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 ORDER

Before me is Plaintiff's motion for a preliminary injunction. (D.I. 25). I have considered the parties' briefing. (D.I. 26, 52, 65). I heard oral argument on April 23, 2024.[1] For the reasons set forth below, Plaintiff's motion is DENIED.

I. BACKGROUND

Plaintiff sells products for the treatment of pulmonary hypertension ("PH"), including TYVASO (a nebulized inhaler) and TYVASO DPI (a dry powder inhaler). (D.I. 26 at 2).

In 2009, the Food and Drug Administration 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.

[1] Citations to the transcript of the argument, which is not yet docketed, are in the format "Hearing Tr. at __." After the argument, Defendant filed a motion for leave to submit a one-page brief responding to the Court's questions at the preliminary injunction hearing. (D.I. 77). Plaintiff responded. (D.I. 87). Both parties also filed letters about bond amounts. (D.I. 78, 79). Defendant further filed notices of supplemental authority (D.I. 88, 89), and Axicon Partners, as amicus curiae, filed a motion to supplement the record with a Delaware District Court decision (D.I. 93). I have considered all the supplemental filings.

26 at 2; *see also* D.I. 52 at 2–3). The FDA later approved TYVASO DPI for the treatment of both PAH and PH-ILD. (D.I. 26 at 2).

Plaintiff's work on treprostinil-based therapies resulted in U.S. Patent Nos. 10,716,793 ("the '793 patent") and 11,826,327 ("the '327 patent"). (*Id.* at 2–3). Defendant, meanwhile, seeks FDA approval to market a treprostinil-based product named Yutrepia. (*Id.* at 3). Plaintiff sued Defendant in 2020, alleging that Yutrepia would infringe some of Plaintiff's patents. (*Id.*). After a bench trial, I found that Defendant infringed certain claims of the '793 patent. (*Id.*). The Federal Circuit affirmed my opinion. Subsequently, however, the Federal Circuit affirmed a Patent Trial and Appeal Board decision invalidating the asserted claims of the '793 patent. (*Id.*).

In 2023, Defendant amended its New Drug Application to add a PH-ILD indication. (*Id.*; *see also* D.I. 52 at 3). The present suit alleges that Defendant would infringe claims of the '327 patent by launching Yutrepia for the PH-ILD indication. (D.I. 26 at 4–5). Plaintiff seeks to preliminarily enjoin Defendant from launching Yutrepia for the PH-ILD indication. (*Id.*; *see also* D.I. 52 at 1).

II. LEGAL STANDARD

"The decision whether to enter a preliminary injunction is committed to the sound discretion of the trial court." *Duraco Prods., Inc. v. Joy Plastic Enters., Ltd.*, 40 F.3d 1431, 1438 (3d Cir. 1994) (quoting *Merchant & Evans, Inc. v. Roosevelt Bldg. Prods. Co.*, 963 F.2d 628, 633 (3d Cir. 1992)). The Third Circuit has cautioned that a preliminary injunction is "an extraordinary remedy, which should be granted only in limited circumstances." *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 586 (3d Cir. 2002) (quoting *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 800 (3d Cir. 1989)). When seeking a preliminary injunction, a movant "must establish [1] that he is

likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The movant must establish the first two requirements before a court considers, to the extent relevant, the remaining two prongs of the standard. *Cipla Ltd. v. Amgen Inc.*, 778 F. App'x 135, 138 (3d Cir. 2019).

III. DISCUSSION

A. Likelihood of Success on the Merits

To demonstrate a likelihood of success on the merits, "the patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009).

"[V]alidity challenges during preliminary injunction proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial." *Abbott Lab'ys v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1335 (Fed. Cir. 2006) (citation omitted). "Thus, the patent challenger retains the burden of establishing invalidity, and the applicant for preliminary injunctive relief retains the burden of showing a reasonable likelihood that the attack on the validity of the patent would fail." *Impax Lab'ys, Inc. v. Aventis Pharms., Inc.*, 235 F. Supp. 2d 390, 392 (D. Del. 2002) (citation omitted).

If an alleged infringer raises a substantial question concerning validity or infringement, and the patentee is unable to prove that the question "lacks substantial merit," a preliminary injunction will not issue. *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997).

1. Infringement

Plaintiff argues that Defendant infringes claims 1, 6, 9–11, and 14 of the '327 patent. (D.I. 26 at 6). Plaintiff also argues that Defendant will be liable for induced infringement if it launches Yutrepia for the treatment of PH-ILD. (*Id.*).

Claim 1 of the '327 patent states:

> 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).

"[T]he patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely prove infringement." *Titan Tire Corp.*, 566 F.3d at 1376. The literal infringement analysis involves two steps. First, a court must determine a patent claim's scope. Second, a court must decide whether the claim encompasses the defendant's product. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1581–82 (Fed. Cir. 1996). "Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device, i.e., when the properly construed claim reads on the accused device exactly." *Cole v. Kimberly–Clark Corp.*, 102 F.3d 524, 532 (Fed. Cir. 1996).

a. Claims 1 and 6

Plaintiff argues that Defendant practices the preamble of claim 1 because it instructs patients to take Yutrepia "for the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability." (D.I. 26 at 7 (citation omitted)). Plaintiff contends that a POSA would understand that exercise capacity and exercise

ability are the same thing. (*Id.*). Because Yutrepia's label states that "YUTREPIA capsules are for oral inhalation only," Plaintiff contends that Yutrepia will be "administered by inhalation." (*Id.* (citation omitted)). Plaintiff further contends that the Yutrepia label meets the "effective amount of at least 15 micrograms up to a maximum tolerated dose of treprostinil" because the label recommends 26.5 to 159 micrograms of treprostinil. (*Id.* (citation omitted)). Plaintiff also contends that Yutrepia will be administered "in a single administration event that comprises at least 6 micrograms per breath" because the Yutrepia label instructs that it "should be administered 3 to 5 times per day, in two breaths." (*Id.* (citation omitted)). Lastly, Plaintiff contends that claim 1 will be infringed if Yutrepia is used to improve exercise capacity in patients with PH-ILD. (*Id.*).

Plaintiff argues that use of Yutrepia will infringe claim 6 as well. Claim 6 requires a statistically significant reduction in ILD exacerbations, and Plaintiff contends that the Yutrepia label contains clinical trial data showing that the group of patients who took inhaled treprostinil experienced a statistically significant reduction in ILD exacerbations. (*Id.* at 7–8).

