between the patient's pulmonary hypertension and interstitial lung disease.

However, limitations from the specification should not be read into the claims, and the issued claim 1 does not read "due to." *See Phillips*, 415 F.3d at 1323. Further, "when a word is changed during prosecution, the change tends to suggest that the new word differs in meaning in

some way from the original word." *Ajinomoto Co., Inc. v. ITC*, 932 F.3d 1342, 1351 (Fed. Cir. 2019). Though Plaintiff made multiple changes to claim 1 after original claim 1 was rejected, one change Plaintiff made was to replace "pulmonary hypertension *due to* a condition which is selected from a chronic lung disease, hypoxia and a combination thereof" with "pulmonary hypertension *associated with* interstitial lung disease." Plaintiff's proposed construction of "due to a patient's interstitial lung disease" does not capture this change. Rather, "associated with" suggests a broader meaning than "due to."

Extrinsic evidence in the form of expert testimony can be helpful 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. Plaintiff's expert, Dr. Stephen Nathan, testified that, in the context of the claims of the '327 patent, he understood the claim term "pulmonary hypertension associated with interstitial lung disease" to be "due to or caused by the interstitial lung disease." (D.I. 375-1 at 122 of 166, Ex. 11).

Defendant's expert, Dr. Richard Channick, abbreviated the claim term "pulmonary hypertension associated with interstitial lung disease" as "PH-ILD" in his expert report. (*Id.* at 105 of 166, Ex. 9). Dr. Channick's report states that "PH-ILD is a subset" of WHO Group 3 pulmonary hypertension. (*Id.* at 109 of 166, Ex. 9). Dr. Channick defines WHO Group 3 pulmonary hypertension as "PH due to lung diseases" including "restrictive lung diseases like interstitial lung disease ("ILD"). (*Id.* at 107 of 166, Ex. 9). Dr. Channick also states in his report that ILD "refers to a heterogenous group of progressive lung disorders" and "has a variety of associated causes and conditions." (*Id.* at 108 of 166, Ex. 9). He notes that "[a] significant portion of patients do not fall neatly within" an individual WHO Group and that many patients have "PH involving more than one group[.]" (*Id.* at 84 of 166, Ex. 9).

Experts on both sides provided opinions that "pulmonary hypertension associated with interstitial lung disease" involves pulmonary hypertension that is caused or related in some way to the patient's interstitial lung disease. Dr. Channick testified that patients do not fall neatly into individual WHO groups and that a patient's pulmonary hypertension may result from multiple causes.

Because the patent uses both "associated with" and "due to" in different places, and Plaintiff changed the claim language from "due to" to "associated with" during prosecution, I decline to adopt Plaintiff's construction that "associated with" is synonymous with "due to." Though "associated with" can generally mean "related to," expert testimony indicates that a POSA would regard interstitial lung disease to be one cause of the pulmonary hypertension in a patient with "pulmonary hypertension associated with interstitial lung disease" or "PH-ILD." Therefore, I construe "pulmonary hypertension associated with interstitial lung disease" to mean "pulmonary hypertension due, at least in part, to a patient's interstitial lung disease."

IV. CONCLUSION

I recognize that I have construed the disputed claim term differently than either party's proposed claim construction. The parties should promptly meet and confer to resolve any issues associated with this new claim construction.