# COLLATERAL ESTOPPEL OF PTAB DECISIONS IN THE WAKE OF *UNITED THERAPEUTICS CORP. V. LIQUIDIA TECH., INC.*

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## TABLE OF CONTENTS



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## I. INTRODUCTION

America continues to be at the forefront of innovation, pioneering new technological and scientific inventions throughout its history. Indeed, America's innovative drive is heavily bolstered by its robust patent system, which was established by Congress to "promote the Progress of Science and useful Arts," as mandated by the Constitution.[1] But critical to maintaining this patent system is an equally robust litigation system to balance promoting innovation and defending already established intellectual property.

Congress has long recognized the patent system's role in encouraging innovation, and, in 2011, passed the America Invents Act (AIA)[2] to further improve patent issuance and litigation.[3] In particular, the AIA established the Patent Trials and Appeals Board (PTAB) within the United States Patent and Trademark Office (USPTO).[4] Congress intended for the PTAB to serve as a cost-efficient alternative to the "excessively expensive" district court litigation process by providing an adjudicative process to reexamine the validity of granted patents.[5] But when the resulting post-AIA patent litigation system

1. U.S. CONST. art. I, § 8, cl. 8.
2. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).
3. *Id.*
4. *Id.*
5. *Patent Quality Improvement: Post-Grant Opposition: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Prop. of the H. Comm. on the Judiciary*, 108th Cong. 29 (2004) (statement of Michael Kirk, Executive Director, AIPLA).

allows for a court to hold that a party has infringed a patent that the PTAB has already invalidated, that does not follow with Congress's intent or the Constitution's mandate to promote the Progress of the useful Arts.

The current post-AIA patent litigation system often involves two parallel proceedings in which parties to a case may opt to simultaneously litigate certain causes of action before the PTAB and others in district court. This parallel system arises primarily because the PTAB's primary reexamination proceeding, the *inter partes* review (IPR), is a litigative process limited only to the technical aspects of a patent's validity.[6] However, collateral estoppel doctrine, which prevents parties from relitigating issues that courts have already ruled on, is insufficient in reconciling cases where a district court and an adjudicative administrative agency issue differing rulings in parallel. In the Federal Circuit's recent decision in *United Therapeutics Corp. v. Liquidia Technologies, Inc.*, the court held that PTAB decisions lack collateral estoppel effect until affirmed on appeal.[7] As a result of this decision, the district court held Liquidia liable for infringing a patent that the PTAB had found to be invalid.[8] This decision leaves future litigating parties uncertain as to whether they may fully rely on PTAB litigation as an alternative to district court litigation, which contradicts Congress's intent in passing the AIA.

This Note explores a combination of reforms to resolve this uncertainty surrounding the efficacy of PTAB litigation. In particular, this Note proposes amending the Federal Circuit's Rules of Practice to safeguard future parties from potentially confusing outcomes like the one Liquidia faced, and advocates for legislative reform in Congress to stress that rulings from administrative agencies such as the PTAB should have a collateral estoppel effect similar to that of district court decisions.

Part II of this Note provides background on the history of the administrative reexamination process for patents and the legal framework of collateral estoppel in the context of administrative agencies. Part III discusses *United Therapeutics* in detail, including its ramifications on the current patent litigation system. Part IV proposes a solution to the collateral estoppel issue raised in the wake of *United Therapeutics*. Part V briefly concludes.

6. *See* 35 U.S.C. § 311.

7. United Therapeutics Corp. v. Liquidia Techs., Inc., 74 F.4th 1360, 1363 (Fed. Cir. 2023) [hereinafter *United Therapeutics*].

8. United Therapeutics Corp. v. Liquidia Techs., Inc., 2023 WL 8794633, at *1 (Fed. Cir. Dec. 20, 2023).

## II. THE EVOLUTION OF PARALLEL PATENT LITIGATION DOCTRINE

Accused patent infringers commonly assert both a defense of non-infringement and a separate defense of invalidity. Defendants claiming an invalidity defense, which is at issue in *United Therapeutics*, argue that the asserted patent is not valid and, therefore, could not have been enforceable in the first place.[9] While non-infringement causes of action remain in district court, invalidity causes of action may be split between different forums, even within the same pending case.[10] In particular, the PTAB can only hear arguments regarding a patent's validity based on its technical aspects in comparison to the prior art (i.e., anticipation and obviousness), whereas district courts can hear any invalidity cause of action, including anticipation and obviousness.[11] Consequently, multiple venues may simultaneously hear arguments about certain aspects of a single patent's validity—this is known as parallel litigation.[12]

Because Congress established the PTAB to relieve the burden on district courts and provide parties with a more cost-efficient alternative for challenging a patent's validity, incentives are in place to encourage PTAB litigation, such as a lower standard of review or a defined timeline of twelve to eighteen months to issue a final written decision.[13] As a result, parallel patent litigation has increased post-AIA, raising a key issue: What happens when both venues rule in the same timeframe with opposing outcomes? This Part describes the history of reexamination proceedings in the USPTO and explores the legal background of how courts have previously applied collateral estoppel to administrative proceedings, including PTAB proceedings.

Section II.A includes the evolution of reexamination proceedings in the USPTO, including the significant overhaul introduced in the America Invents Act (AIA). Section II.B discusses how courts define the relationship between

9. *See generally* MaxLinear, Inc. v. CF CRESPE LLC, 880 F.3d 1373, 1376 (Fed. Cir. 2018) ("[A] judgment of invalidity in one patent action renders the patent invalid in any later actions based on the same patent." (internal quotations omitted)).

10. *See generally* Drink Tanks Corp. v. Growlerworks, Inc., No. 3:16-cv-410-SI, 2016 WL 3844209, at *2 (D. Or. July 15, 2016) (considering whether to stay district court proceedings while a parallel IPR for the same patent was being decided in the PTAB); Surfcast, Inc. v. Microsoft Corp., No. 2:12-cv-333-JDL, 2014 WL 6388489, at *2 (D. Me. Nov. 14, 2014) (same).

11. *See* 35 U.S.C. § 311.

12. Jason E. Stach & Benjamin A. Saidman, *Maximizing the Likelihood of a Litigation Stay Pending Inter Partes Review*, FINNEGAN (Sep./Oct. 2016), https://www.finnegan.com/en/insights/articles/maximizing-the-likelihood-of-a-litigation-stay-pending-inter.html ("IPRs often occur in parallel with district court patent litigation on the same patent . . . .").

13. Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part II of II*, 21 FED. CIR. B.J. 539, 627; *see* 35 U.S.C. § 316(a)(11), (e).

invalidity and infringement causes of action in patent litigation. Section II.C introduces the principle of collateral estoppel and its subsequent application by the courts. This Section then analyzes how the Federal Circuit has applied collateral estoppel effect to PTAB-issued decisions.

## A. *INTER PARTES* REVIEW

The IPR system, one of the keynote features in the AIA, was established by Congress to serve as a cost-efficient alternative to district court litigation.[14] IPRs are administrative adjudications conducted by the PTAB in the USPTO.[15] This Section first explores both the history and the shortcomings of prior reexamination proceedings in the USPTO. It then examines the incentives and advantages in place to encourage parties to pursue IPRs. Finally, this Section discusses the estoppel provisions currently in place for IPR proceedings.

### *1. Reexamination Proceedings in the USPTO*

In the preceding decades before the AIA, Congress had granted the USPTO the power to reexamine the validity of issued patents.[16] The USPTO may need to reexamine issued patents because, for example, new prior art could emerge and undermine a patent's validity, or an examiner could have mistakenly allowed a patent. In 1980, Congress established the first reexamination proceeding in the USPTO—*ex parte* reexamination.[17] Congress then reinforced the USPTO's standing to reexamine and potentially invalidate patents in 1999, by establishing an *inter partes* reexamination procedure.[18] Generally, however, both procedures were costly and slow, leading parties to opt for litigation in district court instead.[19]

In 2011, the AIA introduced a series of reforms to modernize the U.S. patent system.[20] Among other legislative reforms, Congress aimed to reform the then highly expensive, inefficient, and rarely used USPTO reexamination procedures.[21] Moreover, Congress intended for the AIA to establish a "more

14. Matal, *supra* note 13, at 627; *see* 35 U.S.C. §§ 311–318.

15. U.S. PAT. & TRADEMARK OFF., INTER PARTES DISPUTES (2012).

16. *See* 35 U.S.C. §§ 301–307.

17. *See id.*

18. Peter S. Menell, *Patent Case Management Judicial Guide,* FED. JUD. CTR. 2-54 (3d ed. 2016).

19. *Id.*

20. *See* 35 U.S.C. §§ 311–318.

21. H.R. REP. NO. 112-98, at 39–40 (2011) (stating that among the goals of the AIA were to "improv[e] patent quality and provid[e] a more efficient system for challenging patents that should not have issued" and to "limit unnecessary and counterproductive litigation costs.").

efficient and streamlined patent system" that would increase patent quality while limiting "unnecessary and counterproductive litigation costs."[22] As such, the AIA codified *inter partes* review (IPR) and established the PTAB within the USPTO to oversee this process.[23]

In particular, an IPR petitioner may only seek to cancel a patent's claims on the grounds that a patent should have been anticipated by the prior art or should have been obvious to a person of ordinary skill in the art in light of the prior art.[24] But this is only a portion of all invalidity proceedings a party may bring in a patent litigation suit in district court.

