No. 2024-1658

United States Court of Appeals for the Federal Circuit

UNITED THERAPEUTICS CORPORATION,

Appellant,

– v. –

LIQUIDIA TECHNOLOGIES, INC.,

Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE, 1:20-cv-00755, JUDGE RICHARD ANDREWS

APPELLANT'S NON-CONFIDENTIAL OPPOSED MOTION FOR A STAY PENDING APPEAL AND TO EXPEDITE APPEAL

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CERTIFICATE OF INTEREST

Counsel for Appellant certifies the following:

1. The full name of every party represented by me is:

United Therapeutics Corporation

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are:

BlackRock Inc. may own 10% or more of the stock of United Therapeutics Corporation.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

MORRIS, NICHOLS, ARSHT & TUNNELL LLP: Jack B. Blumenfeld; Michael J. Flynn; Sarah Elizabeth Simonetti

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5. The title and number of any related or prior case known to me that meet the criteria under Fed. Cir. R. 47.5(a) are:

United Therapeutics Corp. v. Liquidia Technologies, Inc., Nos. 2022-2217, 2023-1021 (Fed. Cir.)

6. Any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees):

None.

Dated: April 18, 2024

/s/ *Douglas H. Carsten*
Douglas H. Carsten

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Exhibit 1 Declaration of Frederic Selck, Ph.D.

CONFIDENTIAL MATERIAL OMITTED

Pursuant to Federal Circuit Rule 25.1(e)(1)(B) and the district court's Stipulated Protective Order in *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 20-cv-000755, Dkt. No. 33 (D.Del. Aug. 31, 2020), pages 5, 24, 26, 28-30, 32-33, 42, 47, 54-55, 64-66, and Attachment C-1 of Exhibit 1, have been partially redacted. The material on these pages contains confidential information that reveals, contains, and/or reflects commercially sensitive, highly confidential information relating to United Therapeutics Corporation's non-public marketing and business strategy plans, financial forecasts, and negotations with payors regarding pharmaceutical pricing, the disclosure of which would result in harm.

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INTRODUCTION

Appellant United Therapeutics Corporation (UTC) obtained a final judgment and a statutory order barring FDA from approving the infringing product, this Court affirmed it, and the Supreme Court denied certiorari. But the district court has now revisited the judgment vacating the order barring final approval. It did so in reliance on an inter partes review (IPR) decision in which appeals have not yet been exhausted. That was legal error, and it is about to cause irreparable harm to UTC.

The district court's order precluded FDA from approving an application by UTC's competitor Liquidia Technologies, Inc., to market an infringing product. That application already obtained tentative approval. With the order lifted, FDA could decide to approve Liquidia's application at any time, and Liquidia has announced it is ready to launch its product upon approval. To ensure UTC is not irreparably harmed, this Court should stay the district court's decision lifting the order pending expedited resolution of UTC's appeal of the modified final judgment. Counsel for UTC sought Liquidia's position on whether it opposes this motion but did not receive a response prior to filling.

After a trial, the district court found that Liquidia's product would induce infringement of UTC's U.S. Patent No. 10,716,793 ('793 patent). And it rejected the challenges to the '793 patent's validity that Liquidia presented at trial. As a result, the court issued the statutorily required order directing FDA not to approve Liquidia's New Drug Application until after the '793 patent expires. This Court affirmed that decision. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1368-72 (Fed. Cir. 2023). The Supreme Court denied Liquidia's petition for certiorari without even requiring that UTC respond. That made the judgment of infringement and the order barring approval final.

But Liquidia has sought to unwind that final judgment based on parallel administrative proceedings. On the eve of trial in the district court, Liquidia decided to withdraw its obviousness arguments and pursued them exclusively in an IPR proceeding before the Patent Trial and Appeal Board (PTAB). The agency concluded that the '793 patent was unpatentable, and this Court affirmed that decision. The mandate issued on March 19, 2024. But, unlike in the district court proceeding, the Supreme Court has yet to decide whether it will grant or deny UTC's forthcoming petition for a writ of certiorari. And because the IPR

proceeding, inclusive of full appellate review, has not yet terminated, the PTO Director has not issued a certificate canceling the '793 patent's claims. But even though the IPR proceeding is still undergoing appellate review and the '793 patent has not been canceled, Liquidia seized on this Court's affirmance in the IPR proceeding to ask the district court to amend its already-affirmed final judgment. The district court held that it did not need to wait for the patent to be canceled; it reopened and reversed its final judgment, declared Liquidia the victor, and removed the order barring FDA approval.

This Court should stay that decision because UTC is likely to succeed on the merits and will suffer irreparable harm without this Court's intervention. In concluding that this Court's affirmance in the IPR proceeding was entitled to preclusive effect, the district court relied on this Court's decision in *XY, LLC v. Trans Ova Genetics, L.C.*, 890 F.3d 1282 (Fed. Cir. 2018). But this Court in *XY* said nothing about setting aside *final* judgments in litigation that is no longer pending—which preclusion generally does not permit. Unless and until the PTO cancels the '793 patent at the conclusion of appellate review, there is no basis for modifying the final judgment.

Because FDA is no longer under any court order preventing it from approving Liquidia's infringing product, a stay of the modified final judgment is the only way to prevent UTC from being irreparably harmed while it challenges the modified final judgment.[1] Were Liquidia permitted to launch, it would likely lead to permanent price erosion and the loss of UTC's goodwill. Accordingly, UTC respectfully requests that this Court stay the district court's decision pending appeal. Given that Liquidia has made clear it will launch as soon as it receives FDA approval, UTC respectfully requests that this Court expedite these proceedings and that this Court expedite the briefing schedule.

BACKGROUND

UTC markets Tyvaso® (treprostinil), a groundbreaking treatment

[1] In February 2024, UTC filed suit against FDA in the U.S. District Court for the District of Columbia, challenging FDA's decision to accept Liquidia's amendment to its New Drug Application (NDA). As part of those proceedings, the court has ordered that FDA "shall provide the Court and the parties with at least three business days' advance notice prior to the issuance of any decision on Liquidia's amended 505(b)(2) application." Scheduling Order, *United Therapeutics Corp. v. FDA*, No. 1:24-cv-484, Dkt. No. 18 (D.D.C. Mar. 7, 2024). FDA has not provided notice under this order. Accordingly, UTC is not seeking an immediate administrative stay at this time, but may seek additional relief from the Court if it appears that FDA will approve Liquidia's NDA before this Court can rule on this motion.

for pulmonary arterial hypertension. Liquidia submitted a New Drug Application to FDA, relying on the prior approval of Tyvaso and seeking approval to market a competing treprostinil product, Yutrepia™ (also referred to as LIQ861). UTC sued Liquidia, alleging infringement of certain patents, including the '793 patent. *See United Therapeutics Corp.*, 74 F.4th at 1364. Liquidia asserted counterclaims, including invalidity of the '793 patent based on anticipation and obviousness. D. Ct. Dkt. No. 23 at 17. But rather than raising all challenges related to the '793 patent to one forum, Liquidia petitioned for inter partes review of the '793 patent, presenting the same anticipation and obviousness grounds as it presented in this action.

The district court conducted a four-day bench trial during which Liquidia elected not to present its anticipation or obviousness arguments for the '793 patent. The court issued its opinion that the asserted claims of the '793 patent were not invalid and that Liquidia infringed them. D. Ct. Dkt. No. 433 at 53. The court accordingly granted the remedy required by the Hatch-Waxman statute: it ordered that "the effective date of any final approval by the FDA" of Liquidia's New Drug Application shall not come before the '793 patent expires. D. Ct. Dkt. No.

436 at 2; *see* 35 U.S.C. § 271(e)(4)(A). This Court affirmed. 74 F.4th at 1374. Liquidia petitioned for a writ of certiorari, which the Supreme Court denied in February 2024. *Liquidia Techs., Inc. v. United Therapeutics Corp.*, 144 S. Ct. 873 (2024).

Before the district court issued its opinion in this action, the PTAB issued a final written decision in the parallel IPR proceeding, finding all challenged claims of the '793 patent unpatentable. D. Ct. Dkt. No. 425-1 at 2. Liquidia moved to stay the statutory order directed to FDA. On December 15, 2023, the district court denied Liquidia's motion. D. Ct. Dkt. No. 460 at 2-3. This Court then affirmed the PTAB's judgment in the parallel IPR proceeding. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 23-1805, 2023 WL 8794633, at *1 (Fed. Cir. Dec. 20, 2023). UTC petitioned for rehearing. Liquidia, asserting that the panel decision in the IPR appeal was enough to overturn the final judgment, moved the district court for post-judgment relief under Rule 60(b)—namely, that the district court vacate the portion of its final judgment barring FDA approval of Liquidia's product before the '793 patent expires. D. Ct. Dkt. Nos. 461, 461-1.

This Court denied rehearing, and the mandate issued on March 19,

2024. But the appellate proceedings have not yet terminated: UTC intends to petition the Supreme Court of the United States for a writ of certiorari. The PTO Director thus has not canceled the claims of the '793 patent.

Despite the further proceedings to come in the IPR appeal, the district court granted Liquidia's Rule 60(b) motion on March 28, 2024. It reasoned that this Court's affirmance has "immediate issue-preclusive effect," even though appellate review has not ended and the PTO Director has not canceled any claims of the '793 patent. Add8-9 (quoting *XY*, 890 F.3d at 1294).

UTC filed its notice of appeal the same day as the district court's order. Add1-4. On the next court day, April 1, 2024, UTC moved the district court to stay its order; the district court denied that motion on April 17, 2024. Add14-17. UTC now moves this Court, under Federal Rule of Appellate Procedure 8(a)(2), for a stay of the district court's decision pending appeal.

LEGAL STANDARD

Four factors govern a request for a stay pending appeal: "(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 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.*, 897 F.2d 511, 512 (Fed. Cir. 1990) (quoting *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987)). However, each factor "need not be given equal weight." *Id.* Accordingly, if the harm to the applicant "is great enough, a court will not require 'a strong showing' that [the] applicant is 'likely to succeed on the merits.'" *Id.* at 513 (citation omitted).

ARGUMENT

Liquidia's strategic choice to litigate the obviousness of the '793 patent at the PTAB—rather than in this action—does not justify altering the mandatory statutory remedy entered by the district court. In the district court proceeding, UTC obtained a final judgment of patent infringement that was affirmed on appeal; not only did this Court issue a mandate, but the Supreme Court also denied Liquidia's petition for a writ of certiorari. In contrast, the IPR proceeding is not fully resolved. UTC intends to file a petition for a writ of certiorari with respect to this

Court's decision affirming the PTAB's decision. That petition is due by June 10. And, with UTC's appellate rights unexhausted, the PTO Director has not issued a certificate cancelling the '793 patent's claims. Accordingly, this Court should stay the district court's decision—which unwinds a final judgment by an Article III court—based on a parallel administrative process that has yet to conclude.

I. UTC is likely to succeed on the merits.

UTC is likely to succeed on the merits because the district court's decision to amend its final judgment rested on the incorrect assumption that the '793 patent had been irrevocably invalidated, even though appellate review has not concluded and the PTO Director has not issued a certificate of cancellation. At a minimum, UTC's appeal presents a sufficiently substantial merits question to warrant a stay in light of the grave and irreparable harm UTC faces in the event of an FDA approval.

A. A final judgment based on the '793 patent remains valid unless and until the PTO cancels its claims.

This case involves a statutory form of relief, not a discretionary equitable injunction. Under the Patent Act, Liquidia's infringement of the '793 patent requires that "the court *shall* order the effective date of any approval of the drug … involved in the infringement to be a date

which is not earlier than the date of the expiration of the patent which has been infringed." 35 U.S.C. § 271(e)(4)(A). And that is precisely what the district court did in its original final judgment. D. Ct. Dkt. No. 436 at 2. When "the judgment of the district court" in the infringement case "[wa]s affirmed," FDA was required to follow the district court's order and not to approve Liquidia's application before "the date specified by the district court." 21 U.S.C. § 355(c)(3)(C)(ii)(II). In rescinding that judgment in view of the PTAB decision, *see* Add11-12; Add8, the district court impermissibly deprived UTC of the statutory relief to which it is entitled based on a projected administrative outcome that has not occurred.