Defendant's answering brief does not address infringement with respect to claims 1 and 6, other than to argue that Defendant cannot infringe invalid claims. (*See* D.I. 52 at 12–14). At oral argument, Defendant conceded that it infringes claims 1 and 6 if those claims are valid. (Hearing Tr. at 9:8–17). Plaintiff has therefore established that it will likely prove infringement of claims 1 and 6.

b. Claims 9 and 10

Plaintiff contends, "The use of Yutrepia will meet each and every limitation of claims 9 and 10, which require an increase in the patient's forced vital capacity ('FVC') that is statistically significant (claim 9) or at least 20 mL (claim 10))." (D.I. 26 at 8). Plaintiff contends

that the INCREASE trial on which Yutrepia's label relies indicates that "patients experienced a statistically significant increase in FVC after both 8 and 16 weeks." (*Id.*). Plaintiff thus argues that individuals with PH-ILD who "us[e] Yutrepia according to its label to improve exercise capacity will practice the methods of claims 9 and 10." (*Id.*).

Defendant responds that it does not induce infringement of claims 9 and 10. (D.I. 52 at 13). Defendant contends that the Yutrepia label, which references the INCREASE study, does not mention FVC. (*Id.*). Defendant contends that the label "does not suggest improving a patient's FVC," as "improving FVC is not FDA-approved," so Defendant cannot induce infringement. (*Id.*). Defendant further argues that the reference to the INCREASE study cannot be understood as "an instruction to improve a patient's FVC" because "implied uses are not approved uses." (*Id.*).

Because Defendant's answering brief does not address direct infringement of claims 9 and 10 (*see* D.I. 52 at 12–14), Defendant has conceded that it infringes those claims unless they are invalid. Plaintiff has thus established a likelihood of success on the merits with respect to direct infringement of claims 9 and 10.[2]

c. Claims 11 and 14

Plaintiff also argues that the use of Yutrepia will infringe claims 11 and 14, "which require that the method of claim 1 be performed using a pulsed inhalation device and dry powder inhaler, respectively." (D.I. 26 at 8). Plaintiff contends that "a POSA would understand [Defendant's] dry powder inhaler to be a 'pulsed inhalation device.'" (*Id.*).

[2] Because Plaintiff has established a likelihood of success on the merits of its direct infringement argument with respect to claims 9 and 10, I do not need to reach the induced infringement issue for those claims.

Defendant argues that its product is not a pulsed inhalation device. (D.I. 52 at 13). Defendant contends that Plaintiff cannot show otherwise if it only establishes that some dry powder inhalers are pulsed inhalation devices. (*Id.* at 14). Defendant also argues that Plaintiff's expert, Dr. Nathan, is not credible, as "he has never used or seen" the device used with Yutrepia "or reviewed any literature to factually establish infringement." (*Id.* at 13–14).

Plaintiff replies that Defendant's "attempt to narrow the meaning of 'pulsed inhalation device' lacks support in the claims or specification." (D.I. 65 at 2). Plaintiff contends that Defendant "ignores the inventors' lexicography and improperly imports a limitation from extrinsic sources." (*Id.*).

I conclude that Plaintiff has not established that it will likely prove infringement of claims 11 and 14. Dr. Nathan opines that "[a] POSA would understand Yutrepia to utilize a pulsed inhalation device." (D.I. 28 ¶ 149). Dr. Nathan relies on the '327 patent specification's reference to a patent application ("Guarneri") that describes a "breath powered dry powder inhaler." (*Id.*). The specification itself, however, only states that "a pulsed inhalation device[] may be a dry powder inhaler . . . ." ('327 patent at 21:6–11). Although the specification teaches that some pulsed inhalation devices are dry powder inhalers, the specification does not teach that all dry powder inhalers are pulsed inhalation devices. I disagree with Plaintiff that the inventors have relied on lexicography to define dry powder inhalers and pulsed inhalation devices.

Defendant's expert, Dr. Channick, opines that "not all dry powder inhalers are pulsed inhalation devices." (D.I. 54 ¶ 150). Dr. Channick opines that the dry powder inhaler used with Yutrepia "does not include any electronic machinery; it does not generate a 'pulse' of inhaled treprostinil; and it does not itself generate any energy or power to expel powder from the device." (*Id.* ¶ 56; *see also id.* ¶ 149 ("Yutrepia™ reaches a patient through the inhaler through

the patient's breathing alone, without any assistance from the device.")). Plaintiff does not address these opinions in a substantive way.

Based on this record, I cannot conclude that Plaintiff will likely show infringement of claims 11 and 14.[3]

2. Invalidity

Defendant challenges the validity of the '327 patent on anticipation and obviousness grounds. (*See, e.g.*, D.I. 12 at 18).[4]

To establish invalidity at trial, Defendant will have "the ultimate burden of persuasion to prove invalidity by clear and convincing evidence, as well as the initial burden of going forward with evidence to support its invalidity allegation." *Titan Tire Corp.*, 566 F.3d at 1376. At the preliminary injunction stage, however, Defendant's burdens are "tailored to fit the preliminary injunction context." *Id.* at 1377. Defendant thus bears the initial burden "to come forward with evidence of invalidity." *Id.* If Defendant comes forward with such evidence, I will consider both parties' evidence to determine if Defendant has raised a substantial question of validity. *Id.* at 1379.

To defeat a preliminary injunction, Defendant does not need to prove invalidity by clear and convincing evidence, as it would need to in order to succeed at trial. *Id.* Defendant only

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[3] Plaintiff also argues that Defendant will induce infringement of claims 11 and 14. (D.I. 26 at 9). Defendant responds that it cannot infringe an invalid claim, so it has "raised a substantial question as to whether it induces infringement." (D.I. 52 at 13). "It is axiomatic that '[t]here can be no inducement or contributory infringement without an underlying act of direct infringement.'" *In re Bill of Lading Transmission & Processing Sys. Pat. Litig.*, 681 F.3d 1323, 1333 (Fed. Cir. 2012) (citation omitted). I therefore do not need to consider induced infringement for claims 11 and 14.

[4] Plaintiff's opening brief also addresses Defendant's inequitable conduct allegations. (D.I. 26 at 14–16). In its answering brief, however, Defendant states, "For purposes of Liquidia's opposition only, it does not raise the issue of inequitable conduct." (D.I. 52 at 11 n.6).

needs to present evidence showing that there is a substantial question of validity, such that Plaintiff's likelihood of success is in question. *Id.* at 1377–80.

a. Anticipation

Plaintiff argues the '327 patent is not expressly anticipated by the '793 patent because the latter does not teach "each and every limitation" of the '327 patent's asserted claims. (D.I. 26 at 10). Specifically, Plaintiff contends that the '793 patent "does not teach administering inhaled treprostinil to improve exercise capacity and does not disclose any data regarding improved exercise capacity . . . ." (*Id.*). Plaintiff also argues that the '793 patent does not disclose limitations found in the '327 patent's dependent claims. (*Id.*).