As described in 35 U.S.C. § 101, a valid patent must satisfy all of the "conditions and requirements" of Title 35 (i.e., novelty, nonobviousness, adequate disclosure, and written description, etc.).[25] A patent claim that fails the validity analysis under just one of these sections is rendered wholly invalid. Therefore, to fully assess a patent's validity, all invalidity arguments must be considered. Since IPR proceedings are limited to evaluating invalidity claims under § 102 (anticipation) and § 103 (obviousness), they cannot wholly address a patent's validity.[26]

Under 35 U.S.C. § 318(a), the PTAB is required to issue a "Final Written Decision" (FWD) with respect to the "patentability of any patent claim challenged" in an IPR (or *ex parte*) proceeding.[27] PTAB FWDs can be directly appealed to the Court of Appeals for the Federal Circuit.[28] For any patent claims held to be unpatentable in a PTAB FWD, 35 U.S.C. § 318(b) requires that the Director of the USPTO "issue and publish a certificate canceling any [such] claim[s]."[29]

A question arises from § 318(a) and § 318(b): When exactly is a PTAB decision final? Is the decision final when the FWD is issued by the PTAB, or when the USPTO Director cancels the claims? In 2020, the Federal Circuit definitively answered this question in *Sec. People, Inc. v. Iancu*, holding that the agency's decision-making process in an IPR "is complete after issuance of the final written decision."[30] The Federal Circuit ultimately reasoned that the certificate of cancellation mandated by 35 U.S.C. § 318(b) is "irrelevant to the

22. *Id.* at 40.
23. 35 U.S.C. §§ 311–318.
24. 35 U.S.C. § 311(b) (noting that "section[s] 102 or 103" refer to the anticipation and obviousness statues, respectively).
25. 35 U.S.C. § 101.
26. 35 U.S.C. § 311(b).
27. 35 U.S.C. § 318(a).
28. 35 U.S.C. § 141.
29. 35 U.S.C. § 318(b).
30. Sec. People, Inc. v. Iancu, 971 F.3d 1355, 1361 (Fed. Cir. 2020).

finality of the agency's action."[31] The court clarified that the Director's cancellation was a mere "nondiscretionary formality" because there is "no agency *decision-making*" involved in issuing the certificate.[32]

Today, the PTAB continues to reexamine patent validity as parties continue to petition for IPR proceedings. The next Section discusses why parties are incentivized to bring parallel litigation proceedings to the PTAB and explores why the IPR system has been growing in popularity for parties in patent litigation.

### *2. Why Parallel Litigation in the PTAB is Increasing in Popularity*

Because the PTAB only hears a subset of the possible invalidity causes of action—limited to whether the challenged patent was anticipated or rendered obvious by prior art (including patents and printed publications)—the current patent litigation scheme often involves parallel proceedings.[33] In this scheme, the defendant may split its invalidity causes of action between two tribunals.[34] For example, a common scenario may involve an accused infringer filing an IPR in the PTAB to invalidate the patent under § 102 or § 103, while simultaneously raising a non-infringement defense and other invalidity causes of action in district court.[35]

While litigating in multiple venues may seem burdensome, there are several advantages to bringing an IPR before the PTAB while defending an infringement suit in district court. First, under 35 U.S.C. § 316(e), IPR petitioners need only establish invalidity by a preponderance of the evidence.[36] This evidentiary standard is lower than the standard in district court, which requires clear and convincing evidence to establish invalidity.[37] Moreover, the patent statute defines the PTAB's decision timeline: 35 U.S.C. § 316(a)(11) requires that the final determination in an IPR be issued within one year of

31. *Id.* at 1361.

32. *Id.* (emphasis added).

33. *See* Stach & Saidman, *supra* note 12.

34. Katherine K. Vidal, Memorandum on the Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation (June 21, 2022), https://perma.cc/Z7GM-RC3F.

35. *Id.* (stating that the PTAB will not deny institution of an IPR if the petitioner stipulates that they will not assert the same invalidity grounds in the district court case (i.e., that each parallel forum will hear different invalidity arguments)).

36. 35 U.S.C. § 316(e).

37. Jeffrey A. Freeman & Jason E. Stach, *District Court or the PTO: Choosing Where to Litigate Patent Invalidity*, FINNEGAN (Mar./Apr. 2014), https://www.finnegan.com/en/insights/articles/district-court-or-the-pto-choosing-where-to-litigate-patent.html.

institution.[38] This timeline is much more predictable and well-defined than the timeline in district courts, which have discretion to move at their own pace.[39]

Since 2019, an average of roughly 1,200 IPR petitions have been filed yearly.[40] Of these petitioners, "about 80% or higher" have been sued in parallel by patent owners in another venue.[41] Thus, PTAB litigation (and subsequently, parallel litigation) is a popular choice for defendants in district court proceedings.

### B. HOW INVALIDITY AFFECTS INFRINGEMENT IN PATENT LITIGATION

Although the PTAB only reexamines a subset of patent validity actions and does not consider infringement actions at all, it still has a critical influence in patent litigation outcomes. A party sued for infringing a patent can completely avoid liability (whether they actually infringed or not) by proving that the asserted patent is invalid.

The Supreme Court emphasized this point in its 2015 decision in *Commil USA, LLC v. Cisco Systems, Inc.*, holding that when an act "would have been an infringement or an inducement to infringe pertains to a patent *that is shown to be invalid*, there is *no patent to be infringed*."[42] The Court repeatedly underscored that holding a patent invalid ultimately overrides whatever decision is reached in infringement proceedings and implied that a patent's validity should be decided before an infringement judgment is made.[43]

The Supreme Court then detailed the "various proper ways" to obtain a ruling of invalidity, with one of them being that the accused party "can seek *inter partes* review at the Patent Trial and Appeal Board and receive a decision as to validity."[44] If the accused infringer "is successful, he will be immune from liability."[45] However, *Commil* does not address parallel proceedings or what happens if an administrative agency (*e.g.*, the PTAB) and a district court issue differing decisions on patent invalidity.

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38. 35 U.S.C. § 316(a)(11).

39. FED. R. CIV. P. 40 advisory committee's notes to 2007 amendment ("The best methods for scheduling trials depend on local conditions. . . . It is not useful to limit or dictate the provisions of local rules.").

40. U.S. PAT. & TRADEMARK OFF., PTAB TRIAL STATISTICS FY23 END OF YEAR OUTCOME ROUNDUP (2023).

41. U.S. PAT. & TRADEMARK OFF., PATENT TRIAL AND APPEAL BOARD PARALLEL LITIGATION STUDY (2022).

42. *Commil USA, LLC v. Cisco Sys.*, 575 U.S. 632, 644 (2015) (emphases added).

43. *Id.* at 645.

44. *Id.*

45. *Id.*

### C. COLLATERAL ESTOPPEL AND ITS APPLICATION TO ADMINISTRATIVE AGENCY DECISIONS

Collateral estoppel (i.e., issue preclusion) is a judicial doctrine that prevents multiple claims from being brought on a singular issue once the issue has been litigated. The Restatement (Second) of Judgments, Section 27 provides the definition of collateral estoppel as follows:

> When an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment, the determination is conclusive in a subsequent action between the parties, whether on the same or a different claim.46

The Supreme Court has similarly long recognized that "the determination of a question directly involved in one action is conclusive as to that question in a second suit."[47] The Court iterated that the purpose of collateral estoppel was to protect against "the expense and vexation attending multiple lawsuits, conserv[ing] judicial resources, and foster[ing] reliance on judicial action by minimizing the possibility of inconsistent decisions."[48]

This Section begins by analyzing the Supreme Court's 2015 decision in *B & B Hardware, Inc. v. Hargis Industries, Inc.*, where the Court held that administrative agency decisions can have collateral estoppel effect.[49] This Section then explores how the Federal Circuit has applied collateral estoppel with respect to the PTAB and discusses how current collateral estoppel doctrine is inadequate in addressing the challenges posed by the parallel patent litigation system.

#### *1. B & B Hardware*

In 2015, the Supreme Court held in *B & B Hardware, Inc.* that collateral estoppel is "not limited to those situations in which the same issue is before two *courts*."[50] Here, Hargis attempted to register its trademark SEALTITE in the USPTO, but B & B Hardware opposed the registration before the Trademark Trial and Appeal Board (TTAB), arguing that it was too similar to its SEALTIGHT mark.[51] B & B Hardware then sued Hargis in district court, alleging, in parallel to the TTAB proceedings, that Hargis's use of SEALTITE amounted to trademark infringement of the SEALTIGHT mark.[52] In both

46. RESTATEMENT (SECOND) OF JUDGMENTS § 27 (A.L.I. 1980).
47. Cromwell v. Cnty. of Sac, 94 U.S. 351, 354 (1877).
48. Montana v. United States, 440 U.S. 147, 153–54 (1979).
49. *B & B Hardware Inc.*, 575 U.S. 138, 148 (2015).
50. *Id.*
51. *Id.* at 141.
52. *Id.*

proceedings, the tribunals considered whether a "likelihood of confusion" existed between the two marks as the legal standard.[53] So when the TTAB held that there was a likelihood of confusion and denied Hargis's registration, B & B Hardware argued to the district court that the TTAB's decision precluded Hargis from contesting likelihood of confusion in the then-pending district court litigation.[54]

The Supreme Court held that the TTAB's decision did have collateral estoppel effect, despite the two tribunals considering different factors when evaluating likelihood of confusion.[55] The Supreme Court referred to the Restatement (Second) of Judgments, Section 27, to define the ordinary elements of issue preclusion.[56]