The Patent Act establishes a clear process for administrative challenges to patents. An issued patent remains in force unless and until the PTO "Director … issue[s] and publish[es] a certificate canceling any claim of the patent finally determined to be unpatentable." 35 U.S.C. § 318(b). Under the statute, the Director "shall" take this action only after (1) the PTAB has issued a final written decision, *and* (2) "the time for appeal has expired or any appeal has terminated." *Id.*

Thus, as this Court explained in an earlier appeal in this case, "the Board's final written decision does not cancel claims; the claims are cancelled *when the Director issues a certificate* confirming unpatentability, which occurs only after 'the time for appeal has expired or any appeal has terminated.'" *United Therapeutics*, 74 F.4th at 1372 (emphasis added) (quoting 35 U.S.C. § 318(b)). This principle is well-established, predating even the creation of inter partes review. *See, e.g.*, *In re Bingo Card Minder Corp.*, 152 F.3d 941, at *2 (Fed. Cir. Feb. 25, 1998) ("A claim is not canceled until the Board acts and the Commissioner cancels the claim. Because the Commissioner has not yet issued a certificate canceling the claims, they have not been finally determined to be unpatentable.").

Under this principle, unless the PTO Director has "cancelled the patent claim" on which a final judgment for infringement was premised, there is no ground for disturbing that judgment based on an interim PTAB decision—absent cancellation, the legal basis for an injunction has not "ceased to exist." *ePlus, Inc. v. Lawson Software, Inc.*, 789 F.3d 1349, 1355-56 (Fed. Cir. 2015) (vacating injunction because "the PTO cancelled the claim"); *see also Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d

1330, 1332 (Fed. Cir. 2013) (concluding that a cause of action for infringement did not survive "cancellation of the asserted claims" by the PTO).

Congress reinforced this conclusion through its approach to patent listing for pharmaceuticals. In 2021, Congress enacted the Orange Book Transparency Act, which addresses various issues with patent listing under the Hatch-Waxman framework. As relevant here, Congress set conditions for when a brand manufacturer would need to delist a patent, tying the obligation to when any claim of the patent "has been cancelled" pursuant to a decision by the PTAB, or invalidated by a court, and no further appeal "has been, or can be, taken." Orange Book Transparency Act of 2020, Pub. L. No. 116-290, § 2(d), 134 Stat. 4889, 4891 (Jan. 5, 2021) (codified at 21 U.S.C. § 355(j)(7)(D)). This congressional directive reflects the statutory sequence set by 35 U.S.C. § 318. If the PTO Director cancels the patent after the conclusion of all appellate proceedings, then the brand manufacturer must promptly delist the patent. But before that time, an adverse decision by the PTAB that is subject to further appellate review does not support delisting from the Orange Book, and a claim for patent infringement may still be pursued.

B. The district court committed legal error by vacating the statutory order before UTC has exhausted its appeal of the PTAB decision.

Notwithstanding the precise sequencing of events dictated by Congress for the administrative cancellation of patents, the district court concluded it need not "wait for claim cancellation." Add9. The district court reasoned that the panel's judgment affirming the PTAB's decision had "*immediate* issue-preclusive effect on any pending or co-pending actions involving the ['793] patent," which "entitled" Liquidia to "modification of the final judgment." Add8 (quoting *XY*, 890 F.3d at 1294). But the district court did not explain why any *issue* determined in the appeal, which concerned only obviousness, was preclusive here, in a proceeding from which Liquidia had withdrawn its obviousness arguments before trial. The district court then brushed off the mandatory nature of the remedy under 35 U.S.C. § 271(e)(4)(A), concluding that "[t]he underlying act of infringement that warranted relief … is no longer a basis for relief due to the invalidation of the '793 patent." Add8-9. But under the Hatch-Waxman scheme, Liquidia's statutory act of infringement remains. The district court's determination is suffused with legal error.

As noted, the district court relied on this Court's decision in *XY*, but the very passage from the opinion quoted by the district court reveals the court's mistake. In *XY*, the court concluded that a Federal Circuit affirmance of a PTAB final decision has immediate "issue-preclusive effect on any *pending or co-pending actions* involving the patent." 890 F.3d at 1294 (emphasis added); *see also id.* ("[A]n affirmance of an invalidity finding … has a collateral estoppel effect on all *pending or co-pending actions*." (emphasis added)). At no point in *XY* did this Court suggest that affirmance of an invalidity judgment, standing alone, has an immediate preclusive effect on *terminated* cases involving the same patent. And such an extension is unwarranted, given the importance of respecting final judgments and preserving them against collateral attacks. *See Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211, 240 (1995).[2]

[2] In denying UTC's application for a stay, the district court reasoned that this case was "still under judicial consideration" "when the Federal Circuit affirmed the PTAB's invalidity decision" because the time had not yet run on Liquidia's opportunity to seek Supreme Court review. Add17. That is non-responsive. By the time of the district court's Rule 60(b) action in this case, the judgment of infringement of the '793 patent was indisputably final, with the Supreme Court having denied Liquidia's petition for certiorari—a petition that relied on the same basic PTAB issue preclusion argument that Liquidia pressed in its Rule 60(b) motion. *See Liquidia Techs.*, 144 S. Ct. 873. As this Court noted, "the Board's

Here, the district court had entered a final judgment that Liquidia infringed the '793 patent. This Court affirmed that judgment and issued its mandate, and the Supreme Court denied Liquidia's petition for a writ of certiorari in February 2024—three weeks before this Court denied UTC's petition for rehearing in the IPR proceeding. By contrast, the IPR proceeding remains ongoing and could still be vacated, as UTC intends to file a petition for certiorari to the Supreme Court.

Issue preclusion from a decision still subject to further appellate review provides no basis for disturbing a final judgment and vacating a mandatory order under 35 U.S.C. § 271(e)(4). Unless and until the PTO Director cancels the patent after the end of the appellate process, the legal basis for the statutory relief has not "ceased to exist." *ePlus*, 789 F.3d at 1355-56. Setting aside the continued pendency of the appellate process and the petition for certiorari, it is no answer to dismiss the cancellation process as a "nondiscretionary formality." Add9 (quoting

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final written decision does not cancel claims" and "[t]he '793 IPR decision thus has no impact here on [the] finding of induced infringement" that produced the judgment and statutory order in UTC's favor. *United Therapeutics*, 74 F.4th at 1372.

Security People, Inc. v. Iancu, 971 F.3d 1355, 1361 (Fed. Cir. 2020)).[3] Congress prescribed a specific order of events before the legal rights under a patent may be extinguished, which allows patent owners to fully exhaust their appellate options. The district court is not free to skip to the end of Liquidia's chosen process based on a prediction of how it may turn out. The Patent Act requires that this "formality" take place before a patent's claims are canceled, a formality that has not occurred here.

Because the judgment resting on the '793 patent persists until the PTO Director issues a cancellation certificate, the district court's decision modifying its final judgment and lifting the order it had issued under 35 U.S.C. § 271(e)(4)(A) was both premature and contrary to the statutory scheme. Accordingly, UTC is likely to succeed on the merits.

II. UTC will suffer irreparable harm in the absence of a stay.

A stay is also necessary to prevent UTC from suffering irreparable harm while this Court considers the appeal on the merits. Following the

[3] *Security People* considered an entirely different question: when to raise a due-process challenge to an IPR decision. The Court held the right time was, at the latest, after the final written decision. But the district court did not hold that *that* would have been the right time to reopen its final judgment—nor could it, given its (misplaced) reliance on *XY*. *Security People* involved no infringement judgment or statutory remedy and is not relevant to the question here.

district court's Rule 60(b) order, FDA is no longer prevented by court order from approving Liquidia's NDA, and the last independent regulatory exclusivity blocking approval expired on March 31, 2024. With FDA having already granted tentative approval to part of Liquidia's application, *see* p. 1, *supra*, final approval is likely imminent. And such an approval would have immediate and irreversible consequences for UTC, with Liquidia able to flood the market with its product before UTC has a chance to pursue appellate relief. Indeed, Liquidia has announced that it will launch Yutrepia immediately upon FDA approval. D. Ct. Dkt. No. 485-1; D. Ct. Dkt. No. 485-2.

This Court has consistently recognized that a patent owner like UTC suffers irreparable harm from "having to directly compete with an infringer," which leads to, for example, "lost sales, lost research and development, [and] price erosion." *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 872-73 (Fed. Cir. 2017); *see also Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012) ("Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm."); *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1362 (Fed. Cir. 2008) (recognizing

that lost market position is irreparable harm that is not adequately compensated by infringement damages); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1381-82 (Fed. Cir. 2006) (affirming irreparable harm findings based on price erosion).

If Liquidia is allowed to launch its Yutrepia product, UTC will suffer harm from exactly these types of irreparable injuries. UTC will experience lost market share, along with a significant and irrecoverable diminution of its first-mover advantages in the market for Tyvaso and Tyvaso-DPI if Yutrepia is permitted to come to market prematurely. *E.g.*, Ex. 1 ¶¶ 15-17, 80-92**.** Allowing Liquidia to enter the market prematurely will also enable it to freeride on UTC's goodwill, which UTC has expended significant resources to develop. *Id.* ¶¶ 92-94. And having relied upon UTC's innovations as a shortcut for market entry, Liquidia is expected to offer a substantial discount relative to UTC's Tyvaso products. *Id.* ¶¶ 58-60, 67. That price erosion will likely be permanent: because of the complex and "sticky" nature of the pharmaceutical market, prices will not revert to their pre-Yutrepia values *even if* UTC ultimately prevails on appeal. *Id.* ¶ 69.

Moreover, even if some of UTC's damages could in theory be quantified, they will be irreparable in practice because Liquidia likely would be unable to pay UTC's full monetary damages. *See Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1155-56 (Fed. Cir. 2011) (finding of irreparable harm supported by evidence of defendant's inability to satisfy a potential judgment); *accord Eli Lilly & Co. v. Premo Pharm. Labs., Inc.*, 630 F.2d 120, 137 (3d Cir. 1980). Liquidia operates at a significant net loss, and even were it to start generating revenue, a conservative estimate of UTC's damages would be significantly higher than Liquidia's potential revenue. Ex. 1 ¶¶ 133-40.

III. The balance of harms and public interest strongly weigh in UTC's favor.

Both the balance of harms and the public interest favor staying the district court's judgment. As discussed, pp. 16-18, *supra*, the district court's Rule 60(b) order exposes UTC to imminent irreparable harm, as Liquidia will be allowed to permanently alter the market by launching its product before UTC can secure appellate relief. As this Court has recognized, "requiring [a patent owner] to compete against its own patented invention, with the resultant harms …, places a substantial hardship on [the patent owner]." *See Robert Bosch*, 659 F.3d at 1156.

By contrast, any harm that Liquidia would face from maintenance of the status quo is comparatively minimal. Liquidia has not yet entered the market, and it had no reasonable expectation to launch before expiration of the '793 patent unless and until the PTO Director cancels that patent. Liquidia has touted to the public that it is "very well capitalized" and has "never been in a stronger position," demonstrating that it will not suffer from a stay preserving the status quo during an expedited appeal. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 1:23-cv-975 (D. Del. filed Mar. 4, 2024), Dkt. No. 34-1 at 40-41, 45-46. Moreover, any perceived "delay" in Liquidia's ability to launch Yutrepia is the result of its own tactical litigation decisions, as Liquidia chose to pursue certain invalidity challenges solely before the PTAB, leaving them out of the district court litigation. *See* p. 5, *supra*. In making that choice, Liquidia must accept the bitter with the sweet: it was able to take advantage of a substantially reduced burden of proof for patent invalidity in the inter partes process, *see* 35 U.S.C. § 316(e), but it cannot short-circuit the opportunity for full appellate review before patent cancellation, *see id.* § 318(b).

Finally, the relief UTC requests would also serve the public interest. The "public generally does not benefit when … competition comes at the expense of a patentee's investment-backed property right." *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 647 (Fed. Cir. 2015). This conclusion is "base[d] … not only on the Patent Act's statutory right to exclude, which derives from the Constitution, but also on the importance of the patent system in encouraging innovation." *Id.* Permitting Liquidia to launch on the basis of an administrative decision still subject to further appellate review, despite a final, affirmed district court judgment that Liquidia infringed a valid patent, would erode the value of those patents and reduce the incentive for companies to develop lifesaving medicines in the first place.

