

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

UNITED THERAPEUTICS CORP.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 20-755-RGA-JLH
)	
LIQUIDIA TECHNOLOGIES, INC.,)	
)	
Defendant.)	
)	

REPORT AND RECOMMENDATION

Plaintiff United Therapeutics Corporation (UTC) alleges that Defendant Liquidia Technologies, Inc.’s (Liquidia’s) submission of a New Drug Application infringes three patents owned by UTC, in violation of 35 U.S.C. § 271(e)(2). Liquidia moves for summary judgment of invalidity of two of those patents. (D.I. 281.) Essentially, Liquidia contends that UTC is precluded from contesting the invalidity of those patents as a result of the Federal Circuit’s affirmance of a 2017 Patent Trial and Appeal Board (PTAB) decision that found that a different (unasserted) UTC patent was invalid.

Liquidia’s motion is fully briefed, and I held a hearing on March 10, 2022. (Tr __.) For the reasons announced from the bench on March 11, 2022, I recommend that the Court DENY the motion.

I. LEGAL STANDARDS

A party may move for summary judgment under Federal Rule of Civil Procedure 56. Summary judgment must be granted where “there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). The burden is on the

movant to demonstrate the absence of a genuine issue of material fact. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585–86 (1986).

“An assertion that a fact cannot be—or, alternatively, is—genuinely disputed must be supported either by ‘citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials,’ or by ‘showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.’” *Resop v. Deallie*, No. 15-626, 2017 WL 3586863, at *2 (D. Del. Aug. 18, 2017) (quoting Fed. R. Civ. P. 56(c)(1)(A) & (B)). A factual dispute is genuine only where “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The Court must “draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence.” *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

II. DISCUSSION

My Report and Recommendation was announced from the bench on March 11, 2022, as follows:

This is my Report and Recommendation on Defendant Liquidia’s Motion for Summary Judgement of Invalidity of the ’066 and ’901 Patents Due to Collateral Estoppel.¹

I will summarize the reasons for my recommendation in a moment. But before I do, I want to be clear that my failure to address a particular argument advanced by a party does not mean that I did not consider it. We have carefully considered the parties’ briefs and attached exhibits, and the arguments made at yesterday’s

¹ (D.I. 281.)

hearing, as well as the letter I received last night.² We will not be issuing a separate opinion, but we may put on the docket a written document containing a transcript of the recommendation that I am about to state that also refers to the applicable legal standards and case citations.

For the following reasons, I recommend that Liquidia's motion be DENIED.

There are three patents at issue in this litigation. This motion concerns two of those patents: [U.S. Patent No. 9,593,066] (the '066 patent) and [U.S. Patent No. 9,604,901] (the '901 patent). Both are part of a family of patents owned by Plaintiff UTC. That family also includes [U.S. Patent No. 8,497,393] (the '393 patent).

The '066, '901, and '393 patents have a common specification. The specification describes an allegedly new process for making a prior art pharmaceutical ingredient, treprostinil. UTC uses the claimed process to make [active pharmaceutical ingredient] (API) for branded drugs, including Tyvaso®.

The '393 patent contained product-by-process claims. In 2015, a former UTC competitor, SteadyMed, filed an [inter partes review] (IPR) proceeding on the '393 patent. On March 31, 2017, the PTAB issued a decision invalidating every claim of the '393 patent because it found that SteadyMed had demonstrated, by a preponderance of the evidence, that the claims were anticipated by and obvious over the prior art. In reaching its conclusion, the PTAB found, among other things, that treprostinil product made according to the process recited in the '393 claims was not structurally or functionally different from a prior art treprostinil product.³ The Federal Circuit summarily affirmed the PTAB's decision in 2017.⁴

UTC had several continuations of the '393 patent, two of which eventually resulted in the patents at issue in this motion—the '066 and '901 patents. Those patents include product-by-process claims and process claims.

On June 4, 2020, UTC filed this suit against Liquidia for infringement of the '066 and '901 patents. The suit triggered a

² (D.I. 282, 290–93, 303, 348.)