Plaintiff further argues that the '327 patent is not inherently anticipated. (*Id.*). Plaintiff contends that some people "may benefit hemodynamically from inhaled treprostinil without also experiencing increased exercise capacity." (*Id.* at 11). Plaintiff contends that "the post-priority date INCREASE trial results described in the '327 specification show that not all PH-ILD patients necessarily and inevitably experience an improvement in exercise capacity." (*Id.*).

Defendant responds that "[a]ny allegation that the '793 patent only discloses hemodynamic data does not negate its anticipatory effect, because [Plaintiff's] experts have equated a positive hemodynamic effect with clinical benefits, including improvement in exercise capacity as shown by the 6MWD [Six-Minute Walk Distance] test." (D.I. 52 at 7).[5]

Even if the '793 patent does not expressly anticipate the '327 patent's claims, Defendant argues that the claims are inherently anticipated. (*Id.* at 8). Defendant contends that the results

[5] Plaintiff calls this a mischaracterization. (D.I. 65 at 3–4). Plaintiff argues, "The experts here agree that while hemodynamic improvements *may* be associated with improved exercise capacity, this is far from guaranteed." (*Id.* at 4).

of the INCREASE study show the inherent properties of treprostinil "at the same dose and in the same PH-ILD population as claimed by the '327 patent." (*Id.* at 8–9).[6] Defendant further argues that "inherency does not require the claimed element to occur in every patient." (*Id.* at 9).[7] Defendant contends, "Moreover, claims 6, 9, and 10 only require a statistically significant change, rendering irrelevant the 'not all patient' argument." (*Id.*).

First, I think Defendant has not shown a substantial question regarding express anticipation. Based on the record before me, the '793 patent does not teach administering inhaled treprostinil to specifically improve exercise capacity, nor does the disclosed data discuss improved exercise capacity. Defendant's contention that Plaintiff's own experts have equated a positive hemodynamic effect with improvements in exercise capacity is unpersuasive. The exhibits Defendant relies on do not support Defendant's position. (*See* D.I. 53-1 at 356–57 of 561 (Ex. 11 ¶ 277), *id.* at 490–91 of 561 (Ex. 16 ¶¶ 60–61), *id.* at 498–500 of 561 (Ex. 17 ¶¶ 73–75), *id.* at 515–18 of 561 (Ex. 18 at 57:5–60:2), D.I. 53-2 at 456, 458, 462 of 482 (Ex. 37 at 40:12–14, 42:14–22, 152:1–8)). This evidence merely shows that depending on context, a therapeutically effective amount may be defined based on hemodynamic effects or based on improvements in exercise capacity. The record does not show that Plaintiff has equated the two.

Second, I think Defendant has not shown a substantial question regarding inherent anticipation. Whereas Dr. Channick opines that "a POSA would have understood that inhaled treprostinil necessarily and inevitably improves exercise capacity in a patient having PH-ILD"

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[6] Plaintiff disputes that the dosing regimens are the same. (*See* D.I. 65 at 5).

[7] Plaintiff responds that Defendant "could only satisfy its burden if 'virtually all the designated recipients' of treprostinil under the '793 patent, including those who suffer from PH-ILD, would necessarily exhibit the outcome claimed by the '327 patent, i.e., improved exercise capacity." (D.I. 65 at 5).

(D.I. 54 ¶ 88), Dr. Nathan opines that the '327 patent and the INCREASE study "show that not every patient who was administered treprostinil exhibited an improvement in exercise capacity" (D.I. 28 ¶ 178). Even if I accept Defendant's contention that the dosing regimens in the '793 patent and the INCREASE study are identical, I think the present record is insufficient to establish that patients who take treprostinil necessarily experience an improvement in exercise capacity. *See Glaxo Grp. Ltd. v. Teva Pharms. USA, Inc.*, 2004 WL 1875017, at *19 (D. Del. Aug. 20, 2004) ("Although inherent anticipation does not require the element to be present each and every time, it does require the result to be a necessary and inevitable consequence of practicing the invention claimed in the prior art under normal conditions.").

In *Teva*, the record showed that not every migraine patient experienced nausea and vomiting. *Id.* Among those who suffer severe migraine attacks, "up to 90% of patients may suffer from nausea as a symptom and 50% from vomiting as a symptom." *Id.* The court concluded that "the relief of nausea and vomiting is not a necessary consequence of the administration of ondansetron to treat migraine under normal conditions." *Id.* Such specific information is missing in the record before me. The parties' dispute regarding treprostinil is closer to the issue in *Glaxo Group Ltd. v. Kali Lab'ys, Inc.*, 2005 WL 1398507, at *3 (D.N.J. June 10, 2005, where the district court found that the record did not support a finding that a reference called COATES invalidated two patents (TYERS I and TYERS II). The court reasoned,

> To be sure, COATES teaches that ondansetron can be administered in conjunction with anti-nauseants, and, a priori, to those suffering from nausea. But this teaching would only invalidate TYERS I and II if virtually all the designated recipients of the drug under COATES, such as schizophrenics and the obese, also suffered from nausea, in which case the administration of ondansetron demonstrated by COATES would necessarily result in the outcome claimed by TYERS, namely "relief of nausea and vomiting" for those "in need thereof."

(*Id.* at *4 (citations omitted)). I think the record before me similarly cannot support Defendant's position that the '327 patent is inherently anticipated. Defendant has not shown that "virtually all" patients who take treprostinil experience an improvement in exercise capacity.

I therefore conclude that Defendant has not shown a substantial question of validity with respect to anticipation.

b. Obviousness (claims 1 and 6)

Plaintiff argues that a POSA "would have no reason to believe that using treprostinil would treat ILD and certainly no motivation to 'modify the disclosure of the '793 patent' to improve exercise capacity in PH-ILD patients." (D.I. 26 at 12 (citation omitted)). Plaintiff also contends that Defendant has "fail[ed] to explain why a POSA would be motivated to combine the '793 patent with any of the other asserted references." (*Id.*).

Plaintiff argues that "[e]ven if a POSA were motivated to administer treprostinil to PH-ILD patients," a POSA "would not have had a reasonable expectation of success in achieving the claimed treprostinil methods." (*Id.* at 13). Plaintiff contends that "numerous clinical trials seeking to apply PAH treatments to PH-ILD patients failed." (*Id.*). Plaintiff argues, "It is only by impermissibly relying on hindsight that [Defendant] can hope to establish a reasonable expectation of success." (*Id.*). Plaintiff addresses objective indicia of non-obviousness in one sentence. (*Id.*).