IV. This Court should expedite the appeal.

If this Court does not expedite the appeal, it could potentially become moot before the Court decides it. And any delay in considering the appeal will compound the harm to UTC if, as a result of the order under review, FDA approves Liquidia's New Drug Application while UTC is still pursuing its appellate rights.

UTC is prepared to self-expedite its opening and reply briefs and the joint appendix. UTC will file its opening brief not later than May 15, 2024. UTC will file its reply brief not later than 14 days after Liquidia's response brief, and the joint appendix 3 days after the reply brief. UTC respectfully requests that the Court direct Liquidia not to expect any extensions and direct the Clerk to calendar the case for argument at the first available date following the conclusion of briefing.

For the reasons stated herein, the limited nature of the issues in this appeal, the fact that Liquidia recently opposed UTC's motion to stay before the District Court, and Liquidia's desire to launch its product as soon as possible, UTC also respectfully requests that the Court shorten Liquidia's time to file a response brief, from 40 days to 30 days.

CONCLUSION

The Court should issue a stay of the district court's judgment pending appeal and should expedite the briefing and oral argument.

April 18, 2024

Respectfully submitted,

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ADDENDUM

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04/17/2024	490	Memorandum Order Denying Motion to Stay	Add14

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

PLAINTIFF'S NOTICE OF APPEAL

Plaintiff United Therapeutics Corporation hereby appeals to the United States Court of Appeals for the Federal Circuit from all aspects of paragraph 3 of the March 28, 2024 Amended Final Judgment (D.I. 480) resolved adversely to Plaintiff, as well as any and all underlying or interlocutory decisions, orders, opinions, rulings, determinations, judgments, findings, or conclusions merged therein that are adverse to Plaintiff, including, but not limited to, the Court's March 28, 2024 Memorandum Order (D.I. 479).

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March 28, 2024

CERTIFICATE OF SERVICE

I hereby certify that on March 28, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on March 28, 2024, upon the following in the manner indicated:

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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).[1] 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

[1] 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 28th day of March, 2024.

/s/ Richard G. Andrews
United States District Judge

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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

AMENDED FINAL JUDGMENT

At Wilmington, Delaware, this 28th day of March, 2024:

WHEREAS, Plaintiff United Therapeutics Corporation ("UTC") commenced this action against Defendant Liquidia Technologies, Inc. ("Liquidia") asserting infringement of U.S. Patent Nos. 9,593,066 (the "'066 patent"), 9,604,901 (the "'901 patent"), and 10,716,793 (the "'793 patent") by the products that are the subject of Liquidia's New Drug Application No. 213005 seeking approval by the U.S. Food and Drug Administration ("FDA") for the manufacture, use, and sale of its proposed product LIQ861 (Yutrepia™);

WHEREAS, on January 3, 2022, the Court granted UTC's stipulation of non-infringement of the '901 patent based on the Court's construction of the claim term "contacting the solution comprising treprostinil from step (b) with a base to form a salt of treprostinil," with UTC preserving all rights to appeal the Court's construction of that term (D.I. 278);

WHEREAS, at trial, UTC asserted infringement of claims 1, 2, 3, 6, 8, and 9 of the '066

patent and claims 1, 4, 6, 7, and 8 of the '793 patent against Liquidia, and Liquidia asserted counterclaims of non-infringement and invalidity of those claims;

WHEREAS, the Court held a bench trial in the above-captioned action on March 28 to March 31, 2022;

WHEREAS, the Court issued a Trial Opinion setting forth its Findings of Facts and Conclusions of Law on August 31, 2022 (D.I. 433);

WHEREAS, the Court issued a Final Judgment on September 9, 2022 (D.I. 436);

WHEREAS, in parallel proceedings, the Patent Trial and Appeal Board issued a Final Written Decision holding the asserted '793 patent claims invalid on July 19, 2022;

WHEREAS, the United States Court of Appeals for the Federal Circuit in *United Therapeutics Corp. v. Liquidia Techs, Inc.*, Case No. 23-1805, affirmed the Patent Trial and Appeal Board's '793 patent Final Written Decision on December 20, 2023;

WHEREAS, the United States Court of Appeals for the Federal Circuit issued its mandate affirming the Patent Trial and Appeal Board's '793 patent Final Written Decision on March 19, 2024;

WHEREAS, Liquidia filed a Motion for Post Judgment Relief Pursuant to Federal Rule of Civil Procedure Rule 60(b), seeking relief from the Court's Final Judgment (D.I. 436); and

WHEREAS, the Court granted Liquidia's Motion for Post Judgment Relief Pursuant to Federal Rule of Civil Procedure Rule 60(b) and VACATED Paragraphs 3 and 4 of the Court's Final Judgment;

IT IS HEREBY ORDERED AND ADJUDGED:

1. Judgment is hereby entered in favor of Liquidia and against UTC that claims 1, 2, 3, 6, and 9 of the '066 patent are invalid for the reasons set forth in the Court's Trial Opinion of August 31, 2022 (D.I. 433);

2. Judgment is hereby entered in favor of Liquidia and against UTC that Liquidia's proposed LIQ861 product will not infringe claim 6, 8, and 9 of the '066 patent for the reasons set forth in the Court's Trial Opinion of August 31, 2022 (D.I. 433); and

3. Judgment is hereby entered in favor of Liquidia and against UTC that Liquidia will not induce infringement of claims 1, 4, 6, 7, and 8 of the '793 patent because those claims have been found by the United States Court of Appeals for the Federal Circuit to be invalid.

IT IS FURTHER ORDERED:

4. In the event that any party appeals this Amended Final Judgment, any motion for attorneys' fees and/or costs under Fed. R. Civ. P. 54(d) and/or Local Rules 54.1 and/or 54.3, including any motion that this case is exceptional under 35 U.S.C. § 285, shall be considered timely if filed and served within thirty days after final disposition of any such appeal; and

5. In the event that no party appeals this Amended Final Judgment, any motion for attorneys' fees and/or costs under Fed. R. Civ. P. 54(d) and/or Local Rules 54.1 and/or 54.3, including any motion that this case is exceptional under 35 U.S.C. § 285, shall be considered timely if filed and served within thirty days after the expiration of the time for filing a notice of appeal under Federal Rules of Appellate Procedure 3 and 4; and

6. Except as provided herein, all other claims and counterclaims in this action are withdrawn and dismissed with prejudice.

/s/ Richard G. Andrews
United States District Judge

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 UTC's motion for a stay of the Order and Amended Final Judgment granting Liquidia's Rule 60(b) motion for post-judgment relief. (D.I. 484).

This case concerns Liquidia's New Drug Application ("NDA") No. 213005. After a bench trial relating to the NDA, I found that the five asserted claims of U.S. Patent No. 10,716,793 ("the '793 patent") had not been proven invalid. (D.I. 433 at 37–53). I also found those five claims to be infringed, and I duly entered a final judgment. Paragraph 4 of the final judgment stated, "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 Federal Circuit affirmed my decision and issued a mandate. (D.I. 453). The Supreme Court denied Liquidia's certiorari petition on February 20, 2024. (*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 asserted claims as obvious. (*See* D.I. 425-1). A rehearing decision again invalidated the claims as obvious (D.I. 450-1), and the Federal Circuit in a non-precedential decision affirmed the PTAB's decision (D.I. 462-1). The Federal Circuit denied UTC's subsequent requests for panel

rehearing and rehearing en banc (D.I. 474-1), and the mandate issued on March 19, 2024 (D.I. 477-1).

On March 28, 2024, I entered an Order vacating the portion of the judgment that blocked the final approval of Liquidia's NDA. (D.I. 479). UTC appealed the Order and Amended Final Judgment. (D.I. 481). UTC now moves for a stay pending the appeal.[1] I have considered the parties' letter briefs (D.I. 485, 487). I turn to the *Hilton* factors, which 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 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)); *see also In re Revel AC, Inc.*, 802 F.3d 558, 565 (3d Cir. 2015).

UTC argues its "appeal is likely to succeed on the merits or, at least, present a substantial case, because the Court's reliance on *XY, LLC v. Trans Ova Genetics*, 890 F.3d 1282 (Fed. Cir. 2018) was misplaced." (D.I. 485 at 1). UTC contends that *XY* only applies to pending or co-pending actions, whereas this case was already "terminated and closed once" the Supreme Court denied Liquidia's certiorari petition on February 20, 2024. (*Id.* at 1–2). UTC further argues that Liquidia's "premature access to the market" would cause irreparable harm to UTC through price erosion, lost market share, and reputational harm. (*Id.* at 2). UTC contends such harm is "impossible to quantify with precision," and even if it were quantifiable, Liquidia would be unable to compensate UTC in the event UTC prevails. (*Id.*). Lastly, UTC argues that the

[1] UTC requests, "At a minimum, . . . a temporary stay to allow time for the Federal Circuit to consider whether to enter a stay of the Rule 60(b) Decision pending merits review of this issue." (D.I. 485 at 3).

balance of equities and the public interest favor granting a stay. (*Id.* at 3). UTC contends a stay would leave Liquidia in the same position as it is today, and the public would be served by preserving the status quo "before the market is prematurely flooded with Liquidia's follow-on product." (*Id.*).

Liquidia argues UTC has no basis for showing a likelihood of success on the merits, as its future certiorari petition regarding the PTAB invalidation decision would be part of a different proceeding. (D.I. 487 at 1 n.2). Liquidia also disputes UTC's contention about the *XY* case, arguing that this case was still pending on December 20, 2023, when the Federal Circuit affirmed the PTAB's invalidity decision. (*Id.* at 1–2). Liquidia further argues "an invalid patent cannot give rise to an injunction." (*Id.* at 2).

Liquidia also argues that UTC "grossly exaggerates" the harm it would purportedly suffer. (*Id.*). Liquidia contends that UTC's statements to shareholders show "Liquidia's entry into the market will not disrupt UTC's status quo." (*Id.* at 2–3). According to Liquidia, "The 'status quo' is that UTC's patent is invalid and Liquidia is free to provide its product to consumers." (*Id.* at 3). Lastly, Liquidia contends that a stay would be detrimental to the public interest, as it would allow UTC to enjoy exclusivity based on an invalid patent. (*Id.*).

I agree with Liquidia that an invalid patent cannot give rise to an injunction. The PTAB found that the '793 patent is invalid. The Federal Circuit affirmed the PTAB's decision and later denied UTC's petition for rehearing. The mandate has since issued. Given that the patent is invalid, I do not think that UTC has shown it will suffer irreparable harm absent a stay.

I do not think that UTC has shown a likelihood of success on the merits of this appeal either. UTC's argument that this case was terminated prior to the affirmance of the PTAB's

invalidity decision is refuted by the record. As of December 20, 2023, when the Federal Circuit affirmed the PTAB's invalidity decision, this case was still under judicial consideration.

Because UTC has not shown irreparable harm or a likelihood of success on the merits, I DENY UTC's motion for a stay.[2]

IT IS SO ORDERED.

Entered this 17th day of April, 2024

United States District Judge

[2] I also doubt that the public interest is served by keeping a drug off the market because of a competitor's invalid patent.

EXHIBIT 1

INTENSITY
a Secretariat company

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U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT

UNITED THERAPEUTICS CORPORATION, Plaintiff, v. LIQUIDIA TECHNOLOGIES, INC., Defendant.	Case No. 24-1658 **Declaration of Frederic Selck, Ph.D. in Support of Motion to Stay**

April 17, 2024

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Attachment B-1	Tyvaso and Tyvaso DPI Net Revenues and Gross Profits
Attachment B-2	Tyvaso and Tyvaso DPI Net Revenues as a Percentage of United Revenues
Section C	Adjusted Forecast
Attachment C-1	Forecast Adjusted for Decreased Treated Patients and Net Pricing

(1) I, Frederic Selck, Ph.D., do hereby declare:

1. Background

1.1. Qualifications

(2) My name is Frederic Selck and I am a Managing Director at Intensity, a Secretariat company. Before joining Intensity, I was a Partner at Bates White Economic Consulting. Prior to that I was a Senior Service Fellow at the National Center for Health Statistics, part of the Centers for Disease Control and Prevention ("CDC"). I have also served as a consultant for the Center for Health Security (formerly the Center for Biosecurity) and the Center for Global Development. I regularly teach graduate-level courses in microeconomics, health finance, and the analysis of health care markets at both Georgetown and Johns Hopkins University.