³ *SteadyMed Ltd. v. United Therapeutics Corp.*, No. IPR2016-00006, at 29 (P.T.A.B. Mar. 31, 2017) (the '393 IPR) (D.I. 282, Ex. 4).

⁴ *United Therapeutics Corp. v. SteadyMed Ltd.*, 702 F. App'x 990 (Fed. Cir. 2017).

thirty-month stay of the [Food & Drug Administration's] (FDA's) approval of Liquidia's pending New Drug Application. (D.I. 1.) UTC later amended its complaint to allege infringement of another patent not at issue in this motion. (D.I.16.)

On August 5, 2020, Liquidia filed its Answer and Counterclaims to the Amended Complaint. (D.I. 23.) Liquidia's pleading sets forth four "affirmative defenses." The pleading does not list collateral estoppel (or issue preclusion) as an affirmative defense. The pleading contains counterclaims for declaratory judgments of invalidity of the '066 and '901 patents, but nowhere does Liquidia's pleading suggest that the claims of the '066 and '901 patents are invalid on the basis of collateral estoppel or issue preclusion.⁵

As part of discovery, Liquidia served preliminary invalidity contentions on November 13, 2020. Among other theories, Liquidia contended that claim 1 of the '066 patent and claim 1 of the '901 patent, both of which are product-by-process claims, were directed to the same product as invalidated product-by-process claim 1 of the '393 patent, and that the asserted claims were therefore "not directed to a novel and nonobvious product."⁶ But Liquidia's contentions did not suggest that the elements of estoppel (or issue preclusion) would be the applicable legal standard to its assertion of invalidity rather than the ordinary elements of novelty or nonobviousness. Nor do the preliminary contentions suggest to a reasonable reader that Liquidia was contending that the doctrine of issue preclusion applied to estop UTC from litigating the validity of all of the asserted claims of the '066 and '901 patents.

Liquidia served supplemental invalidity contentions on September 28, 2021. Liquidia's supplemental contentions are 265 pages long, not including a 12-page table of contents. In its supplemental contentions, Liquidia referred to the doctrine of issue preclusion and contended that UTC was "precluded" from relitigating the narrow issue of whether a person of skill in the art would have been motivated to combine two prior art references, Moriarty and Phares, because it had litigated and lost that issue in the '393 IPR.⁷ Liquidia also reiterated its earlier contention that the

⁵ Liquidia did refer the '393 IPR in its pleading, but only in the context of its counterclaims for "improper patent listing" of the '066 and '901 patents.

⁶ (D.I. 303, Ex. 42 at 115–19.)

⁷ (D.I. 303, Ex. 43 at 49–50, 114–15.)

'393 IPR was evidence that the asserted claims were “not directed to novel and nonobvious products” without referring to or even suggesting that issue preclusion would estop UTC from contesting the ultimate question of validity.⁸

The deadline to amend pleadings was June 4, 2021. Fact discovery closed on September 17, 2021. Expert reports were due on October 15, November 12, and December 10, 2021.

In the middle of the expert report phase of the case, on November 2, 2021, Liquidia requested leave to file a motion for summary judgment of invalidity of the product-by-process claims in the '066 and '901 patents on the theory that UTC is estopped from relitigating their validity because they claim the same product as the '393 patent claims that the PTAB found invalid in the '393 IPR. The Court granted Liquidia's request for leave on December 14, 2021. Liquidia filed the pending summary judgement motion on January 7, 2022, and briefing was complete on February 11, 2022. The Court referred the motion to me on February 14, 2022. Trial begins in less than three weeks, on March 28, 2022.

In the pending motion, Liquidia argues that, as a result of the PTAB's finding that the '393 product-by-process claims are invalid, UTC is precluded from litigating the validity of the asserted product-by-process claims in the '066 and '901 patents,⁹ as well as the process claims.¹⁰ UTC makes a number of arguments as to why issue preclusion should not apply here. I agree with at least two of them, so I recommend that Liquidia's motion be denied.