Defendant argues that the '327 patent is obvious over the '793 patent in combination with the Agarwal 2015 and Saggar 2014 references. (D.I. 52 at 9). Defendant contends that the Agarwal reference "discloses treating PH-ILD patients with inhaled treprostinil (Tyvaso), using at least 3 breaths with at least 6 μg per breath, for a total of 18 μg of treprostinil, and demonstrating statistically significant improvement in exercise capacity as measured by the

6MWD test, rendering claims 1, 6, 11 and 14 obvious." (*Id.*).[8] Defendant further contends that the Saggar reference "discloses improvement in FVC in PH-ILD patients upon administration of treprostinil," as recited in claims 9 and 10. (*Id.* at 10–11).

Defendant argues that a POSA would have been motivated to combine the teachings of the '793 patent, the Agarwal reference, and the Saggar reference. (*Id.* at 11). Defendant argues that the references are directed to the same field of study and address the same patient populations. Defendant further argues that the '793 patent and Agarwal describe the use of inhaled treprostinil with similar dosages. (*Id.*). Defendant contends, "POSAs were already successfully using Tyvaso in PH-ILD patients and combining these references simply reflects what was being done in practice." (*Id.*).

Defendant further argues that a POSA would have had a reasonable expectation of successfully treating PH-ILD patients. (*Id.*). Defendant contends that the lead investigators of the INCREASE study believed that Agarwal and other publications "provided justification to conduct a larger clinical trial in PH-ILD." (*Id.*). Defendant also contends that Plaintiff's CEO told shareholders in 2018 that "there were unmistakable signals [from] some of the leading physicians in the field" that "[t]his drug works." (*Id.* at 11–12 (citation omitted)).

Plaintiff responds that the findings in Agarwal are "hypothesis-generating at best" and do not establish a reasonable expectation of success. (D.I. 65 at 6 (citation omitted)). Plaintiff contends that both Agarwal and Saggar "describe uncontrolled, no-placebo studies of a small number of patients." (*Id.*). Plaintiff also contends that the record does not support Defendant's "reference to purported use of treprostinil to treat PH-ILD before 2020." (*Id.* at 7).

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[8] Plaintiff responds, "Neither the '793 patent nor Agarwal discusses the exacerbations of ILD or clinical worsening events of claim 6." (D.I. 65 at 8). Plaintiff also contends that "none of Saggar's patients received inhaled treprostinil." (*Id.* at 9).

I think the parties present difficult questions regarding the validity of the '327 patent.

Regarding a motivation to combine, Defendant has submitted some evidence that POSAs used TYVASO in PH-ILD patients prior to the relevant time. (*See* D.I. 52 at 11 (citing D.I. 54 ¶¶ 117–18, D.I. 53-2 at 421, 425, 429 of 482 (Ex. 34), D.I. 53-2 at 434–35 of 482 (Ex. 35))). Plaintiff, on the other hand, has submitted evidence that "several pre-INCREASE publications . . . make no mention of this purported off-label use of treprostinil and instead emphasize that efficacy for PH-ILD had not yet been established." (D.I. 65 at 7 (citing D.I. 66-1 at 13–15, 19, 38 of 515 (Ex. 8 at 44:20–45:3, 51:22–52:1, 65:6–25, 142:6–143:5), *id.* at 243 of 515 (Ex. 13), *id.* at 250 of 515 (Ex. 14), *id.* at 267 of 515 (Ex. 15), *id.* at 279–80 of 515 (Ex. 16), *id.* at 289 of 515 (Ex. 17))).

Regarding a reasonable expectation of success, Defendant has submitted evidence suggesting that the lead investigators of the INCREASE study believed that Agarwal and other publications justified a larger clinical trial for PH-ILD patients. (*See* D.I. 53-1 at 251–52 of 561 (Ex. 9 at 202:13–209:7), D.I. 53-2 at 28 of 482 (Ex. 23), D.I. 53-2 at 88–92 of 482 (Ex. 24)). This evidence is consistent with Defendant's citations to comments that Plaintiff's CEO made to shareholders. Plaintiff, on the other hand, has submitted evidence that various clinical trials seeking to treat PH-ILD patients with PAH treatments failed and that Agarwal was merely a pilot study of a small number of patients. (*See, e.g.*, D.I. 28 ¶¶ 78–87, 228, 233).[9]

[9] Although Plaintiff briefly mentions objective indicia, "there is no analysis or argument explaining how any purported objective indicia factor into the obviousness analysis at issue here." *Abbott Cardiovascular Sys., Inc. v. Edwards Lifesciences Corp.*, 2019 WL 2521305, at *16 (D. Del. June 6, 2019). I am "doubtful that Plaintiff['s] asserted objective indicia are properly before the Court given that they are not clearly addressed or argued in the relevant briefing." *Id.*

"That each side makes compelling arguments renders this Court unable to find that Defendant's obviousness challenge lacks substantial merit, thus weighing against issuance of a preliminary injunction." *Waters Corp. v. Agilent Techs. Inc.*, 410 F. Supp. 3d 702, 713 (D. Del. 2019) (citing *Baxalta Inc. v. Genentech, Inc.*, 2018 WL 3742610, at *8 (D. Del. Aug. 7, 2018)). Defendant has therefore shown a substantial question of invalidity on obviousness grounds with respect to claim 1.

I reach the same conclusion for claim 6. Most of the parties' arguments are not unique to claim 6. For claim 6, Plaintiff contends, "Neither the '793 patent nor Agarwal discusses the exacerbations of ILD or clinical worsening events of claim 6." (D.I. 65 at 8). Plaintiff cites to the deposition of Dr. Nathan, who testified about the meaning of an ILD exacerbation. (D.I. 53-1 at 214 of 561 (Ex. 9 at 55:11–22)). Defendant, on the other hand, cites to the declaration of Dr. Channick, who opines that "a POSA would have expected that the patients also showed an improvement in PH-ILD exacerbations" because "Agarwal describes an overall benefit to the patients." (D.I. 54 ¶¶ 130–31). Dr. Channick further opines, "In my experience, exacerbations are associated with deterioration in functional capacity, while in contrast, Agarwal 2015 reports that patients had improvements on these parameters." (*Id.* ¶ 131). I think Plaintiff has not shown that Defendant's obviousness challenge to claim 6 lacks substantial merit.

c. Obviousness (claims 9 and 10)

The parties make a few arguments regarding obviousness that are particular to claims 9 and 10.