(3) I received my PhD in Applied Economics from Johns Hopkins University and my BA/MA in Economics from Hunter College – City University of New York. I am trained as an econometrician and biostatistician and have applied my data and statistical inference expertise in government, academic, and private sector settings. A major focus of my work has been on health economics and how incentives are affected by health care market structure, payment systems, and regulation. The focus of my academic research has been on the alignment of patient preferences with the incentives physicians and other providers face in the health care market. I have published in and served as a peer reviewer for several journals including *Health Services Research*, *American Journal of Transplantation*, *Statistics in Medicine*, and *Annals of Surgery*.

(4) I have been retained by both plaintiffs and defendants as a testifying and consulting expert in a variety of matters related to alleged anticompetitive conduct, intellectual property, financial and contractual issues, and alleged fraud/false claims. All of these matters have been in the healthcare and life sciences industry, including those concerning government health insurance; pharmaceutical pricing, distribution, and reimbursement; medical devices; and healthcare providers. Relevant to this matter, I have testified on how the insurers and pharmacy benefit managers have induced competition between pharmaceutical products where the entrant was not approved as therapeutically equivalent (or "AB rated") by the U.S. Food and Drug Administration. I have previously been certified as an expert in healthcare markets and health economics in court. More detail on my background can be found in my curriculum vitae and testimony experience, which are presented in Attachment A-1.

(5) In addition to my own time, I directed other Intensity professionals who performed supporting work and analyses in connection with my preparation of this declaration. Neither my compensation nor Intensity's is contingent on the outcome of this matter.

1.2. Scope of work

(6) Intensity has been engaged by Goodwin Procter LLP, who along with McDermott Will & Emery serve as counsel for United Therapeutics Corporation ("United") in this matter.

(7) United alleges that Liquidia Technologies, Inc. ("Liquidia") infringes U.S. Patent No. 10,716,793 ("the '793 patent") via its Yutrepia product.[1] In September 2022, following trial, the Court ordered that "the effective date of any final approval by the FDA of Liquidia's New Drug Application No. 213005 shall be a date which is not earlier than the expiration date of the '793 patent."[2] Subsequently, on March 28, 2024, the Court entered an order that would vacate that portion of the final judgment.[3] United has moved to stay the Court's order pending its appeal to the Federal Circuit.[4] I understand that the request for a stay would prohibit the FDA from granting approval for Yutrepia, preventing Liquidia from manufacturing, marketing, storing, importing, distributing, offering for sale, and/or selling Yutrepia.

(8) I was asked to evaluate and, if called upon, to testify concerning:

a. The harms that will be suffered by United due to Liquidia's infringement and whether those harms are quantifiable and compensable via an award of monetary damages.

b. The harm to United should a stay not be granted relative to the harm to Liquidia should a stay be granted.

c. The impact of a stay on the public interest.

(9) All the opinions throughout my declaration are from the perspective of an economist. I do not offer any legal, medical, or technical opinions.

(10) In connection with my work on this declaration, I had interviews with the following individuals:

a. Dr. Steven Nathan, Inova Fairfax Hospital, Director of the Advanced Lung Disease and Transplant Programs, interviewed on February 9, 2024.

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1 Add14.

2 Add5–6.

3 Add5–9.

4 Add14–17.

b. Mr. David Barton, United, Associated Vice President of Managed Markets and Reimbursement, interviewed on February 14, 2024.

c. Mr. Greg Bottorff, United, Senior Vice President of Sales & Marketing, interviewed on February 14, 2024.

d. Mr. Brian Patterson, United, Manager of Corporate Accounting, interviewed on February 16, 2024.

(11) This declaration is a statement of opinions I currently expect to express in this matter and the bases and reasons for those opinions. In forming the opinions expressed in this declaration, I relied upon my education, experience, and knowledge of the subjects discussed. I have also considered documents, interviews, and other materials, which are cited herein and/or listed in Attachment A-2. This declaration summarizes only my current opinions, which are subject to change depending on additional information.

(12) The entirety of my declaration, including attachments and referenced materials, supplies the bases for my analysis and conclusions. The organizational structure of the declaration is for convenience. To the extent that facts, economic analysis, and other considerations overlap, I generally discuss such issues only once for the sake of brevity. Neither the specific order in which each issue is addressed nor the organization of my declaration or attachments affects the ultimate outcome of my analysis.

1.3. Framework

(13) I understand from counsel that irreparable harm, public interest, and balance of the equities are factors considered by courts in evaluating whether to grant a stay under the circumstances present in this matter. Specifically, I have been informed that there are four factors that govern a request for a stay pending appeal: "(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 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."[5] I further understand that there must be a sufficiently strong causal nexus between the alleged harm and the alleged infringement for a plaintiff to satisfy its required showing of irreparable harm.[6] I understand that the Federal Circuit has deemed harms related to direct competition

[5] *Standard Havens Prods., Inc. v. Gencor Indus.*, 897 F.2d 511, 512 (Fed. Cir. 1990).

Hilton v. Braunskill, 481 U.S. 770, 776 (1987).

[6] *Apple, Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012).

such as lost sales, loss of market share, loss of goodwill, and reputational harm, among others, as valid considerations for a finding of irreparable harm.[7] More generally, the Federal Circuit and district courts have considered harms that are difficult to quantify with reasonable certainty as sufficient for establishing irreparable harm.[8] I am not offering any opinions on the applicable standards or cases cited in this paragraph.

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[7] See:

Celsis In Vitro, Inc. v. CellzDirect, Inc., 664 F.3d 922, 930 (Fed. Cir. 2012).

Douglas Dynamics, LLC v. Buyers Prod. Co., 717 F.3d 1336, 1345 (Fed. Cir. 2013).

Presidio Components v. American Technical Ceramics, 702 F.3d 1351, 1363 (Fed. Cir. 2012).

Broadcom Corp. v. Emulex Corp., 732 F.3d 1325, 1338 (Fed. Cir. 2013).

[8] *Douglas Dynamics, LLC v. Buyers Prod. Co.*, 717 F.3d 1336, 1344–1345 (Fed. Cir. 2013).

Veeco Instruments Inc. v. SGL Carbon, LLC, No. 17-CV-2217 (PKC), at 22 (E.D.N.Y. 2017).

2. Summary of Opinions

(14) Yutrepia is a treprostinil-based inhalation powder made by Liquidia that has been tentatively approved by the FDA for the treatment of pulmonary arterial hypertension ("PAH"). Liquidia has additionally sought FDA approval to market Yutrepia for the treatment of pulmonary hypertension associated with interstitial lung disease ("PH-ILD"). Currently, the only treprostinil-based inhalation products that are FDA-approved for treating PAH and PH-ILD are Tyvaso (a nebulized liquid for inhalation) and Tyvaso DPI (a dry powder inhalation) (collectively, "the Tyvaso products"), developed by United.[9] Yutrepia and the Tyvaso products are all inhaled prostacyclin-class treprostinil therapies. Further, Yutrepia and Tyvaso DPI are both administered using a dry powder inhaler and are expected to be viewed as direct competitors. Given the similarities between the Tyvaso products and Yutrepia, the Tyvaso products will experience price erosion as well as lost unit sales and market share in both the PAH and PH-ILD markets due to direct competition with Yutrepia if Liquidia is allowed to launch.

(15) If Liquidia is allowed to launch Yutrepia, price erosion for the Tyvaso products will result due to competition induced by insurers and pharmacy benefit managers ("PBMs") (collectively, "payors") leveraging their access to patients. Liquidia will have an economic incentive to offer payors favorable pricing relative to Tyvaso and Tyvaso DPI, [redacted]. In exchange for these discounts, payors can steer utilization away from the Tyvaso products and towards Yutrepia through requirements such as step therapy and lower co-insurance amounts. In turn, United will need to counter these discounts to avoid being disadvantaged by payors. The result will be substantial reductions in the Tyvaso products' price and market share, consistent with what has occurred in other markets, such as the Hepatitis C and PCSK9 inhibitor biopharmaceutical markets. Furthermore, if the Court concludes that the district court erred in rescinding its final judgment under Rule 60(b), it will be virtually impossible for United to raise prices back to pre-Yutrepia-entry levels, and it would be costly to its reputation.

(16) The degree to which the Tyvaso products' revenues will be negatively affected by Yutrepia's infringement is infeasible to estimate with precision if the Court concludes that the district court erred in rescinding its final judgment under Rule 60(b). The PAH market contains

[9] Throughout my report, I use the term "Tyvaso" to refer to the nebulized form of Tyvaso and "Tyvaso DPI" to refer to the dry powder inhalation form. I refer to both products collectively as the "the Tyvaso products."

numerous treatments and several candidates seeking FDA approval, making it difficult to isolate the effects of Yutrepia entry. Additionally, Tyvaso and Tyvaso DPI—the only products approved to treat PH-ILD—were approved for that indication in March 2021 and May 2022 respectively; as such, the PH-ILD indication remains a nascent market. The size of the PH-ILD market will be driven in part by uncertain PH-ILD diagnosis rates, which makes long-term market size infeasible to determine. United is engaged in efforts to increase awareness of the importance of diagnosing PH-ILD and early intervention, but it is uncertain what the outcome of these efforts will be. Yutrepia's entry will necessarily muddy the long-term trajectory of the PH-ILD market and make it extremely difficult to disentangle the effects of competition from Yutrepia from the effects of unrelated market factors.

(17) In addition to causing price erosion, lost sales, and lost market share, a Yutrepia launch will further harm United by negating United's first mover advantage benefits and inhibiting United's ability to invest in development efforts for its pipeline candidates. Further, United will suffer reputational harm if Yutrepia is allowed to enter the market and then later forced to withdraw due to the issuance of a stay.

(18) The harms to United will be compounded by the risk that Liquidia will have insufficient assets to adequately compensate United in the event that the Court concludes that the district court erred in rescinding its final judgment under Rule 60(b). United has made significant investments in developing the Tyvaso products with the expectation of being able to both recover its costs and fund development of future products. Liquidia, on the other hand, possesses a limited portfolio and a market capitalization (at the time of this writing) that is less than current annual sales earned by the Tyvaso products. Even accounting for the uncertainty in calculating potential damages at this stage—and acknowledging that damages are unable to fully compensate United for the harm due to Liquidia's infringement in this case—it is likely that even an understated estimate of damages would be significantly higher than the revenue Liquidia currently generates.

(19) From a public interest perspective, allowing firms to recoup profits associated with their investments and innovations creates incentives for further innovation. A stay protects United's intellectual property rights. By contrast, allowing Yutrepia to enter the marketplace prematurely will harm drug development incentives. This is particularly true since I understand that Liquidia is relying on United's clinical trial data for Tyvaso as part of its efforts to secure approval for Yutrepia. By relying on Tyvaso as the reference product for Yutrepia to earn approval, Liquidia is freeriding on United's efforts to bring the Tyvaso products to market without incurring the significant costs that United had to spend and risks that United had to take on the development and commercialization of the Tyvaso products.

(20) On the other hand, the benefits to the public from Yutrepia's at-risk entry are likely to be small for several reasons. First, I understand that there are unlikely to be therapeutic benefits of Yutrepia over and above the benefits of the Tyvaso products, and United has sufficient capacity to meet market demand if Yutrepia does not enter the market. Any convenience benefits associated with the dry powder formulation of Yutrepia will also be conferred by Tyvaso DPI. Second, the Tyvaso products are generally covered by insurance and have generous patient-assistance programs sponsored by United, thereby reducing the risk that any patient will be unable to access the Tyvaso products because of cost. Yutrepia's premature entry will harm United and will reduce development incentives in the market, while providing limited to no incremental benefits to patients.