In its reasoning, the Court addressed administrative agencies generally, even though the case pertained only to the TTAB. The Court reiterated its "longstanding view" that when an "administrative agency . . . act[s] in a judicial capacity and resolves disputed issues of fact properly before it," courts have "not hesitated to apply *res judicata* to enforce repose."[57] The Court stressed that "our precedent holds that the Seventh Amendment [providing the right to a jury trial] does not strip competent tribunals of the power to issue judgments with preclusive effect."[58] So long as the "ordinary elements of issue preclusion are met," courts should give preclusive effect to administrative agency decisions.[59] If the facts presented to the agency and the federal court are materially the same, and the other requirements of collateral estoppel are satisfied, "[i]ssue preclusion is available unless it is 'evident' [] that Congress does not want it."[60]

What remains unclear is whether the Court in *B & B Hardware* intended for its decision to apply to an administratively decided issue that arises while parallel district court litigation over the same issue is occurring under a *different* legal standard. In applying its reasoning, the Supreme Court critically consolidated the likelihood of confusion issue into a single legal standard across both tribunals.[61] However, modern patent litigation frequently involves a parallel scheme in which IPR proceedings occur before the PTAB while the

53. *Id.*
54. *See id.* at 154.
55. *Id.* at 141–42.
56. *Id.* at 148 (citing RESTATEMENT (SECOND) OF JUDGMENTS § 27).
57. *Id.* (quoting Univ. of Tenn. v. Elliott, 478 U.S. 788, 797–98 (1986)).
58. *Id.* at 150.
59. *Id.* at 141–42.
60. *Id.* at 153 (quoting Astoria Fed. Sav. & Loan Assn. v. Solimino, 501 U.S. 104, 108 (1991)).
61. *Id.* at 154.

same patents are simultaneously litigated in district court. As discussed in Section II.A.2, the PTAB applies a lower evidentiary standard than district courts.[62] Because this specific question was not at issue in *B & B Hardware*, the application of its rule to PTAB proceeding poses a unique question: What happens if a district court and the PTAB issue conflicting rulings on patent validity?

### 2. *Federal Circuit Holdings on the Collateral Estoppel Effect of PTAB Decisions*

Through a series of cases, the Federal Circuit has moved toward answering this question but has not definitely determined whether a PTAB ruling has collateral estoppel effect while pending appeal. In 2013, the Federal Circuit held in *Fresenius USA, Inc. v. Baxter International, Inc.* that "when a claim is cancelled, the patentee loses any cause of action based on that claim, and any pending litigation in which the claims are asserted becomes moot."[63] However, in the same decision, the Federal Circuit also underscored that this collateral estoppel effect cannot be used to "reopen a final damages judgment ending a suit based on those [patent] claims."[64]

As a result of *Fresenius*, parties litigating in parallel in district court and the PTAB have engaged in a race to final judgment.[65] It intuitively follows that a petitioner in an IPR proceeding would want to secure a final PTAB decision as quickly as possible. According to *Fresenius*, a final judgment of invalidity by the PTAB would immediately render the district court litigation moot.[66] By contrast, if the PTAB upholds a patent's validity, the district court proceeding would continue.[67] Meanwhile, the patent owner (i.e., generally the plaintiff in district court) often has the opposite incentive—hoping that the district court will reach its final judgment before the PTAB has a chance to render the patent invalid.[68]

In the race to final judgment, parties may attempt to manipulate the separate timelines of the two venues to advance their interests. For instance,

62. *See* 35 U.S.C. § 316(e).

63. Fresenius USA, Inc. v. Baxter Int'l, Inc., 721 F.3d 1330, 1340 (Fed. Cir. 2013).

64. *Id.*

65. Lauren A. Degnan, Joshua A. Griswold, Ryan Patrick O'Connor & Kristi L. R. Sawert, *How the Timing of Director Review May Affect Co-Pending Litigation*, FISH & RICHARDSON P.C. (July 30, 2024), https://perma.cc/7G95-AVTM.

66. *See* Fresenius, 721 F.3d at 1340.

67. Jeffery C. Totten, *An Accused Infringer's Guide to Parallel Proceedings*, FINNEGAN (Apr. 21, 2014), https://www.finnegan.com/en/insights/articles/an-accused-infringer-s-guide-to-parallel-proceedings.html.

68. *See* Degnan et al., *supra* note 65.

before appealing a PTAB decision to the Federal Circuit, a party (usually the patent owner) may seek Director Review, which allows for the USPTO Director to discretionarily review FWDs issued in IPR proceedings.[69] Because it takes time for the Director to institute or deny review, seeking Director Review may be "part of a strategy to delay the finality of a final written decision [by the PTAB], which is useful if a co-pending litigation is not stayed and especially if the litigation has already proceeded to judgment."[70] This strategy can delay the start of a PTAB appeal by about three months.[71]

While parties race towards final judgment, the Federal Circuit faces its own challenges because it hears patent appeals from both district courts and the PTAB. As a result, the court may hear multiple appeals from different venues for the same case (i.e., between the same parties and/or for the same patent numbers).[72] The Federal Circuit has dealt with an appeal from both a district court ruling and a PTAB ruling over the same patent number in *XY, LLC v. Trans Ova Genetics*, where it held that "affirmance [of a PTAB's invalidity ruling] renders final a judgment . . . and has an immediate issue-preclusive effect on any pending or co-pending actions involving the patent."[73] The court maintained that it had "previously applied collateral estoppel to such co-pending cases," emphasizing that a patentee has already had his day in court, and a defendant should not be forced to continue defending a suit for infringement of a patent already found to be invalid.[74] As such, the court declined to address Trans Ova's invalidity arguments in the district court appeal, and subsequently dismissed Trans Ova's appeal "as moot."[75]

On its face, the Federal Circuit's reasonings and holdings in both *Fresenius* and *XY* appear logical. However, in today's parallel litigation system, where parties race to a final judgment, these cases do not establish a complete doctrine. For example, *Fresenius* pertained to the older *ex parte* reexamination proceeding and does not address the IPR system or any of the new statutes introduced in the AIA.[76] Under the statutes governing these older reexamination procedures, Congress did not distinguish between cancellation and a final decision[77] as it does for IPRs under the AIA.[78] Moreover, in

69. U.S. PAT. & TRADEMARK OFF., DIRECTOR REVIEW PROCESSES (2025).
70. *See* Degnan et al., *supra* note 65.
71. *See id.*
72. *See, e.g.*, *XY, LLC v. Trans Ova Genetics, L.C.*, 890 F.3d 1282, 1294 (Fed. Cir. 2018).
73. *Id.*
74. *Id.* (internal quotations omitted).
75. *Id.* at 1295.
76. *See Fresenius*, 721 F.3d at 1334.
77. *See* 35 U.S.C. §§ 302–307.
78. *See* 35 U.S.C. § 318(a)–(b).

*Fresenius*, the Federal Circuit had remanded a prior appeal back to the district court and later ruled on the reexamination appeal before the second district court decision was appealed back to the Federal Circuit.[79] Similarly, though *XY* pertained to an IPR appeal specifically in parallel with a district court appeal, the court issued rulings for both appeals on the same day.[80] But Federal Circuit procedure does not mandate that appeals from the PTAB and district courts regarding the same patent number or issues be combined.[81] In fact, only in the Practice Notes for Rule 15 in the Federal Circuit Rules of Practice is it mentioned that the clerk of court "will usually" consolidate appeals or petitions for review involving the "same or related patents," but only if they originate "from the same tribunal."[82]

As such, it has not been definitively determined whether a PTAB ruling has a collateral estoppel effect while pending appeal. This differs from the collateral estoppel effect of district court decisions, for which the Federal Circuit has plainly ruled that "collateral estoppel can be applied based on a district court decision" even if it "is still pending on appeal."[83]

Currently, this lack of clarity poses potential problems. For example, it almost seems as if a PTAB ruling's estoppel effect on a district court decision is based on considerations outside litigants' control, such as whether the district court decides to consider the PTAB's FWD, whether the Federal Circuit's clerk of court opts to consolidate the district court and PTAB appeals, or whether the Federal Circuit opts to decide both appeals simultaneously. As the IPR system introduced by the AIA continues to grow in popularity as a faster and more cost-efficient alternative to district court litigation, the unresolved issues with parallel litigation system remain unaddressed by the courts. The facts in *United Therapeutics* fall into the gray area leading to an ultimately confusing outcome.

*3. 3. Federal Rules of Civil Procedure Rule 60*

The FRCP 60(b) motion is a last resort for parties seeking relief from an unjust judgment or order. FRCP 60(b) states that a court "*may* relieve a party" from a final judgment for reasons such as newly discovered evidence, mistake or neglect, fraud, a void judgment, or "any other reason that justifies relief."[84]

79. *See Fresenius*, 721 F.3d at 1341.
80. *XY, LLC*, 890 F.3d at 1294.
81. *See generally* FED. CIR. RULES OF PRAC. (2023).
82. *Id.* at 47.
83. Uniloc USA Inc. v. Motorola Mobility LLC, 52 F.4th 1340, 1347 (Fed. Cir. 2022).
84. FED. R. CIV. P. 60(b) (emphasis added).