Plaintiff argues that "the '793 patent, Agarwal, and Saggar do not disclose the limitations of claims . . . 9 and 10." (D.I. 65 at 8). Plaintiff contends that "Saggar has grave limitations []

and none of Saggar's patients received inhaled treprostinil." (*Id.* at 9).[10] Plaintiff thus argues that a "POSA would not have expected an increase in 'FVC' in PH-ILD patients from inhaled treprostinil based on Saggar." (*Id.*).

Defendant contends that Saggar "discloses improvement in FVC in PH-ILD patients upon administration of treprostinil." (D.I. 52 at 10–11 (citing D.I. 53-2 at 7 of 482 (Ex. 22), D.I. 54 ¶¶ 132–34)). Defendant also contends that a POSA would have been motivated to combine the teachings of Saggar with the '793 patent and Agarwal "because they are directed to the same field of study, PH and PH-ILD, in the same patient populations . . . ." (D.I. 52 at 11). Dr. Channick opines that a POSA would have been motivated to combine the '793 patent with Saggar because both publications "describe the use of treprostinil to treat PH, including PH-ILD." (D.I. 54 ¶ 134). Dr. Channick also opines, "With respect to the improvement in FVC, 20 mL of lung volume is approximately 1–2% of lung volume, and Saggar 2014 discloses a 1% improvement in FVC predicted %." (*Id.* ¶ 133).

Similar to my conclusion regarding claims 1 and 6, I cannot conclude that Defendant's obviousness challenge regarding claims 9 and 10 lacks substantial merit, as each side has made plausible arguments. I think that weighs against the issuance of a preliminary injunction.

B. Irreparable Harm

"A party seeking a preliminary injunction must establish that it is likely to suffer irreparable harm if the preliminary injunction is not granted and there is a causal nexus between the alleged infringement and the alleged harm." *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1368 (Fed. Cir. 2017). The moving party must show that immediate irreparable

[10] Plaintiff contends that Saggar, like Agarwal, describes "uncontrolled, no-placebo studies of a small number of patients." (D.I. 65 at 6).

harm—rather than possible harm in the future—is likely in the absence of an injunction. *See Winter*, 555 U.S. at 22 ("Issuing a preliminary injunction based only on a possibility of irreparable harm is inconsistent with our characterization of injunctive relief as an extraordinary remedy . . . ."). The moving party must make a "clear showing" regarding a likelihood of irreparable harm. *See Apple, Inc. v. Samsung Elecs. Co.*, 678 F.3d 1314, 1325 (Fed. Cir. 2012).

Plaintiff contends "there is no doubt that there is 'some connection' between the harm alleged and the infringing acts." (D.I. 26 at 19 (citation omitted)). Plaintiff argues that Defendant's launch of Yutrepia for PH-ILD would cause irreparable harm in multiple ways. (*Id.* at 16).

First, Plaintiff argues that Defendant's "entry in the PH-ILD market would cause lasting price erosion to [Plaintiff's] TYVASO products." (*Id.*). Plaintiff contends that Defendant would sell Yutrepia at a 20% to 30% discount compared to Plaintiff's product. (*Id.*). If Yutrepia launches, Plaintiff contends that payors will "demand[] additional rebates or discounts from [Plaintiff] for TYVASO products." (*Id.* at 16–17). Plaintiff contends it "is already fielding such demands premised on the mere possibility that Yutrepia would launch on both PAH and PH-ILD." (*Id.* at 17). Absent an injunction, Plaintiff argues that it "could not feasibly raise prices back to pre-Yutrepia levels," and even if it tried, it would be criticized and lose goodwill. (*Id.*).

Second, Plaintiff argues that Defendant's entry into the PH-ILD market would "significantly erode sales and market share for [Plaintiff's] TYVASO products." (*Id.*). Plaintiff contends that Yutrepia would directly compete with TYVASO among PH-ILD patients. (*Id.*). Plaintiff argues that direct competition in the same market supports a showing of irreparable harm. (*Id.*).

Third, Plaintiff argues that Defendant's "premature market entrance would negatively impact [Plaintiff's] research and development efforts." (*Id.* at 18).

Fourth, Plaintiff contends that its reputation would be damaged if Defendant launched its product. (*Id.*).

Fifth, Plaintiff further contends that even if the harm were quantifiable, Defendant would "likely be unable to approach anything close to full satisfaction [of] monetary damages following judgment." (*Id.* at 16; *see also id.* at 18). Plaintiff contends that Defendant "operates at a significant net loss," and Plaintiff's damages would be "significantly higher" than Defendant's "potential revenue." (*Id.* at 18–19).

Defendant argues that Plaintiff will not suffer irreparable harm if the preliminary injunction motion is denied. (D.I. 52 at 14).

First, Defendant contends that Plaintiff's delay in filing the present motion shows that any alleged harm is not imminent. (*Id.*). Defendant contends that Plaintiff knew as early as July 2023 that Defendant would amend its NDA to add the PH-ILD indication and knew that its own regulatory exclusivity would end on March 31, 2024, yet did not file its motion until February 2024. (*Id.*).

Second, Defendant contends that Plaintiff's recent forecasts predict growth, not harm. (*Id.* at 15). Defendant argues that a forecast made after Defendant provided notice of its NDA amendment shows that Plaintiff "expects to see growth from 2023 through 2035." (*Id.*). Defendant further contends that Plaintiff's president told shareholders after Plaintiff filed the present motion that Plaintiff still intends to reach its goal of a "$4 billion run rate by mid-decade." (*Id.* (citation omitted)).

Third, Defendant contends there is no nexus between Plaintiff's alleged harm and Defendant's PH-ILD launch. (*Id.* at 16). While Defendant's lawful competition in PAH may result in price erosion, Defendant argues that Plaintiff has "offered no evidence that any discount would be larger if [Defendant] also launched in PH-ILD." (*Id.* at 16–17). Defendant also contends that Plaintiff "has not increased its discounts on Tyvaso and has not yet decided that it will do so." (*Id.* at 17). Defendant further contends that the statements of Plaintiff's CEO negate any allegations of irreparable harm. (*Id.*). Defendant also argues that Plaintiff's own documents disprove any allegations of lost sales and market share, as the documents show "there is an untapped PH-ILD patient population" that Plaintiff will not treat. (*Id.* at 18).

Fourth, Defendant argues that it could compensate Plaintiff for any monetary losses. (*Id.*). Defendant contends that its "unencumbered sales in PAH can be used to pay damages if [Plaintiff] were to later prevail at trial." (*Id.* at 19).