(21) Absent a stay, United will suffer significant harm that cannot be fully quantified and compensated via an award of monetary damages. Furthermore, the economic injury to United if a stay is not granted outweighs the economic injury that Liquidia may suffer from the stay being granted. In addition, several economic factors indicate that a stay on Yutrepia's entry will not disserve the public interest.

3. Marketplace

3.1. Entities

3.1.1. United

(22) United is a biotechnology company whose stated mission is to "find a cure for pulmonary arterial hypertension (PAH) and other life-threatening diseases."[10] United also is "the first publicly-traded biotech or pharmaceutical company to take the form of a public benefit corporation (PBC)."[11] According to United, its public benefit purpose "is to provide a brighter future for patients through (a) the development of novel pharmaceutical therapies; and (b) technologies that expand the availability of transplantable organs."[12]

(23) United's 10-K filing states:[13]

> We market and sell the following commercial therapies in the United States to treat PAH: Tyvaso DPI (treprostinil) Inhalation Powder (Tyvaso DPI); Tyvaso (treprostinil) Inhalation Solution (nebulized Tyvaso), which includes the Tyvaso Inhalation System; Remodulin (treprostinil) Injection (Remodulin); Orenitram (treprostinil) Extended-Release Tablets (Orenitram); and Adcirca (tadalafil) Tablets (Adcirca). Tyvaso DPI and nebulized Tyvaso are also approved to treat pulmonary hypertension associated with interstitial lung disease (PH-ILD). In the United States, we market and sell an oncology product, Unituxin (dinutuximab) Injection (Unituxin), which is approved for the treatment of high-risk neuroblastoma, and the Remunity Pump for Remodulin (Remunity).

(24) As of December 31, 2023, United reported that it "had approximately 1,168 employees working across [its] 13 locations worldwide."[14] United was founded in 1996 and is co-headquartered in Silver Spring, Maryland and Research Triangle Park, North Carolina.[15]

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10 United, Form 10-K, 2023, at 3.

11 United, Form 10-K, 2023, at 3.

12 United, Form 10-K, 2023, at 3.

13 United, Form 10-K, 2023, at 3.

14 United, Form 10-K, 2023, at 33.

15 United, Form 10-K, 2023, at 3, 35.

3.1.2. Liquidia

(25) Liquidia Corporation describes itself as "a biopharmaceutical company focused on the development, manufacture, and commercialization of products that address unmet patient needs, with current focus directed towards the treatment of pulmonary hypertension ('PH')."[16] Liquidia Corporation operates through its two wholly owned subsidiaries, Liquidia PAH, LLC ("Liquidia PAH") and Liquidia.[17]

(26) Liquidia Corporation currently only generates revenue from a "Liquidia PAH subsidiary (formerly RareGen)" that "commercializes generic Treprostinil Injection in a partnership with Sandoz, the first-to-file manufacturer[.]"[18] Liquidia Corporation's "Treprostinil Injection is a generic for the brand-name medicine, Remodulin (treprostinil) Injection, that is used to treat PAH (WHO Group 1). Treprostinil Injection is therapeutically equivalent to the brand-name medicine."[19] Liquidia Corporation reported revenue of $15.9 million and loss from operations of -$38.8 million in 2022.[20]

(27) In its 2019 10-K filing, Liquidia described itself as "a late-stage clinical biopharmaceutical company focused on the development and commercialization of novel products utilizing our proprietary PRINT technology to transform the lives of patients."[21] Liquidia has developed

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16 Liquidia Corporation, Form 10-K, 2022, at 3.

17 Liquidia Website, Home Page, https://www.liquidia.com/ (accessed 1/8/2024).

Liquidia Corporation, Form 10-K, 2022, at 2.

Liquidia Technologies, Inc. merged with RareGen, LLC in 2020 to form Liquidia Corporation. See:

Liquidia, Form 15, 11/30/2020. ("On November 18, 2020, pursuant to the terms and conditions of that certain Agreement and Plan of Merger (the 'Merger Agreement'), dated as of June 29, 2020, by and among Liquidia Technologies, Inc. (the 'Company'), RareGen, LLC, a Delaware limited liability company ('RareGen'), Gemini Merger Sub I, Inc., a Delaware corporation ('Liquidia Merger Sub'), Gemini Merger Sub II, LLC, a Delaware limited liability company ('RareGen Merger Sub'), PBM RG Holdings, LLC, a Delaware limited liability company, as Members' Representative, and Liquidia Corporation, a newly formed Delaware corporation ('Liquidia Corporation')[.]")

18 Liquidia Website, Commercial Products, https://www.liquidia.com/products-and-pipeline/Commercial-Products (accessed 1/2/2024).

Liquidia Corporation, Form 10-K, 2022, at 3.

19 Treprostinil Injection Website, Home Page, https://trepinjection.com/ (accessed 12/29/2023).

20 Liquidia Corporation, Form 10-K, 2022, at 72.

21 Liquidia, Form 10-K, 2019, at 3.

Liquidia was pursuing FDA approval of LIQ861, which would ultimately become Yutrepia. See:

Liquidia, Form 10-K, 2019, at 6. ("Obtain regulatory approval of LIQ861, our proprietary dry powder inhalation formulation of treprostinil. In January 2020, we submitted an NDA to the FDA for LIQ861, our lead product candidate, as a potential treatment for patients with PAH.")

Liquidia Corporation's lead product candidate, Yutrepia (treprostinil), an inhaled dry powder formulation of treprostinil for the treatment of pulmonary arterial hypertension (PAH).[22] Yutrepia was "tentatively approved by the FDA in November 2021."[23] Liquidia Corporation claims that Yutrepia is "designed to improve the therapeutic profile of treprostinil by enhancing deep lung delivery and achieving higher dose levels than current inhaled therapies while using a convenient, easy-to-use dry-powder inhaler, the RS00 Model 8 DPI."[24] Liquidia noted in its 2022 10-K filing that it had "developed YUTREPIA under the 505(b)(2) regulatory pathway using the nebulized form of treprostinil, Tyvaso, as the reference listed drug."[25] Liquidia further noted that "[t]his regulatory pathway [allowed it] to rely in part on the FDA's previous findings of efficacy and safety of Tyvaso and the active ingredient treprostinil."[26]

(28) Liquidia Corporation was incorporated in Delaware in June 2020 and is headquartered in Morrisville, North Carolina.[27] As of March 2, 2023, Liquidia Corporation reported that it "employed 59 salaried and four hourly employees[.]"[28]

3.2. Relevant medical conditions

3.2.1. Pulmonary hypertension

(29) Pulmonary hypertension ("PH") is "a type of high blood pressure that affects the arteries in the lungs and the right side of the heart."[29] The Mayo Clinic explains:[30]

> The typical heart has two upper chambers and two lower chambers. Each time blood moves through the heart, the lower right chamber pumps blood to the

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See also: Liquidia Website, Pipeline, https://www.liquidia.com/products-and-pipeline/overview (accessed 1/2/2024). ("[Yutrepia was] [p]reviously referred to as LIQ861 in investigational studies[.]")

22 Liquidia Corporation, Form 10-K, 2022, at 3.

Liquidia Website, Home Page, https://www.liquidia.com/ (accessed 1/8/2024).

23 Liquidia Corporation, Form 10-K, 2022, at 4.

24 Liquidia Corporation, Form 10-K, 2022, at 4.

25 Liquidia Corporation, Form 10-K, 2022, at 5.

26 Liquidia Corporation, Form 10-K, 2022, at 5.

27 Liquidia Corporation, Form 10-K, 2022, at 15.

28 Liquidia Corporation, Form 10-K, 2022, at 14.

29 Mayo Clinic Website, Pulmonary Hypertension, https://www.mayoclinic.org/diseases-conditions/pulmonary-hypertension/symptoms-causes/syc-20350697 (accessed 12/29/2023).

30 Mayo Clinic Website, Pulmonary Hypertension, https://www.mayoclinic.org/diseases-conditions/pulmonary-hypertension/symptoms-causes/syc-20350697 (accessed 12/29/2023).

> lungs. The blood passes through a large blood vessel called the pulmonary artery. Blood usually flows easily through blood vessels in the lungs to the left side of the heart. These blood vessels are the pulmonary arteries, capillaries and veins. But changes in the cells that line the lung arteries can cause the artery walls to become narrow, stiff, swollen and thick. These changes may slow down or stop blood flow through the lungs, causing pulmonary hypertension.

(30) There are "five different groups of PH based on different causes" that are sometimes referred to as "WHO Groups" because they were originally defined by the World Health Organization.[31] The five PH WHO Groups are:[32]

- Group 1: Pulmonary Arterial Hypertension (PAH)
- Group 2: Pulmonary Hypertension Due to Left Heart Disease
- Group 3: Pulmonary Hypertension Due to Lung Disease
- Group 4: Pulmonary Hypertension Due to Chronic Blood Clots in the Lungs
- Group 5: Pulmonary Hypertension Due to Unknown Causes

(31) It is often difficult to detect and diagnose PH and its groups due to overlaps with other diseases.[33] While there is no best method to screen patients,[34] there are many tests that can inform healthcare professionals including cardiac catheterization, echocardiography, blood tests, heart imaging tests (e.g. cardiac MRIs), lung imaging tests (e.g. chest x-rays), and electrocardiograms (ECGs).[35]

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31 Pulmonary Hypertension Association Website, About Pulmonary Hypertension, https://phassociation.org/types-pulmonary-hypertension-groups/ (accessed 12/29/2023).

32 Pulmonary Hypertension Association Website, About Pulmonary Hypertension, https://phassociation.org/types-pulmonary-hypertension-groups/ (accessed 12/29/2023).

33 National Organization for Rare Disorders Website, Pulmonary Arterial Hypertension, https://rarediseases.org/rare-diseases/pulmonary-arterial-hypertension/ (accessed 1/11/2024). ("It can often be hard to detect PAH in a routine clinical examination, even if the disease has progressed. Symptoms of PAH are not unique and may be confused with many other diseases that cause a lack of oxygen in the blood.")

Parikh, Raj, et al. (2022), "Pulmonary Hypertension in Patients With Interstitial Lung Disease: A Tool For Early Detection," *Pulmonary Circulation* 12(4): 1–11, at 2. ("Furthermore, the diagnosis of PH in the context of ILD is often difficult because of the overlap in symptoms and diagnostic testing.")

34 Parikh, Raj, et al. (2022), "Pulmonary Hypertension in Patients With Interstitial Lung Disease: A Tool For Early Detection," *Pulmonary Circulation* 12(4): 1–11, at 2. ("However, no standard currently exists regarding which patients to screen for PH-ILD nor the optimal method to do so.")

35 National Heart, Lung, and Blood Institute Website, Pulmonary Hypertension – Diagnosis, https://www.nhlbi.nih.gov/health/pulmonary-hypertension/diagnosis# (accessed 1/11/2024).

3.2.2. PAH

(32) PAH (PH WHO Group 1[36]) is one form of PH where the "blood vessels in the lungs are narrowed, blocked, or destroyed."[37] According to United:[38]

> PAH is a life-threatening disease that affects the blood vessels in the lungs and is characterized by increased pressure in the pulmonary arteries, which are the blood vessels leading from the heart to the lungs. The elevated pressure in the pulmonary arteries strains the right side of the heart as it pumps blood to the lungs. This eventually leads to right heart failure and, ultimately, death.

(33) United has estimated that "PAH affects about 500,000 individuals worldwide"[39] and "approximately 45,000 patients in the United States[.]"[40] According to the National Organization for Rare Disorders, "PAH occurs 3-5 times more frequently in females than in males. It tends to affect females between the ages of 30 and 60. New cases are estimated to occur in one to two individuals per million each year in the U.S. The incidence is estimated to be similar in Europe. Approximately 500-1000 new cases of PAH are diagnosed each year in the U.S."[41]

(34) Due to its overlap with other diseases, "[t]he diagnosis of PAH is also one of exclusion, meaning that PAH is only diagnosed when other causes of pulmonary hypertension have been ruled out and there seems to be no known cause of the hypertension."[42] In addition to other tests

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36 Pulmonary Hypertension Association Website, About Pulmonary Hypertension, https://phassociation.org/types-pulmonary-hypertension-groups/ (accessed 12/29/2023).