However, there are several issues that would make FRCP 60(b) extremely difficult to rely on for resolving discrepancies in parallel patent litigation outcomes. FRCP 60(b) motions are rarely granted and are often narrowly limited to specific provisions in the rule and to "extraordinary circumstances" that "must justify reopening."[85] Moreover, the rule's language (i.e., that a court "*may*" relieve a party) grants courts full discretion to grant or deny relief.[86] Finally, FRCP 60(b) is necessarily retroactive—meaning that future or currently litigating parties do not have certainty as to the outcome of a future FRCP 60(b) motion.[87] Taken together, these factors strongly discourage parties from relying on FRCP 60(b) as a reliable and effective means of addressing conflicting outcomes in parallel litigation.

## III. *UNITED THERAPEUTICS CORP. V. LIQUIDIA TECH., INC.*

*United Therapeutics* exemplifies the lack of clarity surrounding the collateral estoppel effect of the PTAB within the current parallel litigation system. In the district court decision, the court held Liquidia liable for infringing the patent-at-issue,[88] despite the PTAB having issued a Final Written Decision a month before invalidating the patent.[89] Instead, the district court declined to be bound by the PTAB's decision when issuing its own decision.[90] While both decisions were appealed to the Federal Circuit, the court first heard only the district court appeal and affirmed the district court's decision.[91] In particular, the Federal Circuit ultimately held that Liquidia was liable for infringing the '793 patent because the PTAB's FWD did not have collateral estoppel effect while pending appeal.[92] Later, however, the Federal Circuit affirmed the PTAB's invalidity decision as well.[93] As a result, Liquidia was left with a strange and intuitively confusing outcome—being held liable for infringing a patent that had been declared invalid. Such a result seems to conflict with both Congress's intent behind the AIA and the Supreme Court's previous precedents.

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85. Kemp v. United States, 596 U.S. 528, 533 (2022).

86. FED. R. CIV. P. 60(b).

87. *See id.*

88. United Therapeutics Corp. v. Liquidia Techs., Inc., 624 F. Supp. 3d 436, 473 (D.D.E. Aug. 31, 2022) [hereinafter *District Court Decision*].

89. Liquidia Techs., Inc. v. United Therapeutics Corp., 2022 Pat. App. LEXIS 3685, *52 (P.T.A.B. July 19, 2022) [hereinafter *PTAB FWD*].

90. *District Court Decision*, 624 F. Supp. 3d at 473 ("[T]he PTAB's decision . . . has no impact on my finding of induced infringement.")

91. *United Therapeutics*, 74 F.4th at 1374.

92. *Id.* at 1371.

93. United Therapeutics Corp. v. Liquidia Techs., Inc., 2023 WL 8794633, at *1 (Fed. Cir. Dec. 20, 2023) [hereinafter *United Therapeutics II*].

Section III.A details the factual background of the case. Section III.B delineates the timeline of proceedings: Section III.B.1 details the timeline of district court proceedings, Section III.B.2 details the timeline of PTAB proceedings, and Section III.B.3 delineates the timeline of the two Federal Circuit appeals. Section III.C analyzes the ramifications of the case's final outcome and the issues posed as a result of the Federal Circuit's decisions.

### A. FACTUAL BACKGROUND

United Therapeutics Corporation ("United Therapeutics") is a biotechnology company that primarily develops drugs to treat rare diseases and end-stage lung diseases.[94] United Therapeutics owns the '793 patent, which is "generally directed to methods of . . . pharmaceutical compositions comprising treprostinil."[95] Treprostinil is a drug used to treat pulmonary arterial hypertension, a highly dangerous form of high blood pressure that affects the arteries in the lungs and heart.[96]

Liquidia, Inc. ("Liquidia") is a biopharmaceutical company that develops therapies for patients with cardiopulmonary diseases.[97] Liquidia created a dry powder inhalation formulation of treprostinil, which it called Yutrepia, and filed a New Drug Application with the Food and Drug Administration (FDA) in an effort to market the product.[98] United Therapeutics ultimately sued Liquidia in the United States District Court for the District of Delaware alleging that Liquidia induced infringement of the '793 patent, among other asserted patents.[99] In response, Liquidia filed a petition for IPR of the '793 patent, arguing that all claims of the '793 patent were unpatentable (i.e., invalid) as obvious over the prior art at the time of the invention.[100]

While the specific infringement and validity causes of action are not particularly significant to this Note, understanding the timeline of the parallel proceedings is critical.

94. *Therapeutic Areas*, UNITED THERAPEUTICS CORP., https://perma.cc/Q3PL-35CK (last accessed May 4, 2025).

95. *United Therapeutics*, 74 F.4th at 1363.

96. Pegah Zare & Daniel Heller, *Treprostinil*, NAT'L LIBR. MED. (May 8, 2023), https://perma.cc/V8YU-47ZZ.

97. *About Us*, LIQUIDIA, https://www.liquidia.com/about-us (last accessed May 4, 2025).

98. *United Therapeutics*, 74 F.4th at 1364.

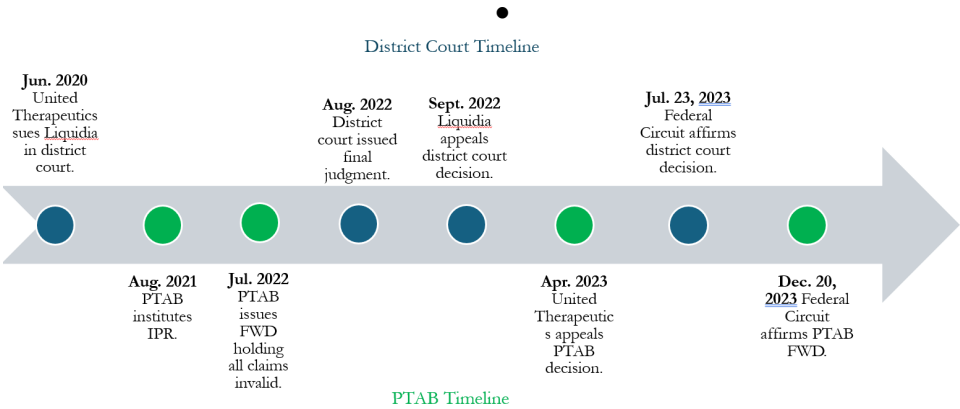
99. *Id.* at 1363.

100. *See PTAB FWD*, at *2.

## B. PROCEDURAL HISTORY

The timeline of both parallel proceedings is summarized in the following chart and further discussed below:

**Figure 1. Timeline of proceedings in the litigation between United Therapeutics and Liquidia. In particular, the blue and green dots on the timeline represent the separate proceedings in district court and in the PTAB, respectively.**




This Section outlines the timeline of proceedings in both venues. This Section also analyzes how the district court and the Federal Circuit reached this counterintuitive decision regarding collateral estoppel.

### *1. PTAB*

As shown in Figure 1, United Therapeutics first filed suit against Liquidia in the United States District Court of Delaware in June 2020.[101] In response, Liquidia petitioned the PTAB for an IPR proceeding for the '793 patent, and the PTAB ultimately issued a ruling of invalidity before the district court issued its opinion.[102]

The PTAB instituted review on August 11, 2021.[103] The parties litigated the IPR in parallel with the district court proceedings, and the PTAB issued a Final Written Decision on July 19, 2022.[104] In that decision, the PTAB held that all claims in the '793 patent were unpatentable as obvious over the prior art at the time of the invention.[105] United Therapeutics sought a Board

101. United Therapeutics Corp. v. Liquidia Techs., Inc., 2020 U.S. Dist. LEXIS 205150, at *2 (D.D.E. Nov. 3, 2020) ("Plaintiff United Therapeutics filed a complaint for patent infringement against Defendant Liquidia on June 4, 2020.").

102. *PTAB FWD*, at *52.

103. *PTAB FWD*, at *2.

104. *United Therapeutics*, 74 F.4th at 1364.

105. *Id.*; *PTAB FWD*, at *52.

rehearing, delaying the timeline to appeal the PTAB decision to the Federal Circuit until April 5, 2023.[106]

*2. District Court*

Although United Therapeutics sued Liquidia in June 2020, the district court did not hold a bench trial until March 28, 2022.[107] During the trial, Liquidia did not maintain any grounds raised in its IPR (i.e., under 35 U.S.C. § 102 and 35 U.S.C. § 103) in district court.[108] Liquidia instead attempted to introduce the PTAB's FWD to the district court before the court rendered its decision.[109]

However, the court issued its final opinion on August 31, 2022, ruling that all asserted claims of the '793 patent were not invalid and that Liquidia had induced infringement of the '793 patent.[110] In its holding, the court noted that the PTAB had issued a FWD which invalidated all claims, but cited to the Federal Circuit's decision in *XY* and interpreted the Federal Circuit's holding that an "affirmance of an invalidity finding . . . has a collateral estoppel effect" to mean that "an IPR decision does not have collateral estoppel effect until that decision is affirmed or the parties waive their appeal rights."[111] Ultimately, the court held that "the PTAB's decision—which is not yet final—has no impact on [its] finding of induced infringement."[112] In other words, by interpreting the Federal Circuit's decision in *XY* to determine that the PTAB's decision lacked collateral estoppel effect, the district court obviated the PTAB's invalidity ruling.[113]

*3. Federal Circuit Court of Appeals*

Liquidia appealed the district court decision to the Federal Circuit on September 16, 2022.[114] United Therapeutics appealed the PTAB's decision to

106. Notice of Appeal, United Therapeutics Corp. v. Liquidia Techs., Inc., IPR2021-00406 (P.T.A.B. Apr. 5, 2023), ECF No. 83.