Plaintiff responds that it did not delay. (D.I. 65 at 9). Plaintiff contends that it "filed its motion before its PH-ILD regulatory exclusivity expired and briefing would have been completed before that expiration but for [Defendant's] requested extension." (*Id.*).

Even if I assume that Plaintiff has established a sufficiently strong causal nexus between the alleged harm and the allegedly infringing acts, I conclude that Plaintiff has not shown a likelihood of irreparable harm based on price erosion, sales, market share, research and development, reputation, or Defendant's ability to pay damages.

1. Price Erosion

"Price erosion can justify a finding of irreparable harm." *Symbol Techs., Inc. v. Janam Techs. LLC*, 729 F. Supp. 2d 646, 664 (D. Del. 2010). Plaintiff's argument as to price erosion, however, is too speculative.

Plaintiff contends it "is already fielding [] demands premised on the mere possibility that Yutrepia would launch on both PAH and PH-ILD." (D.I. 26 at 17). To support this assertion, Plaintiff cites to Dr. Selck's declaration. (*Id.* (citing D.I. 29 ¶¶ 65, 74). These portions of Dr. Selck's declaration, however, do not provide a factual basis for Plaintiff's argument. Paragraph 65 of Dr. Selck's declaration states:

> Aside from formulary placement or exclusion of certain products from the formulary entirely, there are other levers that payors can use to incentivize price competition. These include utilization management via step therapy and prior authorization.

(D.I. 29 ¶ 65). Paragraph 74, meanwhile, states:

> Furthermore, if a preliminary injunction is not granted but a subsequent permanent injunction is granted, Yutrepia may be allowed to enter the market and then be forced to withdraw. In this case, it is unlikely that eroded prices will return to pre-entry prices as prices for the Tyvaso products are likely to be downward sticky. Indeed, I understand from Mr. Barton that it is unlikely that United will be able to pull back discounts offered after the fact, and that discounts offered at this stage could also impact pricing for future indications the Tyvaso products are approved for.

(*Id.* ¶ 74). Paragraph 64 of Dr. Selck's declaration seems more related to Plaintiff's proposition. In that paragraph, Dr. Selck vaguely states that "there has been a tremendous push for greater discounts." (*Id.* ¶ 64). He further states, "David Barton, who is heavily involved in payor negotiations for [Plaintiff]," "has been surprised by how aggressive payors have been." (*Id.*). I agree with Defendant that these portions of Dr. Selck's declaration do not distinguish between Yutrepia as applied to PAH patients and Yutrepia as applied to PH-ILD patients, which weighs against a finding of price erosion on PH-ILD treatments.

Plaintiff's assertion that Yutrepia will be offered at a discount of 20% to 30% relative to Plaintiff's product is speculative as well. To support its position, Plaintiff only cites to Dr. Selck, who states he understands from David Barton, "Yutrepia *may* be expected to enter the PH-ILD

indication with initial pricing of up to 20% to 30% less than that of the Tyvaso products, placing pressure on [Plaintiff] to offer price concessions as well." (D.I. 29 ¶ 62 (emphasis added)). Without more evidence, I think the record is insufficient to support Plaintiff's assertion that a Yutrepia launch for PH-ILD would cause price erosion.

Because I think that Plaintiff's price erosion argument is speculative, I conclude that Plaintiff's price erosion argument cannot support a finding of irreparable harm.

2. Lost Sales and Market Share

"[L]ost sales standing alone are insufficient to prove irreparable harm; if they were, irreparable harm would be found in every case involving a 'manufacturer/patentee, regardless of circumstances.'" *Automated Merch. Sys., Inc. v. Crane Co.*, 357 F. App'x 297, 300–01 (Fed. Cir. 2009) (citation omitted). As to market share, "lost market share must be proven (or at least substantiated with some evidence) in order for it to support entry of a preliminary injunction, because granting preliminary injunctions on the basis of speculative loss of market share would result in granting preliminary injunctions 'in every patent case where the patentee practices the invention.'" *Id.* at 301 (citation omitted). Here, I think that Plaintiff's arguments regarding lost sales and loss of market share are too speculative.

The record does not show that sales of Defendant's Yutrepia product would necessarily result in lost sales of Plaintiff's TYVASO product. Even if there were overlap in the targeted patient populations, Plaintiff has conceded that it would only reach roughly 25% of the PH-ILD patient population by 2025 and roughly 50% of that population by 2030. The evidence suggests that if both parties sold their products, some patients would nevertheless remain untreated. Defendant has also submitted some evidence that certain patients may be able to take Defendant's product but not Plaintiff's product. (*See* D.I. 53-1 at 232–33 of 561 (Ex. 9 at

128:21–130:2), D.I. 54 ¶ 56). I thus conclude that Plaintiff's arguments regarding lost sales do not support a finding of irreparable harm.

I similarly do not think that the evidence supports a finding of irreparable harm based on loss of market share. Plaintiff's own documents show that Plaintiff expects the PH-ILD market (i.e., the size of the PH-ILD population) to remain the same through 2030 while Plaintiff treats a higher percentage of that market in 2030 than in 2023. (*See* D.I. 53-2 at 320 of 482 (Ex. 26)). Comments made by Plaintiff's CEO after Plaintiff filed the present motion are also consistent with an expectation of substantial growth. Because Plaintiff currently treats less than a quarter of estimated PH-ILD patients, and expects even without Yutrepia as a competitor that by 2030 it will only treat half of the market, it does not appear that Yutrepia's launch would significantly harm Plaintiff's share of the potential market.[11]

3. Damages

Even if Plaintiff had made a concrete showing regarding price erosion, lost sales, or loss of market share, I think Plaintiff has failed to show that any harm cannot be remedied through monetary damages.

"The burden is . . . on the patentee to demonstrate that its potential losses cannot be compensated by monetary damages." *Automated*, 357 F. App'x at 301. Plaintiff relies on Dr. Selck's declaration to support its argument. Dr. Selck opines that Defendant "possesses a limited portfolio and a market capitalization . . . that is less than current annual sales earned by the Tyvaso products." (D.I. 29 ¶ 20). Dr. Selck thus opines that "even an understated estimate of damages would be significantly higher than the revenue [Defendant] currently generates." (*Id.*).

[11] Surely Plaintiff will lose some sales to Yutrepia. In that sense, Plaintiff, who currently has 100% of the sales, will no longer have 100% of the sales.