First, I agree with UTC that Liquidia did not timely raise its issue preclusion argument. Issue preclusion is an affirmative defense that must be pleaded.¹¹

Liquidia filed its responsive pleading in 2020—three years after the '393 IPR was affirmed by the Federal Circuit—but that pleading does not mention or suggest collateral estoppel or issue preclusion. Nor does the record before me reflect that Liquidia gave

⁸ (D.I. 303, Ex. 43 at 161–68.)

⁹ Claims 1–3, 6, and 9 of the '066 patent and 1–4 and 8 of the '901 patent.

¹⁰ Claim 8 of the '066 patent and claim 6 of the '901 patent.

¹¹ Fed. R. Civ. P. 8(c); *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 350 (1971).

fair notice of its preclusion theory as to the product-by-process claims, in its contentions or otherwise, before raising it for the first time in its request for leave to file a summary judgment motion in November 2021, just after the close of fact discovery. Liquidia did not raise its preclusion theory as to the process claims until January 2022, just over two months before trial.

Liquidia has not demonstrated good cause to amend its pleadings now.¹² Nor has it shown good cause to move for summary judgment of invalidity on a basis not fairly raised in its contentions. And I agree with UTC that permitting Liquidia to raise this issue at this late stage would be unfair to UTC. For example, it would deprive UTC of an opportunity to develop additional evidence to respond to Liquidia's estoppel arguments. In so concluding, I recognize that the question of issue preclusion is a legal determination. But it is a legal determination that rests on underlying facts, some of which UTC disputes and did not have a fair chance to develop.¹³

I also recognize that the Court has discretion to permit a defendant to raise an unpleaded affirmative defense by motion if the relevant legal and factual issues were raised early enough to give the plaintiff a fair chance to respond.¹⁴ To be clear, I recognize that the Court has that discretion, but I recommend declining to exercise it because I cannot say on this record that UTC was not prejudiced by Liquidia raising this issue so late.

¹² Fed. R. Civ. P. 16(b)(4); *E. Minerals & Chems. Co. v. Mohan*, 225 F.3d 330, 340 (3d Cir. 2000). The court-ordered deadline for amendments was June 4, 2021. (D.I. 20.)

¹³ *Blonder-Tongue*, 402 U.S. at 333; *Westwood Chem., Inc. v. United States*, 525 F.2d 1367, 1375 (Ct. Cl. 1975) (citing *Graham v. John Deere Co.*, 383 U.S. 1 (1966)); *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013) (citing *Westwood Chem.* with approval). UTC correctly points out that some of the facts underlying issue preclusion differ from the typical issues underlying validity. (Tr __.) For example, Liquidia's theory of issue preclusion depends on how a person skilled in the art would understand the language of the invalidated claims of the '393 patent and whether the different claim language used by the '066 and '901 patents would result in structural or functional differences from the prior art that were not considered in the '393 IPR.

¹⁴ *Corteau v. United States*, 287 F. App'x 159, 161 (3d Cir. 2008) (quoting *Charpentier v. Godsil*, 937 F.2d 859, 864 (3d Cir. 1991)). The Court did grant Liquidia leave to file its motion for summary judgement, but in doing so it did not decide whether raising issue preclusion so late in the case was procedurally proper. (D.I. 267.)

I also note that, given the late hour at which Liquidia presented its motion, I don't see how issue preclusion effectively accomplishes the goals of conserving judicial resources or preventing unfair burden. Having carefully reviewed the record, I am confident that the Court's consideration of Liquidia's issue preclusion theory is at least as great of an expenditure of judicial resources as trying the issue of validity. And Liquidia has saved no appreciable burden by making this motion after it has already litigated to the eve of trial.

There is a second independent reason that I recommend denying Liquidia's motion: Liquidia cannot demonstrate that the rules of issue preclusion permit its application here.

As an initial matter, there is no dispute that issue preclusion can apply to the decision of an administrative agency such as the PTAB.¹⁵ But issue preclusion only applies if the ordinary elements are met, and the rules restricting its application must be "carefully observed."¹⁶ One element that must be shown is that the "issue sought to be precluded is the same as that involved in the prior action."¹⁷ However, it is black letter law that issue preclusion does not apply if the party seeking preclusion has a significantly heavier burden of proof on that issue in the second action than they did in the first.¹⁸

¹⁵ *B & B Hardware, Inc. v. Hargis Indus., Inc.*, 575 U.S. 138, 148 (2015).