37 Mayo Clinic Website, Pulmonary Hypertension, https://www.mayoclinic.org/diseases-conditions/pulmonary-hypertension/symptoms-causes/syc-20350697 (accessed 12/29/2023).

38 United, Form 10-K, 2023, at 4.

39 United, Form 10-K, 2023, at 4.

40 United Press Release, "United Therapeutics Announces FDA Approval of Tyvaso DPI," 5/24/2022, https://ir.unither.com/press-releases/2022/05-24-2022. ("PAH is life-threatening high blood pressure in the arteries of the lungs, affecting the ability of the heart and lungs to work properly. PAH affects an estimated 45,000 patients in the United States. Interstitial lung disease (ILD) is a group of conditions in which marked scarring occurs within the lungs. It is often complicated by pulmonary hypertension (PH; high blood pressure in the lungs), which furthers symptoms and decreases survival. PH is estimated to affect at least 15% of patients with early-stage ILD (approximately 30,000 PH-ILD patients in the United States) and may affect up to 86% of patients with more severe ILD. Tyvaso (treprostinil) Inhalation Solution and Tyvaso DPI are the only therapies approved by the FDA to treat PH-ILD.")

41 National Organization for Rare Disorders Website, Pulmonary Arterial Hypertension, https://rarediseases.org/rare-diseases/pulmonary-arterial-hypertension/ (accessed 1/11/2024).

42 National Organization for Rare Disorders Website, Pulmonary Arterial Hypertension, https://rarediseases.org/rare-diseases/pulmonary-arterial-hypertension/ (accessed 1/11/2024).

mentioned in Section 3.2.1, healthcare professionals may utilize the "'6-minute walk test', which measures how far an individual can walk in that time period."[43]

(35) According to the American Lung Association, "[a]lthough there is no cure for PAH, there are medications and procedures that can slow the progression of the disease and improve [a patient's] quality of life."[44] There are a variety of methods for treatment of pulmonary arterial hypertension, including treatment of relevant underlying conditions as well as treatments to improve breathing or address blood pressure, such as blood thinners, calcium channel blockers, and more targeted therapies.[45] These targeted therapies are available in the following forms: oral (*i.e.*, pills), inhaled, and intravenous ("IV")/subcutaneous.[46]

(36) I understand that treatments for PAH generally focus on three pathways: the prostacyclin, nitric oxide, and endothelin pathways.[47] Research has found that using any of these three

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43 National Organization for Rare Disorders Website, Pulmonary Arterial Hypertension, https://rarediseases.org/rare-diseases/pulmonary-arterial-hypertension/ (accessed 1/11/2024).

See also: Parikh, Raj, et al. (2022), "Pulmonary Hypertension in Patients With Interstitial Lung Disease: A Tool For Early Detection," *Pulmonary Circulation* 12(4): 1–11, at 2.

44 American Lung Association, "Treating and Managing Pulmonary Arterial Hypertension," 10/26/2023, https://www.lung.org/lung-health-diseases/lung-disease-lookup/pulmonary-arterial-hypertension/treating-and-managing.

45 WebMD, "Pulmonary Arterial Hypertension," 8/10/2023, https://www.webmd.com/lung/pulmonary-arterial-hypertension. ("Pulmonary hypertension varies from person to person, so your treatment plan will be specific to your needs. Ask your doctor what your options are and what to expect. First, your doctor will treat the cause of your condition. For example, if emphysema is causing the problem, you'll need to treat that to improve your pulmonary hypertension. Most people also get treatment to improve their breathing, which makes it easier to be active and do daily tasks. Oxygen therapy, when you breathe pure oxygen through prongs that fit in your nose, will help if you're short of breath and have low oxygen levels in your blood. It helps you live longer when you have pulmonary hypertension. If you are at risk for blood clots your doctor will recommend blood thinners. Other medicines improve how well your heart works and keep fluid from building up in your body. If you have severe pulmonary hypertension, your doctor may prescribe medications called calcium channel blockers. These medicines lower blood pressure in the lungs and the rest of the body. If calcium channel blockers aren't enough, your doctor may refer you to a specialized treatment center. You may need more targeted therapies that can open up your narrowed blood vessels. They may be pills, medicines you breathe in, or drugs that are given through an IV.")

46 WebMD, "Pulmonary Arterial Hypertension," 8/10/2023, https://www.webmd.com/lung/pulmonary-arterial-hypertension. ("If calcium channel blockers aren't enough, your doctor may refer you to a specialized treatment center. You may need more targeted therapies that can open up your narrowed blood vessels. They may be pills, medicines you breathe in, or drugs that are given through an IV.")

American Lung Association, "Treating and Managing Pulmonary Arterial Hypertension," 10/26/2023, https://www.lung.org/lung-health-diseases/lung-disease-lookup/pulmonary-arterial-hypertension/treating-and-managing.

47 Tettey, Abraham, et al. (2021), "Therapy for Pulmonary Arterial Hypertension: Glance on Nitric Oxide Pathway," *Frontiers in Pharmacology* 12: article 767002, at 2.

pathways or treatment classes are associated with reduced risk of mortality.[48] I further understand that combined use of more than one therapy class is associated with reduced risk of clinical worsening as "studies have shown superiority of combination therapy regimens over monotherapy."[49]

(37) According to United, many of these therapies are "manufactured and marketed by large pharmaceutical companies such as Johnson & Johnson, Gilead Sciences, Inc., and Bayer Schering Pharma AG, as well as a variety of large generic drug manufacturers."[50] PAH treatments commercialized by United[51] include Tyvaso, Tyvaso DPI, Adcirca,[52] Orenitram,[53] and Remodulin.[54]

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48 Qaiser, Kanza, and Adriano Tonelli (2021), "Novel Treatment Pathways in Pulmonary Arterial Hypertension," *Methodist Debakey Cardiovascular Journal* 17(2): 106–114, at 107, 110. ("Several meta-analyses have explored the effect of therapies on PAH. A meta-analysis of 26 trials with a total of 3,519 patients reported an all-cause mortality risk reduction of 39% regardless of the class of therapy used. . . . Currently approved medications for pulmonary arterial hypertension (PAH) mainly act on three traditional pathways: the nitric oxide, endothelin, and prostacyclin pathways. These medications have greatly improved survival, and studies have shown superiority of combination therapy regimens over monotherapy.")

49 Qaiser, Kanza, and Adriano Tonelli (2021), "Novel Treatment Pathways in Pulmonary Arterial Hypertension," *Methodist Debakey Cardiovascular Journal* 17(2): 106–114, at 107, 110. ("Another meta-analysis of 17 RCTs with 4,095 total patients compared sequential combination therapy with monotherapy and reported a 35% reduced risk of clinical worsening with combination therapy[.]")

50 United, Form 10-K, 2023, at 19.

51 United, Form 10-K, 2023, at 3.

52 United, Adcirca Label, 9/2020, available at: https://pi.lilly.com/us/adcirca-pi.pdf. ("ADCIRCA is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of pulmonary arterial hypertension (WHO Group 1) to improve exercise ability. Studies establishing effectiveness included predominately patients with NYHA Functional Class II – III symptoms and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (23%).")

53 United, Orenitram Label, 8/2023, available at: https://www.orenitramhcp.com/media/content/files/Orenitram-Prescribing-Information.pdf. ("Orenitram is a prostacyclin mimetic indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to delay disease progression and to improve exercise capacity. The studies that established effectiveness included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (66%) or PAH associated with connective tissue disease (26%).")

54 The Remodulin prescribing information states: "Remodulin is a prostacyclin mimetic indicated for:" (1) "Treatment of pulmonary arterial hypertension (PAH; WHO Group 1) to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with NYHA Functional Class II-IV symptoms and etiologies of idiopathic or heritable PAH (58%), PAH associated with congenital systemic-to-pulmonary shunts (23%), or PAH associated with connective tissue diseases (19%)" and (2) "Patients who require transition from epoprostenol, to reduce the rate of clinical deterioration. The risks and benefits of each drug should be carefully considered prior to transition." See: United, Remodulin Label, 7/2021, available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/021272Orig1s032lbl.pdf.

3.2.3. PH-ILD

(38) PH-ILD falls under PH WHO Group 3[55] and is "a debilitating condition that frequently develops in the setting of interstitial lung disease, likely related to chronic alveolar hypoxemia and pulmonary vascular remodeling."[56] PH-ILD is also described as a "condition comprising a diverse collection of disease processes, characteristically due to elevated pulmonary artery pressures from either precapillary, postcapillary, or mixed etiologies."[57] Interstitial lung diseases ("ILDs") are a group of disorders that can cause scarring in the lungs, affecting the lungs' ability to carry oxygen and making it harder for a patient to breathe normally.[58] It is "common for ILD patients to also develop" PH.[59] PH is usually suspected when a patient's symptoms are "out of proportion to the severity of the patient's ILD."[60] As mentioned in Section 3.2.1, there are many tests that can be utilized to rule out other diseases—the most common currently being an echocardiogram[61]—leaving PH as the last remaining possible explanation for a patient's symptoms. United has estimated that PH-ILD impacts "at least 30,000 patients in the United States[,]"[62] whereas Liquidia has estimated that there are around 60,000 prevalent patients in the United States.[63]

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55 Pulmonary Hypertension Association Website, About Pulmonary Hypertension, https://phassociation.org/types-pulmonary-hypertension-groups/ (accessed 12/29/2023).

United Press Release, "United Therapeutics Announces FDA Approval of Tyvaso DPI," 5/24/2022, https://ir.unither.com/press-releases/2022/05-24-2022. ("PH-ILD is included within Group 3 of the WHO classification of PH.")

56 Haynes, Zachary, Abhimanyu Chandel, and Christopher King (2023), "Pulmonary Hypertension in Interstitial Lung Disease: Updates in Disease, Diagnosis, and Therapeutics," *Cells* 12(19): 2394.

57 Haynes, Zachary, Abhimanyu Chandel, and Christopher King (2023), "Pulmonary Hypertension in Interstitial Lung Disease: Updates in Disease, Diagnosis, and Therapeutics," *Cells* 12(19): 2394.

58 National Institutes of Health Website, What are Interstitial Lung Diseases?, https://www.nhlbi.nih.gov/health/interstitial-lung-diseases (accessed 1/11/2024).

59 UCSF Health Website, Pulmonary Hypertension and Interstitial Lung Disease, https://www.ucsfhealth.org/education/pulmonary-hypertension-and-interstitial-lung-disease (accessed 1/11/2024).

60 UCSF Health Website, Pulmonary Hypertension and Interstitial Lung Disease, https://www.ucsfhealth.org/education/pulmonary-hypertension-and-interstitial-lung-disease (accessed 1/11/2024).

61 Parikh, Raj, et al. (2022), "Pulmonary Hypertension in Patients With Interstitial Lung Disease: A Tool For Early Detection," *Pulmonary Circulation* 12(4): 1–11, at 2. ("To obviate these issues, there have been multiple attempts to incorporate various noninvasive parameters into a clinical prediction tool, but none has been widely adopted. Currently, the most common recommendation is an echocardiogram annually or sooner if there is a significant change in symptoms.")

62 United, Form 10-K, 2023, at 4.

63 Liquidia, "J.P. Morgan Healthcare Conference," 1/10/2024, at 5, available at: https://liquidia.com/static-files/83cf40bb-70ba-4345-90ed-307e89e0bafb.

See also:

(39) According to United's 2023 10-K filing, "Tyvaso DPI and nebulized Tyvaso are the only available therapies the FDA has approved to treat PH-ILD."[64] I understand that Liquidia is pursuing FDA approval of Yutrepia for the treatment of PH-ILD.[65]

3.3. Key products

3.3.1. Tyvaso and Tyvaso DPI

(40) Tyvaso is a prostacyclin class therapy which delivers treprostinil through inhalation.[66] Tyvaso is offered as an inhalation solution to be used with a nebulizer (Tyvaso), and an inhalation powder to be used with a dry powder inhaler (Tyvaso DPI).[67]

(41) Tyvaso received FDA approval to treat PAH in July 2009 and FDA approval to treat PH-ILD in March 2021.[68] Approval for the PH-ILD indication was based on "the successful INCREASE study of nebulized Tyvaso in patients with PH-ILD, including patients with underlying idiopathic pulmonary fibrosis (IPF) and combined pulmonary fibrosis and emphysema[.]"[69] The Tyvaso label states: "Tyvaso is a prostacyclin mimetic indicated for the treatment of:" (1) "Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies establishing effectiveness predominately included patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with

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Refinitiv StreetEvents, "Liquidia Corp at JPMorgan Healthcare Conference," 1/10/2024, at 3. ("It's PH associated with lung disease. In this instance, I'm showing that there's about 60,000 prevalent patients, which we can distill from academic research, syndicated academic research.")

