

**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 for a stay of enforcement of Paragraph 4 of the final judgment pending appeal. (D.I. 438).

After a bench trial in March 2022 relating to Liquidia’s New Drug Application (“NDA”) No. 213005, I found that the five asserted claims of U.S. Patent No. 10,716,793 (“the ’793 patent”) had not been proven invalid for lack of enablement or lack of written description. (D.I. 433 at 37–53). Since 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 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). The expiration date is said to be in 2027.

My decision and the entry of the final judgment occurred after the Patent Trial and Appeal Board invalidated those same claims as obvious. (D.I. 425). While my decision was still pending, the parties submitted letters for and against staying my decision. (D.I. 427, 428, 431). I decided that I would not stay my decision. (D.I. 432).

Both parties appealed the final judgment. The Federal Circuit recently affirmed the final judgment, issuing its mandate on October 3, 2023. (D.I. 453).

Litigation before the PTAB continued as well, resulting in a rehearing decision on February 2, 2023, again invalidating the asserted claims as obvious. (D.I. 450). That decision was appealed in No. 23-1805. The Federal Circuit heard oral argument on December 4, 2023. (See D.I. 458 at 1; D.I. 459 at 2). If the Federal Circuit upholds the invalidity of the asserted '793 claims as obvious, it appears that Liquidia could launch its product. (See D.I. 439 at 8 (FDA tentative approval given in 2021); D.I. 442 at 2).

Liquidia filed the present motion to stay enforcement of paragraph 4 of the final judgment pending appeal. (D.I. 438). The motion has been fully briefed. (D.I. 439, 442, 444).<sup>1</sup> No one has treated the pending motion as being urgent.

The parties dispute whether I have the power to stay enforcement of Paragraph 4. (D.I. 442 at 3–8; D.I. 444 at 1–3). Liquidia relies on a per curiam order from 2014 to say the Federal Circuit has done it before, so I have the power. (See D.I. 444 at 1). Liquidia also relies on a decision from the District of Delaware, which also did it before (*see id.* at 2), but that decision did not address the issue. I am inclined to think I have the power to stay my own orders unless some express law says I do not. Here, there is no such express law. I thus conclude I have the power to stay the order.

Since I have the power, I consider what the parties refer to as the *Hilton* factors.<sup>2</sup> The first, and here the most important, is the likelihood of success on the merits. Liquidia has not

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<sup>1</sup> I have also considered the parties' notices of subsequent authority (D.I. 449, 450) and recent letters (D.I. 458, 459).

<sup>2</sup> Four factors guide the stay analysis: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured

demonstrated that there is a likelihood of success on the merits of its IPR appeal. To be clear, I am not saying that there is not a likelihood of success on the merits of the appeal. I am merely saying Liquidia has to demonstrate that in its motion. It does not.

Liquidia states that there is a likelihood of success that the PTAB decision invalidating the asserted '793 patent claims will be upheld by the Federal Circuit. (D.I. 439 at 5–8). The parties argue about the extent to which that is a relevant factor. (See D.I. 442 at 9–12; D.I. 444 at 3–5). I do not think, at least under the facts of this case, that it is a relevant factor. The IPR is a separate proceeding. I am unfamiliar with the record and the issues in that case, and I have no basis on which to evaluate the likelihood of success of Liquidia's appeal of the PTAB's ruling. I do not think the fact that the IPR winner—here, Liquidia—wins three-quarters of the time in the Federal Circuit gives me any insight into the likelihood of Liquidia's success on the merits here. I do not think judges should be granting or denying stays and injunctions based on averages.

Thus, because Liquidia has not shown a probability of success on the merits, I do not have to consider the other *Hilton* factors. The motion for a stay (D.I. 438) is **DENIED**.

IT IS SO ORDERED.

Entered this 15<sup>th</sup> day of December, 2023

  
United States District Judge

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absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.” *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990) (quoting *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987)).