¹⁶ *Id.* at 148, 153.

¹⁷ *Karns v. Shanahan*, 879 F.3d 504, 514 n.3 (3d Cir. 2018) (cleaned up); *Soverain Software LLC v. Victoria's Secret Direct Brand Mgmt., LLC*, 778 F.3d 1311, 1314–15 (Fed. Cir. 2015) (holding that regional circuit law governs issue preclusion except on "issues . . . that implicate substantive patent law," but recognizing that Federal Circuit precedent requires "identity of issues in a prior proceeding").

¹⁸ *Grogan v. Garner*, 498 U.S. 279, 284–85 (1991) (explaining that an issue proved by a preponderance of the evidence in one proceeding could not preclude relitigation of the issue in later proceedings that required proof by clear and convincing evidence); *In re Braen*, 900 F.2d 621, 624 (3d Cir. 1990) ("[D]isparate burdens of proof foreclose application of the issue preclusion doctrine."); Restatement (Second) of Judgments § 28(4) (Am. Law Inst. 1982) ("Although an issue is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment, relitigation of the issue in a subsequent action . . . is not precluded [where] . . . (4) the [party seeking preclusion] has a significantly heavier burden than [they] had in the first action"); see *id.* at cmt. f; 18 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 4422 (3d ed. 1998) ("Preclusion also has been denied when a party who

Liquidia contends that the product-by-process claims at issue in this case claim the same “product” as the ’393 patent claims, which were found invalid by the PTAB in the ’393 IPR (later affirmed by the Federal Circuit). Liquidia also contends that other findings made by the PTAB in the ’393 IPR give rise to issue preclusion that results in invalidation of the process claims.

I will assume, for purposes of the argument only, that (1) there are no “patentably significant”¹⁹ differences between the ’393 product-by-process claims on the one hand, and the ’066 and ’901 product-by-process claims on the other; and (2) the PTAB made other findings on issues relevant to the obviousness of the process claims of the ’066 and ’901 patents.

Even if those were true, the problem for Liquidia is that the PTAB made its findings on a preponderance of the evidence standard,²⁰ and Liquidia must prove invalidity in this case by clear and convincing evidence.²¹ The upshot is that, even if the PTAB made findings on issues identical to issues being litigated here, those findings cannot be given preclusive effect in this case. For that independent reason, Liquidia’s motion should be denied.

Liquidia points out that the PTAB’s decision was affirmed by the Federal Circuit. But all that means is that the Federal Circuit concluded that the PTAB’s factual findings were supported by

has proved an issue by a preponderance of the evidence later must prove the same issue by a higher standard.”).

The Federal Circuit and the Supreme Court “regularly turn[] to the Restatement (Second) of Judgments for a statement of the ordinary elements of issue preclusion.” *B & B*, 575 U.S. at 148 (citing, *inter alia*, Restatement (Second) of Judgments § 28); *see also, e.g., Medtronic, Inc. v. Mirowski Fam. Ventures, LLC*, 571 U.S. 191, 200 (2014) (citing Restatement (Second) of Judgments § 28(4) for the proposition that differences in the burden of proof may prevent issue preclusion); *Power Integrations, Inc. v. Semiconductor Components Indus., LLC*, 926 F.3d 1306, 1312 (Fed. Cir. 2019) (citing Restatement (Second) of Judgments § 28); *Soverain Software*, 778 F.3d at 1316 (same).

¹⁹ *Ohio Willow Wood*, 735 F.3d at 1343.

²⁰ *See, e.g., ’393 IPR* at 3 (“We hold that SteadyMed has demonstrated by a preponderance of the evidence that claims 1–22 are unpatentable under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a).”); 35 U.S.C. § 316(e) (“In an [IPR], the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.”).