64 United, Form 10-K, 2023, at 4.

65 Liquidia Press Release, "Liquidia Corporation Reports Full Year 2022 Financial Results and Provides Corporate Update," 3/16/2023, available at: https://www.liquidia.com/node/10286/pdf. ("If approved, YUTREPIA will provide patients with pulmonary arterial hypertension (PAH) and pulmonary hypertension with interstitial lung disease (PH-ILD) with the option to receive a differentiated inhaled treprostinil product via a low-resistance dry powder inhaler. . . . The FDA has confirmed that YUTREPIA may add the indication to treat pulmonary hypertension with interstitial lung disease (PH-ILD) without additional clinical studies.")

66 United, Form 10-K, 2023, at 4, 5, 20.

67 I will refer to the inhaled solution as "Tyvaso" and the dry powder formulation as "Tyvaso DPI" throughout this declaration.

United, Form 10-K, 2023, at 3.

Tyvaso Website, Tyvaso DPI, https://www.tyvaso.com/pah/about-tyvaso/tyvaso-dpi/ (accessed 1/5/2024).

68 United, Form 10-K, 2023, at 4.

PR Newswire, "United Therapeutics Announces FDA Approval and Launch of Tyvaso for the Treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease," 4/1/2021, https://www.prnewswire.com/news-releases/united-therapeutics-announces-fda-approval-and-launch-of-tyvaso-for-the-treatment-of-pulmonary-hypertension-associated-with-interstitial-lung-disease-301260212.html.

69 United, Form 10-K, 2023, at 4.

connective tissue diseases (33%)[,]" (2) "Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%)."[70] United's 10-K filing explains:[71]

> Nebulized Tyvaso is administered four times a day using our proprietary Tyvaso Inhalation System, which consists of an ultrasonic nebulizer and related accessories. Dose titration is achieved by varying the number of breaths per treatment session typically starting at three breaths per session, and increasing the dose in three-breath increments during the titration process. A single ampule containing nebulized Tyvaso solution is emptied into the Tyvaso Inhalation System once per day, so the Tyvaso Inhalation System only needs to be cleaned once daily. Nebulized Tyvaso is regulated by the FDA as a drug-device combination product consisting of Tyvaso drug product and the Tyvaso Inhalation System.

(42) Tyvaso DPI received FDA approval to treat PAH and PH-ILD in May 2022.[72] United completed two clinical studies for Tyvaso DPI prior to FDA approval.[73] The first "was a study in healthy volunteers, comparing the pharmacokinetics of Tyvaso DPI to Tyvaso Inhalation Solution."[74] United "completed the study in October 2020 and announced in January 2021 that the study demonstrated comparable systemic treprostinil exposure between Tyvaso DPI and Tyvaso Inhalation Solution."[75] The second was a study called *BREEZE*, "which evaluated the safety and pharmacokinetics of switching PAH patients from Tyvaso Inhalation Solution to Tyvaso DPI."[76] *BREEZE* was completed in December 2020 and "demonstrated the safety and tolerability of Tyvaso DPI in subjects with PAH transitioning from Tyvaso Inhalation Solution, and comparable systemic treprostinil exposure between Tyvaso DPI and Tyvaso Inhalation Solution."[77] The FDA also granted Tyvaso and Tyvaso DPI clinical trial exclusivity for the

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70 United, Tyvaso Label, 5/2022, at 1, available at: https://www.tyvaso.com/pdf/TYVASO-PI.pdf.

71 United, Form 10-K, 2023, at 5.

72 United, Form 10-K, 2023, at 4.

73 United, Form 10-K, 2022, at 5.

74 United, Form 10-K, 2022, at 5.

75 United, Form 10-K, 2022, at 5.

76 United, Form 10-K, 2022, at 5.

77 United, Form 10-K, 2022, at 5.

treatment of PH-ILD until March 31, 2024.[78] The Tyvaso DPI label states: "Tyvaso DPI is a prostacyclin mimetic indicated for the treatment of:" (1) "Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies with Tyvaso establishing effectiveness predominately included patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%)[,]" (2) "Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study with Tyvaso establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%)."[79] The Tyvaso DPI label further explains:[80]

> Use Tyvaso DPI only with the Tyvaso DPI Inhaler. Tyvaso DPI is administered using a single inhalation per cartridge. Administer Tyvaso DPI in 4 separate, equally spaced treatment sessions per day, during waking hours. The treatment sessions should be approximately 4 hours apart.

3.3.2. Yutrepia

(43) Yutrepia inhalation powder is an investigational, inhaled dry powder formulation of treprostinil developed by Liquidia.[81] Yutrepia is a prostacyclin treatment[82] that uses a dry

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78 United, Form 10-K, 2023, at 14. ("In March 2021, the FDA granted Tyvaso three-year clinical trial exclusivity for PH-ILD as a result of the INCREASE study and the expansion of the Tyvaso label to include a PH-ILD indication. This exclusivity period will extend through March 2024, and also covers Tyvaso DPI for PH-ILD.")

See also:

Liquidia Corporation, Form 8-K, 11/7/2023, at Exhibit 99.1. ("If approved, YUTREPIA would be indicated for the treatment of both pulmonary arterial hypertension (PAH) and PH-ILD, though final approval of the PH-ILD indication cannot occur until the new clinical investigation exclusivity granted to Tyvaso expires on March 31, 2024.")

Three-year clinical trial exclusivity provides the holder of an approved new drug application limited protection from new competition in the marketplace by precluding approval of certain 505(b)(2) applications or certain abbreviated new drug applications (ANDAs). See:

U.S. Food & Drug Administration, "Small Business Assistance: Frequently Asked Questions for New Drug Product Exclusivity," 2/11/2016, https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-new-drug-product-exclusivity.

79 United, Tyvaso DPI Label, 11/2023, at 1, available at: https://www.tyvaso.com/pdf/TYVASO-DPI-PI.pdf.

80 United, Tyvaso DPI Label, 11/2023, at 2, available at: https://www.tyvaso.com/pdf/TYVASO-DPI-PI.pdf.

81 Liquidia Website, Pipeline, https://www.liquidia.com/products-and-pipeline/overview (accessed 1/2/2024).

82 Hill, Nicholas, et al (2022), "INSPIRE: Safety and Tolerability of Inhaled Yutrepia (treprostinil) in Pulmonary Arterial Hypertension (PAH)," *Pulmonary Circulation* 12(3): 1–11, at Abstract. ("Yutrepia was found to be a convenient, safe, and well-tolerated inhaled prostacyclin treatment option for PAH patients.")

powder inhaler to deliver the drug.[83] Yutrepia received tentative FDA approval on November 5, 2021, and is indicated for "the treatment of pulmonary arterial hypertension (PAH) to improve exercise ability in adult patients with New York Heart Association (NYHA) Functional Class II-III symptoms."[84] Tentative FDA approval means that a drug, in this case Yutrepia, has met all regulatory standards for quality, safety, and efficacy required for approval in the United States but cannot yet be marketed.[85] I understand that Liquidia is also pursuing FDA approval for the PH-ILD indication.[86]

(44) Liquidia claims that "YUTREPIA (treprostinil) inhalation powder was designed using Liquidia's PRINT technology, which enables the development of drug particles that are precise and uniform in size, shape, and composition, and that are engineered for improved deposition in the lung following oral inhalation."[87]

3.4. Regulatory approval pathways

(45) Tyvaso and Tyvaso DPI were approved by the FDA via 505(b)(1) New Drug Applications (NDAs) whereas Yutrepia is seeking approval via the 505(b)(2) pathway.[88]

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83 United, Form 10-K, 2022, at 16. ("Yutrepia, a dry powder formulation of treprostinil developed by Liquidia, which is designed for pulmonary delivery using a disposable inhaler.")

84 Liquidia Website, Pipeline, https://www.liquidia.com/products-and-pipeline/overview (accessed 1/2/2024).

85 Liquidia Press Release, "FDA Grants Tentative Approval for Liquidia's YUTREPIA (Treprostinil) Inhalation Powder," 11/8/2021, https://www.liquidia.com/news-releases/news-release-details/fda-grants-tentative-approval-liquidias-yutrepiatm-treprostinil.

Liquidia Corporation, Form 10-K, 2022, at 5. ("In November 2021, the FDA issued a tentative approval of YUTREPIA which indicated that the NDA had met all the requirements for final approval but cannot yet be marketed.")

See also:

Code of Federal Regulations, 21 C.F.R. § 314.105 (2016).

FDA Website, Drugs@FDA Glossary of Terms, at 6, https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms# (accessed 1/12/2024).

86 Liquidia Press Release, "FDA Accepts Submission to Add PH-ILD to Yutrepia Label," 9/25/2023, https://www.liquidia.com/news-releases/news-release-details/fda-accepts-submission-add-ph-ild-yutrepiatm-label.

87 Liquidia Website, Pipeline, https://www.liquidia.com/products-and-pipeline/overview (accessed 1/2/2024).

88 FDA, Tyvaso (treprostinil) Approval Letter, 7/30/2009, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/022387s000ltr.pdf.

FDA, Tyvaso DPI (treprostinil) Approval Letter, 5/23/2022, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/214324Orig1s000ltr.pdf.

Tyvaso Website, Frequently Asked Questions (PH-ILD), https://www.tyvasohcp.com/ph-ild/what-is-tyvaso/faqs/ (accessed 2/23/2024). ("TYVASO DPI was approved by the FDA via the 505(b)(1) pathway based on the results of the BREEZE study, in addition to prior clinical trials with TYVASO—including INCREASE. The safety and tolerability of switching from TYVASO to TYVASO DPI was assessed in the BREEZE study, an open-label clinical study of 51 patients

(46) The 505(b)(1) NDA is "an application that contains full reports of investigations of safety and effectiveness, in addition to other information. The data in the application is either owned by the applicant or is data for which the applicant has obtained a right of reference."[89] A 505(b)(1) NDA includes clinical safety and effectiveness data, clinical pharmacology information, non-clinical information (toxicology, carcinogenicity, etc.), and information on chemistry, manufacturing, and controls.[90]

(47) The 505(b)(2) process can be used for new products that are "'almost' generics" of a reference product but that have changes relative to the previously approved reference drug.[91] For example, the 505(b)(2) pathway may apply to products that make use of active ingredients that have previously been reviewed and approved by the FDA for different reference products, for different uses, or for delivery by different means.[92] Products reviewed under this process reference clinical evidence produced at least in part by other parties.[93]

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with PAH. It was found that systemic exposure was similar between TYVASO and TYVASO DPI. The BREEZE study only included patients with PAH; the FDA did not require TYVASO DPI to be studied in patients with PH-ILD. The INCREASE trial was a 16-week, phase 3, multicenter, randomized, double-blind, placebo-controlled study of 326 patients with PH-ILD designed to assess the efficacy and safety of TYVASO.")

Liquidia Corporation, Form 10-K, 2022, at 5. ("We have developed YUTREPIA under the 505(b)(2) regulatory pathway using the nebulized form of treprostinil, Tyvaso, as the reference listed drug.")

89 U.S. Food & Drug Administration, "Small Business Assistance: Frequently Asked Questions for New Drug Product Exclusivity," 2/11/2016, https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-new-drug-product-exclusivity.

90 FDA, "Overview of the 505(B)(2) Regulatory Pathway for New Drug Applications," undated, at 3, available at: https://www.fda.gov/media/156350/download.