107. *See* Official Transcript of Bench Trial held on 3/28/22 before Judge Richard G. Andrews, United Therapeutics Corp. v. Liquidia Techs., Inc., No. 20-00755 (D.D.E. 2022), ECF No. 402.

108. *See generally District Court Decision.*

109. *Id.* at 463.

110. *Id.* at 473.

111. *Id.* (citing *XY, LLC*, 890 F.3d at 1294).

112. *Id.* at 464.

113. *Id.*

114. Notice of Appeal, United Therapeutics Corp. v. Liquidia Techs., Inc., No. 20-00755 (D.D.E. 2022), ECF No. 440.

the Federal Circuit on April 26, 2023.[115] Both appeals were on the Federal Circuit's docket, and the court was aware that they were related to the same case, but it nonetheless considered both appeals separately.[116]

On July 24, 2023, the Federal Circuit issued its United Therapeutics decision, ruling only on the district court appeal and affirming the district court's decision.[117] In particular, the Federal Circuit rejected Liquidia's argument that the PTAB's FWD in the IPR proceeding for the '793 patent estopped Liquidia from liability for induced infringement in the district court case.[118] Liquidia cited the Supreme Court's decision in *Commil*, in which the Court held that if "an act that would have been . . . an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."[119] However, the Federal Circuit agreed with United Therapeutics' argument that unpatentability is "relevant to infringement liability only once a final adjudication [made on appeal] of . . . invalidity rules that there is no such patent to infringe."[120]

Additionally, the Federal Circuit repeated the district court's reasoning, including the district court's interpretation of *XY*—that an IPR decision "does not have collateral estoppel effect until that decision is affirmed or the parties waive their appeal rights."[121] Ultimately, the Federal Circuit reached the same result, holding that the "'793 IPR decision . . . has no impact . . . on a finding of induced infringement."[122]

On December 20, 2023, the Federal Circuit then issued *United Therapeutics II*, affirming the PTAB's decision and invalidating the '793 patent as obvious over the prior art at the time of the invention.[123] At this point, Liquidia was liable for infringing the '793 patent, while also having successfully invalidated the same patent.

Six days after the *United Therapeutics II* decision, Liquidia filed a FRCP 60(b) motion with the District of Delaware, seeking to vacate the original judgment

115. Notice of Appeal, United Therapeutics Corp. v. Liquidia Techs., Inc., IPR2021-00406 (P.T.A.B. Apr. 5, 2023), ECF No. 83.

116. *See United Therapeutics*, 74 F.4th at 1364.

117. *Id.* at 1363.

118. *Id.* at 1371.

119. *Commil*, 575 U.S. at 644.

120. *United Therapeutics*, 74 F.4th at 1371.

121. *Id.* at 1372.

122. *Id.*

123. *United Therapeutics II*, at *1.

of infringement because the '793 was invalid and unenforceable.[124] On March 28, 2024, the Delaware district court granted Liquidia's motion and vacated the holding that Liquidia infringed the '793 patent.[125]

The March 28 decision was the final decision in this series of cases. Liquidia filed a petition for a writ of certiorari to the Supreme Court regarding the collateral estoppel portion of the *United Therapeutics* decision, but was denied on February 20, 2024.[126] United Therapeutics also filed a petition for a writ of certiorari to the Supreme Court regarding the *United Therapeutics II* decision, but was denied on October 7, 2024.[127] As such, litigation between United Therapeutics and Liquidia regarding the '793 patent is now concluded.

### C. ANALYZING THE UNITED THERAPEUTICS DECISIONS AND ITS RAMIFICATIONS

The Federal Circuit's decision in *United Therapeutics* is intuitively confusing but, more importantly, at odds with prior precedent from both the Supreme Court and its own prior holdings. On its face, the outcome of the *United Therapeutics* and *United Therapeutics II* decisions resulted in Liquidia being held liable for infringing an ultimately invalid patent—a result that seems to directly contradict the Supreme Court's assertion in *Commil* that "if . . . an act [of infringement or induced infringement] pertains to a patent that is shown to be invalid, there is no patent to be infringed."[128] However, what makes *United Therapeutics* and *United Therapeutics II* noteworthy is that these decisions do not directly contradict or seek to overturn any particular previous decision. Rather, these decisions fall into a gap left unaddressed in prior decisions.

Indeed, the Federal Circuit in *United Therapeutics* (as well as the district court) held, in response to *Commil*, that the '793 patent is not invalid because the IPR proceeding holding the patent invalid was pending appeal in the very same court.[129] But this raises its own immediate question: Why wasn't the IPR appeal designated as a companion to the district court appeal, given that the Federal Circuit knew it was pending? *Commil* states plainly: "if the patent is indeed invalid, and shown to be so under proper procedures, there is no

124. Motion for Post Judgment Relief Pursuant to Federal Rule of Civil Procedure 60(b), United Therapeutics Corp. v. Liquidia Techs., Inc., No. 20-00755 (D.D.E. 2023), ECF No. 461.

125. United Therapeutics Corp. v. Liquidia Techs., Inc., 2024 U.S. Dist. LEXIS 56072, at *7 (D. Del. Mar. 28, 2024).

126. United Therapeutics Corp. v. Liquidia Techs., Inc., 144 S. Ct. 873, 873 (2024).

127. United Therapeutics Corp. v. Liquidia Techs., Inc., 145 S. Ct. 352, 352 (2024).

128. *Commil*, 575 U.S. at 644.

129. *United Therapeutics*, 74 F.4th at 1372.

liability."[130] Under such a framework, it would be inefficient to consider infringement before invalidity, and in particular, to finalize an infringement judgment before finalizing the validity of the patent-at-issue.

Moreover, *Commil* even identifies IPRs as an example of a "proper way[]" to "obtain a ruling [of invalidity]."[131] From a legislative standpoint, an IPR proceeding brought by Liquidia in response to an accusation of infringement should certainly qualify as a proper procedure if Congress intended for the IPR system to be a "cost-efficient alternative to litigation."[132] Therefore, the issue is how to incentivize parties to use the IPR system without also encouraging them to duplicate causes of action in district court. Duplication would, in fact, result in less efficiency, as both parties would be forced to litigate the same invalidity arguments in multiple venues, doubling the work for both parties and for the Federal Circuit if the parties appeal.

Moreover, a petitioner can stipulate that they will not bring any grounds that could be reasonably raised in an IPR to a parallel forum. In exchange, the PTAB would be less likely to exercise its discretion to deny institution of that party's IPR petition. But in this scenario where a party moves one or more of its causes of actions to the PTAB and out of district court entirely, the lack of collateral estoppel effect for PTAB decisions is even more relevant.

Even though Liquidia did not make such a stipulation in this case, the result was functionally the same—only the PTAB heard its § 102 and § 103 arguments (anticipation and obviousness, respectively).[133] However, if a PTAB's finding of invalidity reaches a final decision after infringement proceedings conclude, then the IPR system fails to serve as a "proper procedure" or a cost-efficient alternative to district court litigation.[134] If litigating parties cannot be certain that an IPR invalidity finding will take effect before infringement causes are decided, then there is a strong incentive not to pursue PTAB litigation unless the same invalidity grounds are also duplicated in district court.

Instead, *United Therapeutics* may actually encourage parties to bring duplicative parallel proceedings in district court and the PTAB, which is a practice that directly contradicts Congress's intent in making the IPR process a cost-efficient alternative to district court litigation.[135] By removing 35 U.S.C. § 102 and 35 U.S.C. § 103 invalidity causes from district court proceedings and

130. *Commil*, 575 U.S. at 644.
131. *Id.* at 645.
132. Matal, *supra* note 13, at 640.
133. *See generally District Court Decision.*
134. *Id.*
135. 77 F. Reg. 48680-01 (Aug. 14, 2012).

instead raising them only before the PTAB (as Congress intended with the IPR system), Liquidia ultimately weakened its case.

It would have been safer for Liquidia to raise 35 U.S.C. § 102 and 35 U.S.C. § 103 arguments in both venues or even to forgo an IPR altogether. As it stands, the Federal Circuit may opt to rule on both the PTAB and district court appeals in tandem, as it did in *XY*.[136] However, where the court does not consolidate appeals, such as in *United Therapeutics*, litigants may find that they have a second bite at the apple, like *United Therapeutics* did when it successfully enforced an ultimately invalid patent.[137]

The reasoning behind *United Therapeutics* is also difficult to reconcile with the Supreme Court's holding in *B & B Hardware*. Indeed, the Federal Circuit did not address *B & B Hardware* or any relevant Supreme Court precedent in its determination that IPR decisions have no collateral estoppel effect until affirmed on appeal.[138] While it is true that *B & B Hardware* pertains to a final TTAB decision on the issue of likelihood of confusion, the Supreme Court's analysis was broader.[139] The Court considered generally "whether an agency decision can ever ground issue preclusion," not just the TTAB.[140] As discussed above, the Court observed that collateral estoppel "often applies" when an issue is litigated both "before a court and an administrative agency."[141] The Court detailed in length in its holding that collateral estoppel is so "'well established' at common law" that, as long as the "ordinary elements" of collateral estoppel are met, courts should "take it as given that Congress has legislated with the expectation that [collateral estoppel] will apply except when a statutory purpose to the contrary is evident."[142]

Yet, the Federal Circuit's holding in *United Therapeutics* does not even acknowledge *B & B Hardware* and its considerations.[143] Instead, the court relies on its previous decision in *XY*, holding that "an affirmance of an invalidity finding . . . has a collateral estoppel effect on all pending or co-pending actions."[144] However, the Federal Circuit's subsequent interpretation of this statement, that an IPR decision not yet affirmed must not have collateral estoppel effect, is logically flawed.[145]

136. *See XY, LLC*, 890 F.3d at 1294.
137. *See generally United Therapeutics*.
138. *Id.* at 1372.
139. *B & B Hardware*, 575 U.S. at 141.
140. *Id.* at 147.
141. *Id.* at 148.
142. *Id.* (internal citations omitted).
143. *See generally United Therapeutics*.
144. *Id.* at 1372 (quoting *XY, LLC*, 890 F.3d at 1294).
145. *See id.*

The Federal Circuit's reasoning regarding claim termination conflicts with its own prior decisions. For example, the court reasoned that claims are not canceled under 35 U.S.C. § 318(b) until the Director issues a certificate after the time for appeal has expired or any appeal has terminated.[146] However, in Sec. People, Inc., the Federal Circuit previously held that "[t]he PTO's decision-making process in an IPR is complete after issuance of the final written decision."[147] In that opinion, the Federal Circuit stated that the certificate of cancellation mandated by 35 U.S.C. § 318(b) is wholly "irrelevant to the finality of the agency's action," calling it a mere "nondiscretionary formality."[148] If the Federal Circuit had applied this reasoning to *United Therapeutics*, then the PTAB's FWD of invalidity, issued before the district court case, should have immediately rendered the infringement action moot for the '793 patent.