Dr. Selck also opines that because Yutrepia would enter the market at a lower price than Plaintiff's products, "the profit gained by [Defendant] is likely to be smaller than the profit lost by [Plaintiff] for each unit sale made by Yutrepia that [Plaintiff] would have captured but for Yutrepia's premature entry into the PH-ILD marketplace." (*Id.* ¶ 145; *see also id.* ¶¶ 142–44, 146–49). I agree with Defendant that Plaintiff does not cite to any portions of Dr. Selck's declaration that consider how Defendant's potential Yutrepia launch for the PAH indication affects the damages question.

I conclude that Plaintiff has not met its burden of demonstrating that monetary damages cannot compensate its potential losses.

4. Delay

"Injunctive relief has been found to be inappropriate where a Plaintiff has had no apparent urgency in requesting it." *Waters*, 410 F. Supp. 3d at 714; *see also Apple*, 678 F.3d at 1325 ("The district court correctly noted that delay in bringing an infringement action and seeking a preliminary injunction are factors that could suggest that the patentee is not irreparably harmed by the infringement.").

Here, the '327 patent issued on November 28, 2023. Plaintiff filed its First Amended Complaint to assert the '327 patent against Defendant on November 30, 2023—only two days later. (*See* D.I. 8). That itself does not suggest delay. Plaintiff, however, waited until February 26, 2024, to file the present motion. (*See* D.I. 25). Plaintiff contends that briefing for this motion would have been completed before the end of Plaintiff's regulatory exclusivity for the PH-ILD indication (March 31, 2024) if Defendant had not requested an extension of briefing deadlines. (*See* D.I. 41). I think, however, that Plaintiff caused some delay by waiting nearly three months to request injunctive relief after asserting the '327 patent against Defendant. On

the other hand, I agree with Plaintiff that this motion would have been fully briefed prior to the end of Plaintiff's regulatory exclusivity if the parties had not stipulated to extend the briefing deadlines. I do not think the delay issue weighs against a finding of irreparable harm.

5. Research and Development

Plaintiff briefly argues that Defendant's "premature market entrance would negatively impact [Plaintiff's] research and development efforts." (D.I. 26 at 18). Plaintiff relies on the declaration of Dr. Selck, who offers few details to support his opinion. (*See* D.I. 29 ¶¶ 21 ("[A]llowing Yutrepia to enter the PH-ILD marketplace prematurely will harm drug development incentives in a growing therapeutic space."), 100 ("Cash flows from sales of established products is a preferred method for financing development efforts. . . ."), 101 (Plaintiff's "research and development efforts would be harmed by reduced revenues of Tyvaso and Tyvaso DPI in the PH-ILD market. . . ."), 102). Based on the evidence available, I cannot conclude that Plaintiff is likely to suffer irreparable harm based on an inhibition of research and development efforts.

6. Reputation

Plaintiff devotes only two sentences in its opening brief to address potential harm to its reputation. (D.I. 26 at 18). Plaintiff again relies on Dr. Selck's declaration to support its position. (*See* D.I. 29 ¶¶ 19 (Plaintiff "will suffer reputational harm if Yutrepia is allowed to enter the market and then later forced to withdraw due to a permanent injunction."), 103 ("If [Plaintiff] is viewed as responsible for removing what could be perceived as a 'novel pharmaceutical therapy' (i.e., Yutrepia) from the marketplace, it may be claimed that [Plaintiff] is operating counter to its mission and purpose to help patients, which would cause reputational harm."), 104)).

Assuming Plaintiff has a reputation as an innovator in the treatment of PAH and PH-ILD, the evidence does not show that Plaintiff's reputation will suffer. "Reputational harm has previously been found to weigh in favor of injunctive relief where a plaintiff was itself practicing the patented invention and where there was evidence of consumer confusion, a loss of product distinctiveness, or some risk to that plaintiff's status as an innovator." *Baxalta*, 2018 WL 3742610, at *11. Here, the record does not show that Plaintiff will be harmed by consumer confusion, by a loss of its products' distinctiveness, or by damage to its innovator status. Even if an injunction were granted, Defendant could still launch Yutrepia for the PAH indication upon FDA approval. An injunction would thus not stop doctors and patients from associating the Yutrepia product with Defendant. *Cf. id.* Any damage to Plaintiff's reputation is thus speculative. An injunction could also injure Plaintiff's reputation if doctors and/or patients believed that Plaintiff tried to keep a beneficial therapy from them.

I conclude that Plaintiff has not shown that it would suffer reputational harm in the absence of a preliminary injunction.

C. Balance of Equities

Although I do not think that Plaintiff has shown a likelihood of success on the merits or of irreparable harm, I will address the remaining preliminary injunction factors.

Plaintiff argues it would lose the value of the '327 patent, which is set to expire in 2042, if Defendant is not enjoined. (D.I. 26 at 19). Plaintiff also contends that Defendant would suffer "minimal" harm with an injunction in place. (*Id.*). Plaintiff argues that Defendant "would be 'in the same position as it was before the injunction was granted.'" (*Id.* at 19–20 (citation omitted)). Plaintiff also notes that an injunction would not stop Defendant from launching Yutrepia for the

PAH indication. (*Id.* at 20). Plaintiff thus argues that absent an injunction, it "will suffer severe and irreversible harm that outweighs any potential hardship for [Defendant]." (*Id.* at 19).

Defendant argues that an injunction would not cause irreparable harm to Plaintiff, in part because Plaintiff has two decades of market dominance and more than $2 billion in annual revenue, while Defendant is "a new market entrant." (D.I. 52 at 20). Defendant also contends that an injunction would "improperly stifle [Defendant's] unencumbered sales in the PAH indication" due to "the difficulty in diagnosing PH-ILD from PAH." (*Id.*).

For the balance of equities factor, I consider "the potential injury to the plaintiff if an injunction does not issue versus the potential injury to the defendant if the injunction is issued." *Novartis*, 290 F.3d at 596. This factor "assesses the relative effect of granting or denying an injunction on the parties." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 862 (Fed. Cir. 2010), *aff'd*, 564 U.S. 91 (2011). I think this factor does not favor either party.

As explained above, Plaintiff has not shown that it would be irreparably harmed absent an injunction. Plaintiff is a large company with more than $2 billion in annual revenue and two decades on the market. (*See* D.I. 52 at 20 (citing D.I. 55 ¶¶ 134–35, D.I. 53-2 at 407 of 482 (Ex. 33))).[12] The evidence suggests that Plaintiff has "substantial experience and resources and is prepared to compete" with Defendant's Yutrepia product. *Cf. Abbott*, 2019 WL 2521305, at *25.

