

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

UNITED THERAPEUTICS  
CORPORATION,

Plaintiff,

v.

LIQUIDIA TECHNOLOGIES, INC.,

Defendant.

Civil Action No. 20-755-RGA

MEMORANDUM ORDER

Before me is Liquidia’s motion to modify the portion of the final judgment that blocks the final approval of New Drug Application (“NDA”) No. 213005 until the expiration of U.S. Patent No. 10,716,793 (“the ’793 patent”). (D.I. 461).<sup>1</sup> The motion has been fully briefed. (D.I. 462, 465, 466). I have considered the parties’ supplemental letters. (D.I. 470, 471, 474, 475, 477, 478).

For the reasons set forth below, I will GRANT Liquidia’s motion.

**I. BACKGROUND**

After a bench trial in March 2022 related to Liquidia’s NDA, I found that the five asserted claims of the ’793 patent had not been proven invalid for lack of enablement or lack of written description. (D.I. 433 at 37–53). I also found those five claims to be infringed. I duly entered a final judgment. Paragraph 4 of the final judgment states, “the effective date of any

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<sup>1</sup> UTC also filed a motion for leave to file a two-page sur-reply. (D.I. 468). UTC’s proposed sur-reply addresses arguments in Liquidia’s reply brief about a joint stipulation of dismissal in a related case before this Court. (*See generally* D.I. 468-1). Liquidia filed an opposition. (D.I. 469).

final approval by the FDA of [the NDA] shall be a date which is not earlier than the expiration date of the '793 patent.” (D.I. 436 at 2).

Both parties appealed the final judgment. The Federal Circuit affirmed my decision and issued a mandate in October 2023. (D.I. 453). On February 20, 2024, the Supreme Court denied Liquidia’s petition for a writ of certiorari. (*See* D.I. 470-1 at 2–3 of 5).

Prior to the entry of the final judgment, the Patent Trial and Appeal Board invalidated the same claims as obvious. (*See* D.I. 425-1). A rehearing decision in February 2023 again invalidated the asserted claims as obvious. (D.I. 450-1). The Federal Circuit affirmed the PTAB’s decision in December 2023. (D.I. 462-1). On March 12, 2024—after the present motion was fully briefed—the Federal Circuit denied UTC’s requests for panel rehearing and rehearing en banc. (D.I. 474-1). The Federal Circuit’s mandate issued on March 19, 2024. (D.I. 477-1). UTC states that it intends to file a petition for a writ of certiorari. (*See* D.I. 475).

## **II. LEGAL STANDARD**

Federal Rule of Civil Procedure 60(b) empowers district courts to vacate judgments for several specified reasons. The rule, in relevant part, provides:

[T]he court may relieve a party or its legal representative from a final judgment, order, or proceeding for the following reasons: . . . (5) the judgment has been satisfied, released, or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable; or (6) any other reason that justifies relief.

Fed. R. Civ. P. 60(b). “Because rulings under Rule 60(b) commonly involve procedural matters unrelated to patent law issues as such, [the Federal Circuit] often defer[s] to the law of the regional circuit in reviewing such rulings.” *Fiskars, Inc. v. Hunt Mfg. Co.*, 279 F.3d 1378, 1381 (Fed. Cir. 2002).

“The general purpose of Rule 60(b) . . . is to strike a proper balance between the conflicting principles that litigation must be brought to an end and that justice must be done.” *Coltec Indus., Inc. v. Hobgood*, 280 F.3d 262, 271 (3d Cir. 2002) (alteration in original) (quoting *Boughner v. Sec’y of Health, Educ. & Welfare*, 572 F.2d 976, 977 (3d Cir. 1978)). The Third Circuit instructs, “[C]ourts are to dispense their broad powers under [Rule] 60(b)(6) only in ‘extraordinary circumstances where, without such relief, an extreme and unexpected hardship would occur.’” *Cox v. Horn*, 757 F.3d 113, 120 (3d Cir. 2014) (quoting *Sawka v. Healtheast, Inc.*, 989 F.2d 138, 140 (3d Cir. 1993)).

### **III. DISCUSSION**

Liquidia argues that relief under Rule 60(b)(5) is warranted because the legal basis for this Court’s injunction ceased to exist when the Federal Circuit determined that the asserted claims are invalid. (D.I. 462 at 5–6). Liquidia alternatively seeks relief under Rule 60(b)(6), arguing that a ruling of patent invalidity qualifies as an extraordinary circumstance. (*Id.* at 6–7). Liquidia contends that continued enforcement of the final judgment would be inequitable and detrimental to the public interest. (*Id.* at 7–8).