Finally, although Liquidia was able to successfully petition the district court for an FRCP 60(b) motion to vacate the infringement judgment, the issues posed by *United Therapeutics* are unresolved for future litigants. As discussed in Section II.C.3, FRCP 60(b) is a retroactive remedy and is rarely invoked.[149] FRCP 60(b) motions must also be made within a short and reasonable timeframe.[150] Moreover, Liquidia vacated an injunction on its drug, which it sought to introduce to the market.[151] But the Supreme Court and the Federal Circuit are silent on how a party would be compensated for monetary damages or lost profits due to injunctions on products already in the market under a successful FRCP 60(b) motion. As such, future litigants have little certainty that FRCP 60(b) would be a reliable fallback option capable of providing adequate relief.

Without certainty of what the district courts and Federal Circuit will do, future litigants may find it most worthwhile to bring all invalidity arguments to district court while duplicating their § 102 and § 103 invalidity arguments in a parallel IPR proceeding. This would double the workload for both parties, maintain the same amount of work in district court, and double the burden on the Federal Circuit. The IPR system, in such a scheme, would ultimately become redundant rather than an effective alternative to district court litigation.

146. *Id.*
147. 971 F.3d at 1361.
148. *Id.*
149. *See Kemp*, 596 U.S. at 533.
150. FED. R. CIV. P. 60(c)(1).
151. Memorandum Order, United Therapeutics Corp. v. Liquidia Techs., Inc., No. 20-00755 (D.D.E. 2024), ECF No. 479.

## IV. COURT-SIDE AND LEGISLATIVE PROPOSALS TO RESOLVE THE COLLATERAL ESTOPPEL ISSUE

This Section proposes a multifaceted approach to reforming both the Federal Circuit Rules of Practice (court-side reform) and current AIA statutes. The court-side rule reforms are narrower in scope, specifically aimed at preventing scenarios like *United Therapeutics* from recurring. By targeting amendments to the Federal Circuit Rules of Practice, the proposed court-side solutions can be enacted immediately without waiting for another case with similar merits.

In particular, the proposed solution would require the clerk of court to designate parallel appeals from a district court and the PTAB (e.g., involving the same parties and the same patent number(s)) as companion cases. These companion cases would remain separate appeals (so as to not consolidate different standards of review), but the Federal Circuit would hear and decide them at the same time. This reform balances practicality with the urgent need for change, but it does not overturn the *United Therapeutics* decision and therefore does not affirmatively grant collateral estoppel effect to PTAB decisions. Instead, the court-side proposals aim to prevent situations like Liquidia's, where it was held liable for infringing an ultimately invalid patent because the PTAB appeal was delayed until after the district court appeal was decided.[152]

The legislative reform seeks to address the collateral estoppel issue at its root. In particular, the proposal would amend 35 U.S.C. § 318(a) to explicitly grant PTAB final written decisions the same collateral estoppel effect as district court decisions.

On July 10, 2023, Congress proposed Senate Bill 2220, otherwise known as the "Promoting and Respecting Economically Vital American Innovation Leadership Act" ("PREVAIL Act"), which seeks to address other issues in the patent litigation system that have arisen post-AIA.[153] Indeed, the PREVAIL Act may be amended to include the legislative proposals suggested in this Note—it is a strong vehicle to address the collateral estoppel issue because it already focuses on improving issues in the post-AIA patent system. Thus, by incorporating these changes, Congress could directly address the collateral estoppel issue raised by *United Therapeutics*.

The proposed solution requires reforms across multiple forums given the urgent need to correct the confusing doctrine left in the wake of *United*

152. *See generally United Therapeutics*.

153. *See* PREVAIL Act of 2023, S. 2220, 118th Cong. § 2 (2024) [hereinafter PREVAIL Act].

*Therapeutics*. A legislative solution alone may be impractical due to the difficulty of passing legislation through Congress.[154] On the other hand, a court-side rule reform alone would be insufficient, as it is unknown when the Federal Circuit will next address this issue again. Moreover, a lone court-side reform to address the entire collateral estoppel issue would necessitate a stronger measure, potentially requiring the Federal Circuit to overturn its *United Therapeutics* decision.

Section IV.A introduces the proposed court-side rule reform, analyzing its benefits and limitations. Section IV.B describes the proposed legislative reforms, namely amending 35 U.S.C. § 315(e) to grant final written decisions issued by the PTAB in IPR proceedings the same collateral estoppel effect as district court decisions.

### A. THE FEDERAL CIRCUIT SHOULD REFORM ITS RULES OF PRACTICE TO DESIGNATE PARALLEL APPEALS FROM DISTRICT COURTS AND THE PTAB AS COMPANION CASES.

As a baseline change, the Federal Circuit should adopt a mandate in its Rules of Practice requiring the clerk of court to designate parallel appeals involving the same patent(s) as companion cases. For example, appeals from district courts and the PTAB involving the same parties and the same patent number(s) should be classified as companion cases, allowing the Federal Circuit to hear oral arguments and issue decisions for both appeals simultaneously. By doing so, the court could issue opinions for both appeals with the other in mind, as it did in *XY*.[155] This Section explores the practicality of implementing this reform. analyzing its pros and cons, particularly in comparison to other potential court-side solutions. Additionally, it also examines the impact of this potential reform on the broader collateral estoppel issue raised by *United Therapeutics*.

#### *1. Advantages of Court-Side Reform*

The immediate issue at hand is why court-side reform is necessary at all, particularly when the proposed reforms are so moderate and limited to court rules. However, in light of the *United Therapeutics* decisions, litigating parties now face uncertainty as to (1) whether the district court will rule before the PTAB does; and (2) whether the district court will consider or adopt the PTAB's decision. For example, in *United Therapeutics*, the Delaware district

154. *See Statistics and Historical Comparison*, GOVTRACK, https://perma.cc/9GNE-ZKT8 (last visited Feb. 9, 2025) (tracking that every Congress since 1973 has had less than 10% of proposed legislation passed into law).

155. *See XY, LLC*, 890 F.3d at 1294.

court acknowledged the PTAB's decision but did not change its final ruling, even after Liquidia submitted the PTAB's invalidity finding to the court.[156]

On its face, the most pressing collateral estoppel issue in this series of cases is that United Therapeutics was able to enforce a patent that Liquidia had already invalidated through an IPR, despite the PTAB's issuance of its decision before the district court ruling.[157] Through a combination of the district court disregarding the PTAB's decision in its final opinion, and the PTAB appeal being decided after the district court appeal (despite the PTAB decision being first), the *United Therapeutics* decisions essentially gave United Therapeutics two chances to argue the validity of its '793 patent.[158]

Designating the two appeals concerning the validity of the '793 patent as companion cases would have prevented the Federal Circuit from issuing two conflicting validity holdings on the same patent in the same litigation. It is sensible to classify PTAB and district court appeals as companion cases, so the Federal Circuit can hear the full scope of invalidity arguments raised by a defending party before issuing a decision. Recall from Section II.A.1 that a patent claim that fails the validity analysis under just one statutory requirement is rendered wholly invalid.[159] Therefore, to fully consider a patent's validity, all invalidity arguments must be considered together. However, IPR proceedings are limited to invalidity causes of action under § 102 (anticipation) and § 103 (obviousness).[160] This means that a lone PTAB appeal before the Federal Circuit may not contain the full scope of invalidity proceedings raised by the defending party. Similarly, in a case like *United Therapeutics*, where Liquidia has moved its § 102 and § 103 causes of action out of district court and into the PTAB, the same problem arises if the Federal Circuit hears only the district court appeal without the PTAB appeal.[161]

While the proposed Federal Circuit reform does not directly address this collateral estoppel issue, it prevents the unfair outcome of allowing a party two bites at the apple in similar cases. By adopting this reform, future litigating parties would have reassurance that the full scope of their invalidity arguments would be considered together on appeal if they opt to pursue PTAB litigation. For example, had these reforms been in place, Liquidia could have been assured that even if the district court disregarded the PTAB's FWD, the

156. *See generally District Court Decision*.
157. *See generally United Therapeutics*.
158. *See generally United Therapeutics*; *United Therapeutics II*.
159. *See* 35 U.S.C. § 101.
160. 35 U.S.C. § 311(b).
161. *See generally United Therapeutics*.