On the other hand, Defendant's Yutrepia product has not been approved yet for either the PAH or the PH-ILD indications. Without FDA approval, an injunction would indeed leave Defendant in the same position as it was in before. Plaintiff is also correct that an injunction

[12] Plaintiff does not dispute this. It merely argues, "Liquidia's claims regarding the parties' difference in size is [] unavailing. In fact, that difference in size is exactly the issue that reinforces Liquidia's inability to compensate UTC for the monetary damages stemming from its infringing PH-ILD sales at the conclusion of the case." (D.I. 65 at 10).

would not stop Defendant from launching Yutrepia for PAH, though Defendant makes a reasonable argument that an injunction for PH-ILD could stifle sales of Yutrepia for PAH. (*See* D.I. 52 at 20 (citing D.I. 28 ¶ 67, D.I. 54 ¶ 124, D.I. 55 ¶¶ 135–36)). Lastly, Plaintiff's '327 patent is presumed valid, and without an injunction, Plaintiff could lose some of the value of that patent if Defendant enters the market with an infringing product.

D. Public Interest

Plaintiff argues that the public interest in protecting patent rights supports the issuance of a preliminary injunction. (D.I. 26 at 20). Plaintiff contends, "The public interest in encouraging investment into drug development outweighs obtaining that same drug even via an infringing alternative—even if it were to some extent lower cost—when [Plaintiff's] products meet the current market need." (*Id.*). Plaintiff argues that PH-ILD patients would keep having access to dry powder and nebulized treprostinil treatments while an injunction is in place. (*Id.*).

Defendant argues that an injunction would not be in the public interest. (D.I. 52 at 19). Defendant notes that Plaintiff estimates there are 30,000 PH-ILD patients but only expects to treat a fraction of those patients. (*Id.*). Defendant further contends that some patients may be unable to use Plaintiff's product, as Plaintiff uses an "ultra-high-resistance inhalation device." (*Id.*). Defendant argues that patients who cannot use Plaintiff's device could use Defendant's low-resistance dry powder inhaler instead. (*Id.*).

For the public interest factor, I consider whether granting "an injunction is in the public interest." *Winter*, 555 U.S. at 20. "There is no question that the public has an interest in the enforcement of patent rights . . . ." *Baxalta*, 2018 WL 3742610, at *12. This factor nevertheless "requires consideration of other aspects of the public interest." *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1341 (Fed. Cir. 2012).

"In litigation such as this involving a medical product, the public has 'two primary interests'—i.e., the 'protection of intellectual-property rights and access to necessary and effective medical care.'" *Abbott*, 2019 WL 2521305, at *25 (quoting *Baxalta*, 2018 WL 3742610, at *12). Courts have denied motions for injunctions "when doing so would eliminate 'an important alternative for patients.'" *Id.* (quoting citation omitted).

I am unpersuaded by Plaintiff's contention that its products meet the current market need. One of Plaintiff's documents forecasts Plaintiff's activity between 2023 and 2035. The document states there are roughly 30,000 PH-ILD patients, of which Plaintiff expects to treat 7,500 in 2025 and 15,000 in 2030 and 2031. (D.I. 53-2 at 320 of 482 (Ex. 26)). Plaintiff did not dispute these estimates during oral argument. (*See* Hearing Tr. at 4:5–22). Plaintiff thus expects to eventually treat 50% of PH-ILD patients.[13] I agree with Defendant that "there's no evidence that that 50-percent market capture is only because there are only 15,000 patients that can take the drug," even if some "some patients [] are too far along in the disease progression" to undergo anything other than surgery. (*Id.* at 15:16–19, 17:17–22). Even if there is overlap between the patient populations that Plaintiff and Defendant would treat, I think the evidence suggests that Plaintiff likely does not meet the current market need.

Defendant has also submitted evidence that some patients may be able to use Yutrepia but not Plaintiff's product. Dr. Channick opines:

> The Yutrepia™ dry powder inhaler is also a low-resistance inhalation device in that it only requires the patient to exert a low level of force to inhale the drug properly, allowing patients with a wide range of lung capacities to use the device. This is in contrast to the dry powder inhaler used by Tyvaso®—an ultra-high-resistance inhalation device which requires the patient to exert a high level of force. It has also been my experience that patients who have used UTC's Tyvaso

[13] At oral argument, Defendant suggested that its own documents "indicate there's probably 60,000 patients with PH-ILD," not 30,000 patients. (Hearing Tr. at 14:24–15:3).

> DPI® reverted back to the Tyvaso® nebulized product due to Tyvaso DPI®'s difficulty of use.

(D.I. 54 ¶ 56). Plaintiff's reply brief merely contends, "Liquidia has not offered any evidence that would outweigh the public interest in favor of protecting patent rights." (D.I. 65 at 10). At oral argument, Plaintiff stated that Dr. Nathan "opines that the low resistance is actually not a benefit to the patient population and would be disfavored by doctors." (Hearing Tr. at 6:1–6). While that may be Dr. Nathan's opinion, Plaintiff's briefing does not mention it. Dr. Nathan does opine that physicians would see TYVASO DPI and Yutrepia as "clinical alternatives." (D.I. 28 ¶ 116). Dr. Nathan further opines that patients using Plaintiff's products could easily transfer from dry powder to a nebulized formulation, but that Yutrepia users could not do the same because Defendant does not offer a nebulized version of its product. (*Id.*). Based on the present record, I am convinced that at least some patients would likely suffer negative consequences if Defendant were enjoined from launching Yutrepia for the PH-ILD indication.

I conclude that Plaintiff has failed to show that an injunction would be in the public interest.

IV. CONCLUSION

Although Plaintiff has shown a likelihood of success as to infringement of claims 1, 6, 9, and 10 of the '327 patent, Plaintiff has failed to show that Defendant's obviousness challenge lacks substantial merit. Plaintiff has also failed to show that it is likely to suffer irreparable harm absent an injunction, or that the public interest weighs in favor of an injunction. The balance of equities does not favor either party. Weighing these factors, I conclude that a preliminary injunction is not appropriate based on the present record.

For these reasons, Plaintiff's motion for a preliminary injunction is DENIED.[14]

IT IS SO ORDERED.

Entered this 31st day of May, 2024

Richard G. Andrews
United States District Judge

[14] Axicon Partners' motion to supplement the record with the *Baxalta v. Genentech* decision (D.I. 93) is GRANTED. Defendant's motion for leave to submit a one-page brief responding to the Court's questions at the preliminary injunction hearing (D.I. 77) is also GRANTED. Plaintiff stated that it does not intend to file a response if Defendant's motion for leave is granted. (D.I. 87).