UTC argues that “the purported ‘injustice’ Liquidia seeks to prevent is a problem of its own making.” (D.I. 465 at 5–6). UTC contends Liquidia sought “an improper procedural shortcut” by splitting its invalidity arguments between this Court and the PTAB. (*Id.* at 6). UTC further argues that Liquidia’s motion is premature because the judgment should not be modified until the claims of the ’793 patent are canceled. (*Id.*). Citing 35 U.S.C. § 318, UTC argues that the PTO will only issue a certificate canceling claims after “any appeal has terminated.” (*Id.* at 7). UTC contends, “[T]he ’793 patent cannot be canceled until after UTC has an opportunity to

petition for rehearing, the Federal Circuit issues its mandate, and all appeals terminate.” (*Id.* at 10).

I think Liquidia has established that it is entitled to post-judgment relief. After the PTAB invalidated the asserted claims of the ’793 patent, the Federal Circuit affirmed the PTAB’s decision, denied UTC’s requests for rehearing, and issued a mandate on March 19, 2024. (*See* D.I. 425-1, 450-1, 462-1, 474-1, 477-1). “That affirmance renders final a judgment on the invalidity of the [asserted claims], and has an *immediate* issue-preclusive effect on any pending or co-pending actions involving the patent.” *XY, LLC v. Trans Ova Genetics*, 890 F.3d 1282, 1294 (Fed. Cir. 2018) (emphasis added). Because “an affirmance of an invalidity finding, whether from a district court or the [PTAB], has a collateral estoppel effect on” the present case, Liquidia is entitled to modification of the final judgment. *Id.*; *see also Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 721 F.3d 1330, 1344 (Fed. Cir. 2013) (“[T]here is no basis for distinguishing between the effects of a final, affirmed court decision determining invalidity and a final, affirmed PTO decision determining invalidity on a pending litigation.”).

UTC argues that “the final judgment does not include an equitable injunction but relief prescribed by statute.” (D.I. 465 at 9). UTC contends, “That statutory remedy should not be set aside before such time, if ever, that the ’793 claims are canceled.” (*Id.* at 8). Citing 21 U.S.C. § 355(j)(7)(D), UTC further contends that the ’793 patent “will remain listed in the Orange Book until any actual ‘cancellation’ of patent claims or invalidation by a court ‘from which no appeal has been, or can be, taken.’” (*Id.*). Liquidia argues that Rule 60(b) applies equally to statutory-based injunctions. (D.I. 466 at 4). UTC is correct that the injunction at issue is a statutory remedy. I do not think this matters. The underlying act of infringement that warranted relief under 35 U.S.C. § 271(e)(4)(A) is no longer a basis for relief due to the invalidation of the ’793

patent. In other words, while the statute states that courts “shall” issue an injunction under the applicable circumstances, the statute requires an infringed patent in the first place. Invalid patents cannot be infringed.

UTC’s intent to file a petition for a writ of certiorari does not disturb that conclusion. I am also unpersuaded by UTC’s contention that the final judgment cannot be modified until the PTO cancels the asserted claims. The cases UTC relies on (*see* D.I. 465 at 6–10) do not require courts to wait for claim cancellation, which is generally “a nondiscretionary formality.” *See Sec. People, Inc. v. Iancu*, 971 F.3d 1355, 1361 (Fed. Cir. 2020) (“Issuing the certificate of cancellation is a nondiscretionary formality: the PTO is statutorily compelled to ‘publish a certificate canceling any claim of the patent finally determined to be unpatentable’ in a final written decision.” (quoting 35 U.S.C. § 318(b))).

I will therefore vacate the portion of the final judgment that blocks the final approval of Liquidia’s NDA.

#### **IV. CONCLUSION**

For the reasons discussed above, I GRANT Liquidia’s motion for post-judgment relief. (D.I. 461). Paragraphs 3 and 4 of the final judgment (D.I. 436) are hereby VACATED. I will enter an amended judgment. UTC’s motion for leave to file a two-page sur-reply (D.I. 468) is DISMISSED as moot.

IT IS SO ORDERED.

Entered this 28<sup>th</sup> day of March, 2024.

/s/ Richard G. Andrews  
United States District Judge