Federal Circuit would have reviewed its arguments in light of all previous proceedings regarding the '793 patent.

The reform is also consistent with the spirit of the Supreme Court's doctrine outlined in *Commil* and would further establish IPR proceedings as a "proper procedure" for invalidating a patent, as intended by both the Supreme Court and Congress.[162] As the *Commil* court stated, "there is no liability" if the patent at issue is "shown to be invalid," which strongly implies that invalidity should be considered before liability is assessed.[163]

*2. Difficulties in Expanding Court-side Reforms*

Requiring companion case designation is a fairly modest reform and raises an inevitable question: Why not implement stronger court-side reform? For example, why not mandate district courts to stay their final decision until the PTAB issues its Final Written Decision? Or why not mandate that the Federal Circuit consolidate both appeals from different forums into a single case?

A proposed amendment to the Federal Circuit Rules of Practice requires a cautious approach that weighs the benefits of addressing the collateral estoppel issue against the potential drawbacks of disproportionality benefiting one party. Even the designation of companion cases—where the Federal Circuit groups PTAB and district court appeals between the same parties for the same patent(s)—poses some practical issues.

As described in Section II.C.2, parties in parallel patent litigation are often in a race to final judgment, and even the most moderate reform would likely alter one forum's litigation timeline to the detriment of one party. Currently, the parallel litigation scheme incentivizes patent owners (i.e., plaintiffs in district court and defendants in an IPR) to delay PTAB final judgment because the PTAB can only invalidate a patent in an IPR proceeding.[164] If the Board cannot find that a patent is invalid by a preponderance of the evidence, the patent remains valid.[165] In contrast, for defendants, a PTAB finding of invalidity would immediately render the district court infringement action against them moot once finalized.[166] However, the PTAB's litigation timeline from petition until final judgment varies markedly from that of district court proceedings. Even designating appeals as companion cases, such that they are ruled on together (as in *XY*) necessarily alters one forum's litigation timeline, often to the detriment of one party.

162. *Commil*, 575 U.S. at 644.
163. *Id.*
164. *See* 35 U.S.C. § 311(b).
165. *Id.*
166. *See* Totten, *supra* note 67.

The complex nature of parallel litigation across different forums with different standards of review also makes it difficult to expand the scope of Federal Circuit reform. For example, it may seem logical to consolidate a PTAB appeal and district court appeal involving the same parties and the same patent(s) into a single appeal before the Federal Circuit. Indeed, the Federal Circuit Rules of Practice, Rule 15, states that the clerk of court "will usually" consolidate appeals or petitions for review involving the "same or related patents" if they are "from the same tribunal."[167] However, in reality, the different standards of review between the two forums make full consolidation into a single appeal impractical.

Similarly, mandating a stay (i.e., pausing proceedings) for a district court appeal in the Federal Circuit while the PTAB appeal is pending would also be difficult as it may have practical implications that outweigh its benefits. A mandatory stay would necessarily require delaying the district court decision in every scenario. While this may seem administratively efficient, in the race to final judgment, it would disproportionally benefit the defending party in district court, who often seeks to delay a final verdict on district court litigation. By contrast, designating appeals as companion cases would give litigants more control to petition the court on which decision's timeline should be changed. This would also give the Federal Circuit more flexibility to decide whether to stay the district court appeal or expedite the PTAB appeal on a case-by-case basis.

Mandating that a district court stay its original final verdict while a PTAB parallel proceeding is ongoing is also problematic because of procedural differences across different district courts. The PTAB operates under a statutorily defined timeline to resolve an IPR, and some courts may already prefer to stay proceedings until the PTAB issues its FWD for the related IPR. In particular, if the PTAB issues a decision invalidating the patent, a district court may adopt the PTAB's invalidity finding, effectively ending all remaining causes of action in the case. However, district courts have discretion to stay proceedings or defer to PTAB decisions. Some district courts may choose not to stay because they do not wish to grant too much deference to the PTAB.

Compared to other potential reforms to Federal Circuit proceedings, requiring companion case designation for already related cases is a fairer approach than forcing stays at the appeal or the district court level. Companion case designation would keep timing disruption to a minimum while also preserving feasibility.

167. *See* FED. CIR. RULES OF PRAC. at 47.

### *3. A Band-Aid Fix to the Bigger Collateral Estoppel Problem*

The proposed Federal Circuit Rules of Practice reform, which would designate PTAB and district court appeals between the same parties for the same patent(s) as companion cases, does not resolve the root collateral estoppel issue. For example, it does not grant PTAB decisions the same collateral estoppel effect as that of district court decisions. It also does not overturn the *United Therapeutics* holding, which found that a PTAB decision pending appeal is "non-final litigation" and "does not have collateral estoppel effect."[168] As such, district courts would still have the discretion to disregard PTAB decisions, as the Delaware district court did in this case. Additionally, under this reform, district courts would continue to enjoy the discretion to decide whether to stay a case while PTAB proceedings are pending. It is critical that court-side reforms do not present overly rigid mandates or directly strip district courts of their authority in favor of the PTAB.

It would be difficult to address the collateral estoppel issue solely through court-side reforms. For instance, courts have called have long called on the Federal Circuit to clarify its ambiguous language in *XY*, even before *United Therapeutics*.[169] And in *United Therapeutics*, the Federal Circuit did attempt to clarify its holding in *XY*. But before this case was decided, district courts have already interpreted *XY* differently than the Federal Circuit did, with some courts holding that collateral estoppel does extend to PTAB decisions pending appeal.[170] Cases where PTAB and district court appeals involving the same parties and the same patent(s) are pending in the Federal Circuit at the same time are rare. It may be a while before the Federal Circuit has another opportunity to clarify or overrule its holding in *United Therapeutics*. Because the Supreme Court has denied Liquidia's petition for certiorari, the Federal Circuit's decisions in both appeals are now final.

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168. *United Therapeutics*, 74 F.4th at 1372.

169. *See, e.g.*, TrustID, Inc. v. Next Caller Inc., 2021 WL 3015280, at *3–4 (D. Del. July 6, 2021) (stating that the Federal Circuit's holding in *XY* "suggests" a result that "seems counterintuitive"—that "an IPR decision does not have preclusive effect until that decision is either affirmed or the parties waive their appeal rights"); Indivior Inc. v. Alvogen Pine Brook LLC, 681 F. Supp. 3d 275, 293 (D.N.J. July 10, 2023) (highlighting "difficulties in harmonizing" the *XY* decision with "traditional" collateral estoppel).

170. *See, e.g.*, Inland Diamond Prods. Co. v. Cherry Optical Inc., 695 F. Supp. 3d 1031, 1039 (E.D. Wis. Sep. 28, 2023) ("The Federal Circuit confirmed that this general principle of issue preclusion extends to final written decisions rendered by the PTAB in IPR proceedings.") (citing Google LLC v. Hammond Dev. Int'l, Inc., 54 F.4th 1377, 1381 (Fed. Cir. 2022) and Papst Licensing GMBH & Co. KG v. Samsung Elecs. Am., Inc., 924 F.3d 1243, 1250–51 (Fed. Cir. 2019)).

Even as a band-aid solution, it is important to adopt this proposal to prevent another case like *United Therapeutics*. It would also be an important step in ensuring parties continue to utilize the PTAB's IPR procedure as Congress intended under the AIA.

For other parties observing the *United Therapeutics* case, the safer approach may now be to bring an invalidity challenge in the PTAB while maintaining the same grounds in district court—a strategy that results in duplicative parallel litigation. Duplicative parallel litigation directly contradicts Congress's intent in establishing the IPR system under the AIA.[171] Bringing the same causes of action in two different venues not only increases costs for the parties, but also demands more litigation resources than before the AIA. As such, while reforming Rule 15 of the Federal Circuit Rules of Practice to require the clerk of court to designate PTAB and district court appeals involving the same parties and patent(s) as companion cases is a temporary fix for the collateral estoppel issue, its implementation remains important.

Although a scenario like *United Therapeutics* is rare, it cannot simply be brushed aside. The uncertainty posed by the *United Therapeutics* decisions will affect future litigants, potentially forcing them to pursue duplicative parallel proceedings to avoid an outcome where they are found to infringe an invalid patent. While the proposed court-side reforms can help safeguard defending parties (such as Liquidia) from facing the confusing result of being held liable for infringing an invalid patent, Congress is in a stronger position to implement a more practical and comprehensive resolution.

### B. CONGRESS SHOULD AMEND AND EXPAND 35 U.S.C. § 315(E) TO GRANT COLLATERAL ESTOPPEL EFFECT TO PTAB FINAL WRITTEN DECISIONS WHILE PENDING APPEAL.

The legislative approach proposes a more direct and sweeping solution by amending 35 U.S.C. § 315(e) to directly grant collateral estoppel effect to PTAB final written decisions, like district court decisions. This amendment would ensure that a PTAB decision has a preclusive effect even while pending appeal, unless the Federal Circuit reverses it.

Congress can practically implement this amendment by attaching it into existing legislative proposals aimed at amending post-grant proceedings, specifically the PREVAIL Act.[172] This Note does not comment on the PREVAIL Act's existing provisions. However, the PREVAIL Act is an ideal vehicle for addressing the PTAB collateral estoppel issue, as it explicitly seeks

171. *See* Matal, *supra* note 13, at 653.
172. *See* PREVAIL Act § 2.

to address other PTAB shortcomings.[173] Section IV.B.1 introduces, in more detail, the key provisions of the PREVAIL Act. Section IV.B.2 analyzes the benefits of adding an amendment to 35 U.S.C. § 315(e) that incorporates collateral estoppel effect to PTAB FWDs. Section IV.B.3 addresses counterarguments and reconciles them with Supreme Court precedent.

