

FEDERAL CIRCUIT SUMMARY FOR WEEK ENDING JULY 28, 2023**United Therapeutics Corporation v. Liquidia Technologies, Inc., No. 2022-2217, 2023-1021 (July 24, 2023) (precedential) (3-0); Patent Nos. 10,716,793; 9,593,066****Key point(s):**

- An IPR decision does not have collateral estoppel effect until that decision is affirmed or the parties waive their appeal rights.
- A product-by-process claim is a product claim, even if claimed by a process by which it can be made.

Facts/Background: United Therapeutics sued Liquidia for infringement of two patents related to methods and compositions for treating pulmonary hypertension. Regarding the first patent, the district court found all claims infringed while the Patent Trial and Appeal Board, in a parallel IPR proceeding found all claims of the same patent unpatentable as obvious. Regarding the second patent, the district court held that certain claims were invalid as anticipated (but otherwise infringed) while other claims were invalid and/or not infringed. Liquidia appealed and United Therapeutics cross-appealed.

Holding: Affirmed. On appeal, Liquidia first argued that the district court erred by construing the term “treating pulmonary hypertension” not to require a showing of safety and efficacy. The Federal Circuit disagreed, stating that nothing in the patent specification required importing safety and efficacy limitations into the claims. Further, the Federal Circuit explained that questions of safety and efficacy fall under the purview of the FDA and the court refused to import those requirements where the claims do not recite such limitations. Liquidia also argued that it could not be liable for infringement because the Board had found the claims to be unpatentable in an IPR. The Federal Circuit disagreed, stating that “an IPR decision does not have collateral estoppel effect until that decision is affirmed or the parties waive their appeal rights.” Because the Board’s decision was still pending on appeal, the appellate court ruled that the decision “has no impact” on the question of infringement. Regarding United Therapeutics’s cross-appeal, the Federal Circuit ruled that the district court did not clearly err in finding certain product-by-process claims invalid as anticipated. The court explained that “a product-by-process claim is a product claim, even if claimed by a process by which it can be made.” Here, because “these claims are product claims, they are anticipated by a disclosure of the same product irrespective of the processes by which they are made.”