²¹ *Microsoft Corp. v. i4i LP*, 564 U.S. 91, 97 (2011).

substantial evidence.²² The Federal Circuit did not make any findings by clear and convincing evidence. Nor could it, because the Federal Circuit is not a fact-finding body.

At oral argument, Liquidia cited to the Federal Circuit's opinion in *XY, [LLC] v. Trans Ova Genetics*.²³ Liquidia suggested that *XY* stands for the proposition that, after the Federal Circuit affirms an IPR, issues decided by the PTAB should be given preclusive effect in a district court litigation, even if that litigation involves different patents and different burdens.

I disagree. In *XY*, the Federal Circuit stated that its affirmance of a PTAB IPR decision invalidating a patent had “immediate issue-preclusive effect on any pending or co-pending actions involving *the patent*” in district court.²⁴ The result of that case means that a patentee who gets his patent invalidated in an IPR that is later affirmed by the Federal Circuit cannot go around suing people on *that patent* in district courts. It's unclear to me that the Federal Circuit needed to invoke the doctrine of issue preclusion to reach that commonsense result since the [America Invents Act] already says that the [Patent and Trademark Office] Director must cancel any claim of a patent invalidated by an affirmed IPR.²⁵

Putting that aside, even if *XY* stands for the proposition that there is an exception to the ordinary requirements of issue preclusion for specific claims invalidated by the PTAB and affirmed on appeal, there is no reason that such an exception would apply to a case like this, where different patents are asserted in the district court than were at issue in the IPR.

²² See *In re Nuvasive, Inc.*, 842 F.3d 1376, 1379 (Fed. Cir. 2016) (“We review the PTAB’s factual determinations for substantial evidence and its legal determinations de novo”).

²³ 890 F.3d 1282, 1294 (Fed. Cir. 2018)

²⁴ 890 F.3d at 1294 (emphasis added). The question of issue preclusion was raised *sua sponte* by the court and was decided by a split panel without briefing and without any discussion of the elements or rules governing issue preclusion. *Id.* at 1294, 1300 (Newman, J., dissenting in part).

²⁵ 35 U.S.C. § 318(b); *In re Papst Licensing GmbH & Co. KG Pat. Litig.*, 320 F. Supp. 3d 132, 134 (D.D.C. 2018) (“If the PTAB finds that a claim is unpatentable, and the patent holder fails to file a timely appeal or the appeal is unsuccessful, then the PTO is required to issue a certificate cancelling the claim, and the patent holder may no longer assert that claim in litigation or otherwise.”).

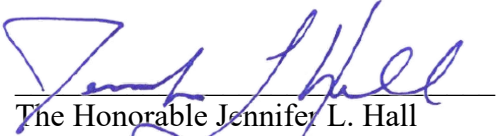
I want to be very clear that the only rule I am talking about is the rule that disparate burdens of proof foreclose application of issue preclusion. That is a completely different issue than the issue presented in the *Ohio Willow Wood* case cited by Liquidia.²⁶ In that case, the Federal Circuit considered the circumstances under which a district court decision invalidating the claims of one patent could operate to preclude the patentee from litigating the validity of similar claims in a different patent. There was no disparity in burdens of proof in that case. And nothing in that case suggested that the ordinary rules of issue preclusion do not apply to patent validity determinations.

In concluding that issue preclusion does not apply, I do not comment in any way on the validity of the asserted claims. Of course, the Court might find at the upcoming trial that the claims asserted in this case are invalid for the same reasons the PTAB found that the '393 patent claims were invalid (subject to any statutory estoppel that might apply against Liquidia [under 35 U.S.C. § 315(e)(2)])—if Liquidia carries its burden to show invalidity by clear and convincing evidence. All I'm saying is that issue preclusion does not compel that result.

III. CONCLUSION

For those reasons, I recommend that Defendant Liquidia's motion (D.I. 281) be DENIED.

Dated: March 18, 2022


The Honorable Jennifer L. Hall
UNITED STATES MAGISTRATE JUDGE

²⁶ *Ohio Willow Wood*, 735 F.3d at 1342–43.