#### 1. *The Proposed PREVAIL Act and its Shortcomings in Dealing with* United Therapeutics

Congress has already recognized the "[u]nintended consequences" of post-grant proceedings under the AIA in its introduction of the PREVAIL Act.[174] As such, the PREVAIL Act seeks to amend Title 35 of the United State Code to address "the strategic filing of post-grant [and *inter partes*] review proceedings," which result in "unnecessary duplication of work by the district courts . . . and the [PTAB]."[175]

The proposed PREVAIL Act begins with an amendment to 35 U.S.C. § 311, which limits IPR petitions to only those parties that have been sued or charged with infringement of the patent in question.[176] This provision clarifies Congress's intentions behind the IPR system—to shift § 102 and § 103 invalidity causes of action (as specified in 35 U.S.C. § 311(b)) out of district court and into the PTAB.[177] In doing so, the PREVAIL Act recognizes and preserves the current parallel litigation framework.

However, the proposed amendment to 35 U.S.C. § 315(c) introduces a significant limitation: Claims, counterclaims, and affirmative defenses brought to the PTAB would be restricted to that forum alone.[178] In other words, while the PREVAIL Act continues to allow for parallel litigation, it eliminates loopholes that would allow parties to duplicate claims in both forums.[179]

While the PREVAIL Act identifies and addresses several key issues in the post-AIA patent system, it only prevents parties from duplicating issues in both the PTAB and a different forum.[180] But it does not address the collateral estoppel effect of a Final Written Decision issued by the PTAB. Additionally, it does not require that PTAB decisions be issued before district court decisions.

173. *Id.*
174. *Id.*
175. *Id.*
176. *See id.* § 4.
177. *See id.*
178. *Id.*
179. *See id.*
180. *See id.*

If Congress intends to preserve parallel litigation, it must determine if PTAB decisions should have collateral estoppel effect, especially in light of the *United Therapeutics* decisions. Notably, the PREVAIL Act was proposed before the *United Therapeutics* decisions were issued by the Federal Circuit, meaning Congress may not have anticipated such an unusual outcome.[181] As it currently stands, the PREVAIL Act is insufficient to fully address the ongoing estoppel issues in the parallel litigation system.

Therefore, Congress should amend 35 U.S.C. § 315(e) to grant collateral estoppel effect to final written decisions by the PTAB in IPR proceedings.[182] For example, Congress could define a PTAB final written decision as carrying the same finality as a district court decision, including its collateral estoppel effect. It is critical to expand the PREVAIL Act to prevent situations like *United Therapeutics*, where a party petitions for an IPR after being accused of patent infringement, only to find out that the IPR decision is ultimately meaningless. Without this expansion, parties trying to utilize the IPR system would face too much uncertainty at the whims of judicial discretion or potential litigation gamesmanship. Currently, the estoppel provision in 35 U.S.C. § 315(e) only bars the IPR petitioner from petitioning the PTAB again after a final decision is issued.[183] However, Congress should expand this section to ensure PTAB final written decisions carry collateral estoppel effect while pending appeal, just as final judgments from district courts do.

*2. Benefits of Adopting the Proposed Legislative Reform*

Like the court-side reform proposals described in Section IV.A, legislative reforms should also cautiously weigh the feasibility and practicality of implementation against the potential advantages and drawbacks. In this case, reforming 35 U.S.C. § 315(e) to grant collateral estoppel effect to PTAB decisions is both practical and aligned with existing legislative efforts, such as the PREVAIL Act. It would also better adhere to Supreme Court precedent set in *B & B Hardware* than the current Federal Circuit doctrine.

Granting collateral estoppel effect to PTAB final written decisions is a practical approach bolstered by Supreme Court precedent. In *B & B Hardware*, the Supreme Court held that administrative proceedings can have collateral estoppel effect if the "ordinary elements of issue preclusion" are met, unless a statutory purpose to the contrary is "evident."[184] The Supreme Court further

181. *See generally id.* The bill was proposed on July 10, 2023, before *United Therapeutics* was decided.

182. *See* 35 U.S.C. § 318(a).

183. *See* 35 U.S.C. § 315(e).

184. *B & B Hardware*, 575 U.S. at 148.

clarified that the ordinary elements of issue preclusion are defined by the Restatement (Second) of Judgments, which states that a final judgment on an issue that was "actually litigated" carries collateral estoppel effect, even if issued by an administrative agency.[185] Moreover, the Court made clear that collateral estoppel can "often appl[y]" even in cases "where a single issue is before a court and an administrative agency."[186]

Indeed, Congress's implementation of the IPR system is necessarily litigative, and 35 U.S.C. § 318(a) explicitly states that the PTAB issues a "final written decision."[187] Therefore, granting collateral estoppel effect to PTAB decisions would be consistent with existing legislation, such as in 35 U.S.C. § 318, and with prior Supreme Court precedent.

*3. Potential Drawbacks—and How Commil Reconciles Them*

Congress has mandated in 35 U.S.C. § 101 that a patent claim found invalid in any proceeding is rendered wholly invalid.[188] Under the single forum clause in the newly proposed 35 U.S.C. § 315(c) of the PREVAIL Act, the grounds for invalidity argued before the PTAB would necessarily differ from those raised in district court.[189] Indeed, Congress appears to view patent validity to be a combination of separate standards, because parties petitioning for an IPR may only bring invalidity arguments under § 102 and § 103 before the PTAB.[190] Other invalidity grounds (if raised by the defendant/petitioner) must continue to be litigated in district court. Under such an interpretation for parallel litigation to remain viable, a final holding of invalidity should immediately render infringement proceedings moot. Likewise, an infringement finding should not be finalized until all validity proceedings are final. As the majority in *Commil* noted, if a patent is shown to be invalid, then it cannot be infringed.[191]

Granting PTAB decisions the same collateral estoppel effect as district court rulings presents potential drawbacks that must be considered. For example, if PTAB decisions are granted collateral estoppel effect while on appeal, a district court would face uncertainty as to (1) whether the PTAB will ultimately invalidate the patent initially, and (2) whether the Federal Circuit will affirm or reverse the PTAB's decision. As such, granting PTAB final written decisions collateral estoppel effect while pending appeal could lead district

185. *Id.* (quoting RESTATEMENT (SECOND) OF JUDGMENTS § 27).
186. *Id.*
187. 35 U.S.C. § 318(a).
188. 35 U.S.C. § 101.
189. *See* PREVAIL Act § 4.
190. *See* 35 U.S.C. § 311(b).
191. *Commil*, 575 U.S. at 644.

courts to delay proceedings until the PTAB issues its decision and the entire appeal process is completed. Implementing a system in which a court must stay proceedings while concurrent PTAB litigation is pending would further delay litigation timelines and reduce court efficiency. Such a system would contradict Congress's intent in the PREVAIL Act, which allows for parallel litigation proceedings.

A potential compromise could help alleviate the uncertainty district courts face in such a scenario. PTAB decisions could carry a collateral estoppel effect without requiring a court to stay all proceedings while parallel PTAB litigation is pending. For example, even if the PTAB decides that a patent should be invalid on §§ 102 or 103 grounds, the district court could still issue its decision regarding the separate invalidity grounds, and vice versa. However, the patent would remain invalid unless the PTAB decision is reversed on appeal. In other words, a district would not need to fully stay all proceedings upon a PTAB invalidity finding—merely holding that its infringement ruling should not be finalized.

The Supreme Court's decision in *Commil* aligns with granting PTAB decisions collateral estoppel effect, without contradicting Congress's intent in the PREVAIL Act. As the majority in *Commil* states, infringement and validity are separate issues under patent law because they fall under separate sections of the Patent Act.[192] Under this interpretation, a district court is free to consider infringement separately from (and in parallel to) invalidity arguments. However, under such an interpretation, if a district court finds that infringement occurred, then by granting collateral estoppel effect to PTAB decisions, the infringement finding cannot be finalized until the PTAB appeal is resolved in the Federal Circuit. A case such as *United Therapeutics*, where Liquidia was found to have infringed a patent that it later invalidated through the IPR system, would not be possible under this approach.

PTAB decisions on invalidity should carry the same collateral estoppel effect as district court decisions if they are to function as an effective alternative to district court litigation. At the same time, recognizing the differences between parallel proceedings in different forums, courts could retain discretion to issue decisions that take effect only if a PTAB's finding of invalidity is overturned.

192. *Id.* at 643.

## V. CONCLUSION

The Federal Circuit's decisions in *United Therapeutics* and *United Therapeutics II* reflect a confusing cumulation of the unclear doctrines governing the parallel patent litigation system introduced post-AIA. However, the PTAB has only existed for just over a decade. Therefore, it is not surprising that time is needed to identify and clarify ambiguities in the parallel litigation framework.

To maintain Congress's intent in the AIA, reform is necessary to prevent the recurrence of the bizarre outcome in *United Therapeutics*, where a party was held liable for infringing an invalid patent. Adopting the proposed combination of court-side and legislative reforms can effectively resolve the issues raised in *United Therapeutics*, while upholding both Supreme Court precedent and Congress's original vision in the AIA.