91 FDA, "Overview of the 505(B)(2) Regulatory Pathway for New Drug Applications," undated, at 5, 10, 11, available at: https://www.fda.gov/media/156350/download. ("Contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval *comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use*[.] Allows for flexibility in the characteristics of the proposed product without having to conduct studies on what is already known about the product[.]") ("Changes compared to previously approved drugs [may include:] Indication[;] Active ingredient[;] Fixed-combination[;] Dosage form[;] Route of administration[;] Dosing regimen[;] Strength[; and] Formulation[.]") ("505(b)(2) NDAs can be New Chemical Entities (NCEs) OR 'almost' generics[.]")

92 FDA, "Overview of the 505(B)(2) Regulatory Pathway for New Drug Applications," undated, at 5, 10, 11, available at: https://www.fda.gov/media/156350/download. ("Contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval *comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use*[.] Allows for flexibility in the characteristics of the proposed product without having to conduct studies on what is already known about the product[.]") ("Changes compared to previously approved drugs [may include:] Indication[;] Active ingredient[;] Fixed-combination[;] Dosage form[;] Route of administration[;] Dosing regimen[;] Strength[; and] Formulation[.]") ("505(b)(2) NDAs can be New Chemical Entities (NCEs) OR 'almost' generics[.]")

93 FDA, "Determining Whether to Submit an ANDA or a 505(b)(2) Application: Guidance for Industry," 5/2019, at 4, available at: https://www.fda.gov/media/124848/download. ("As discussed in section II above, an application submitted through the pathway described in section 505(b)(2) of the FD&C Act contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use (e.g., the Agency's finding of safety and/or

3.5. The ’793 patent

(48) U.S. Patent No. 10,716,793 (“the ”793 patent”), entitled “Treprostinil Administration by Inhalation,” was filed on January 31, 2020 and issued on July 21, 2020.[94] The ”793 patent lists Horst Olschewski, Robert Roscigno, Lewis J. Rubin, Thomas Schmehl, Werner Seeger, Carl Sterritt, and Robert Voswinckel as its inventors and United Therapeutics Corporation as its assignee.[95] The abstract of the ”793 patent reads as follows:

> Treprostinil can be administered using a metered dose inhaler. Such administration provides a greater degree of autonomy to patients. Also disclosed are kits that include a metered dose inhaler containing a pharmaceutical formulation containing treprostinil.[96]

(49) According to United, “[t]he ”793 patent relates to a method of administering treprostinil via inhalation and includes claims covering the dosing regimen used to administer Tyvaso DPI and nebulized Tyvaso”[97]

effectiveness for a listed drug, published literature). A 505(b)(2) applicant may rely on FDA’s finding of safety and/or effectiveness for a listed drug only to the extent that the proposed product in the 505(b)(2) application shares characteristics (e.g., active ingredient, dosage form, route of administration, strength, indication or other conditions of use) in common with the relied-upon listed drug(s).”)

94 Treprostinil Administration by Inhalation, U.S. Patent No. 10,716,793 (filed 1/31/2020, issued 7/21/2020).

95 Treprostinil Administration by Inhalation, U.S. Patent No. 10,716,793 (filed 1/31/2020, issued 7/21/2020).

96 Treprostinil Administration by Inhalation, U.S. Patent No. 10,716,793 (filed 1/31/2020, issued 7/21/2020).

97 United, Form 10-K, 2023, at F-34.

4. Harms that United Will Suffer Absent a Stay

(50) I understand that the stay that United is seeking will prevent the FDA from approving Yutrepia. Absent a stay, there are several apparent harms that would occur as a result of direct competition from Yutrepia.

4.1. The market will view the Tyvaso products and Yutrepia as alternatives

(51) Based on (1) my understanding from Dr. Steven Nathan, (2) the existing and anticipated FDA labels for Tyvaso and Yutrepia, (3) the targeted treatment populations, and (4) market responses to the potential entry of Yutrepia, I expect that the market will view the Tyvaso products and Yutrepia as alternatives and direct competitors for treating patients with PAH or PH-ILD.[98]

(52) I understand from Dr. Nathan that most, if not all, providers will view the Tyvaso products and Yutrepia as alternatives with virtually no clinical differences between Tyvaso DPI and Yutrepia.[99] PAH and PH-ILD treatments are generally characterized by pathway (prostacyclin, nitric oxide, and endothelin), active ingredient, and delivery mechanism.[100] On each of these attributes, Yutrepia is highly similar to the Tyvaso products. Both Tyvaso products (nebulized and DPI) and Yutrepia are inhaled prostacyclin-class treprostinil therapies.[101] Moreover, both

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98 I use the terms alternative(s) and substitute(s) interchangeably in my declaration for ease of exposition. My use of the term alternative is synonymous with the economic concept of a substitute. See:

Varian, Hal (2014), *Intermediate Microeconomics: A Modern Approach*, 9th ed., New York, NY: W.W. Norton & Company, Inc., at 111–112. ("If the demand for good 1 goes up when the price of good 2 goes up, then we say that good 1 is a substitute for good 2. . . . The idea is that when good 2 gets more expensive the consumer switches to consuming good 1: the consumer substitutes away from the more expensive good to the less expensive good.")

99 Interview with Dr. Steven Nathan, 2/9/2024.

Some evidence suggests that the parties are attempting to differentiate Yutrepia and Tyvaso DPI, yet I understand from Dr. Nathan that providers will see virtually no clinical differences between Tyvaso DPI and Yutrepia.

100 See, for example:

United, Form 10-K, 2023, at 4.

United, Form 10-K, 2020, at 18.

101 United, Form 10-K, 2022, at 4.

Liquidia Website, Pipeline, https://www.liquidia.com/products-and-pipeline/overview (accessed 1/2/2024).

Tyvaso DPI and Yutrepia are inhaled powders which utilize a dry powder inhaler to deliver the drug.[102]

(53) This is further supported by the indications approved, tentatively approved, or seeking approval by the FDA for Tyvaso, Tyvaso DPI, and Yutrepia:

- **Tyvaso**: "Tyvaso is a prostacyclin mimetic indicated for the treatment of: Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability . . . . Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability."[103]
- **Tyvaso DPI**: "Tyvaso DPI is a prostacyclin mimetic indicated for the treatment of: Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. . . . Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability."[104]
- **Yutrepia**: "Liquidia Corporation (the Company) (NASDAQ: LQDA) announced today that the U.S. Food and Drug Administration (FDA) accepted for review the Company's amendment to the tentatively approved new drug application (NDA) for YUTREPIA (treprostinil) inhalation powder in which the Company is seeking to add the treatment of pulmonary hypertension associated with interstitial lung disease (PH-ILD) to the label. . . . On November 5, 2021, the FDA issued a tentative approval for YUTREPIA for the treatment of pulmonary arterial hypertension (PAH) to improve exercise ability in adult patients with New York Heart Association (NYHA) Functional Class II-III symptoms."[105]

(54) Direct competition between Yutrepia and the Tyvaso products is also supported by the pathway Liquidia has pursued for regulatory approval, relying on clinical evidence from a

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102 United, Tyvaso DPI Label, 11/2023, at 2, available at: https://www.tyvaso.com/pdf/TYVASO-DPI-PI.pdf.

Liquidia Press Release, "Liquidia Corporation Reports Full Year 2022 Financial Results and Provides Corporate Update," 3/16/2023, available at: https://www.liquidia.com/node/10286/pdf. ("If approved, YUTREPIA will provide patients with pulmonary arterial hypertension (PAH) and pulmonary hypertension with interstitial lung disease (PH-ILD) with the option to receive a differentiated inhaled treprostinil product via a low-resistance dry powder inhaler. . . . The FDA has confirmed that YUTREPIA may add the indication to treat pulmonary hypertension with interstitial lung disease (PH-ILD) without additional clinical studies.")

103 United, Tyvaso Label, 5/2022, at 1, available at: https://www.tyvaso.com/pdf/TYVASO-PI.pdf.

104 United, Tyvaso DPI Label, 11/2023, at 1, available at: https://www.tyvaso.com/pdf/TYVASO-DPI-PI.pdf.

105 Liquidia has sought approval for a PH-ILD indication, but such approval or tentative approval has not yet been granted. See:

Liquidia Press Release, "FDA Accepts Submission to Add PH-ILD to Yutrepia Label," 9/25/2023, https://www.liquidia.com/news-releases/news-release-details/fda-accepts-submission-add-ph-ild-yutrepiatm-label. ("Liquidia Corporation (the Company) (NASDAQ: LQDA) announced today that the U.S. Food and Drug Administration (FDA) accepted for review the Company's amendment to the tentatively approved new drug application (NDA) for YUTREPIA (treprostinil) inhalation powder in which the Company is seeking to add the treatment of pulmonary hypertension associated with interstitial lung disease (PH ILD) to the label.")

reference product that already has been reviewed and approved by the FDA.[106] In the case of Yutrepia, Liquidia used Tyvaso (in nebulized form) as the reference product in order to rely on FDA findings of efficacy and safety for the active ingredient, treprostinil.[107]

(55) Both United and Liquidia have made clear in their financial disclosures that they expect the Tyvaso products and Yutrepia to compete.[108] For example, United's 2023 Form 10-K reports: "if Yutrepia is commercially launched, our Tyvaso revenues could potentially be materially adversely affected, and the impact may be more material if Yutrepia is approved for the treatment of PH-ILD."[109] [redacted][110]

(56) Multiple analyst reports also indicate that investors expect that Liquidia will directly compete with United in the PAH and PH-ILD markets.[111] For example, a Needham analyst report states

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106 FDA, "Determining Whether to Submit an ANDA or a 505(b)(2) Application: Guidance for Industry," 5/2019, at 4, available at: https://www.fda.gov/media/124848/download. ("As discussed in section II above, an application submitted through the pathway described in section 505(b)(2) of the FD&C Act contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use (e.g., the Agency's finding of safety and/or effectiveness for a listed drug, published literature). A 505(b)(2) applicant may rely on FDA's finding of safety and/or effectiveness for a listed drug only to the extent that the proposed product in the 505(b)(2) application shares characteristics (e.g., active ingredient, dosage form, route of administration, strength, indication or other conditions of use) in common with the relied-upon listed drug(s).")

107 Liquidia Corporation, Form 10-K, 2022, at 5.

108 United, Form 10-Q, 2023-Q2, at 39. ("Our competitors are also developing new products that may compete with ours. For example, Liquidia and Merck are developing Yutrepia and sotatercept, respectively, which if successful would compete with our treprostinil-based products.")

Liquidia Corporation, Form 10-Q, 2023-Q3, at 55. ("We expect that our lead program, YUTREPIA, an inhaled Treprostinil therapy for the treatment of PAH and PH-ILD, and L606, a nebulized, liposomal formulation of treprostinil for treatment of PAH and PH-ILD, will face competition from the following inhaled treprostinil therapies that are either currently marketed or in clinical development: Tyvaso, marketed by United Therapeutics, has been approved for the treatment of PAH in the United States since 2009. In April 2021, United Therapeutics announced that Tyvaso was approved by the FDA to include treatment of patients with PH-ILD. Tyvaso is the reference drug in our NDA for YUTREPIA. . . . Tyvaso DPI, licensed from MannKind by United Therapeutics, is a dry-powder formulation of treprostinil that was approved for the treatment of PAH and PH-ILD in the United States in May 2022.")

109 United, Form 10-K, 2023, at 56.

110 United, 2023 Business Planning UT Marketing, c. 2023 (2023 Marketing Business Plan FINAL.docx, at 2, 9).

111 For example:

Needham, "Top Pick for 2024; Yutrepia Opportunity in PAH/PH-ILD Markets Comes Into Focus," 1/5/2024, at 1. ("Yutrepia will compete directly against UTHR's Tyvaso franchise, which now generates >$1.3B in annualized sales (3Q23 sales of $316MM, +26%Y/Y). Growth of the Tyvaso franchise has been driven by a PH-ILD label expansion in Apr. 2021 and approval of Tyvaso DPI in May 2022.")

that "Yutrepia will compete directly against UTHR's Tyvaso franchise[.]"[112] The following excerpt from a Liquidia earnings call also indicates that Yutrepia and Tyvaso DPI are considered competitors:[113]

> Finally, I want to briefly address a comment that was made by United Therapeutics in its earnings call yesterday in which they compared admitted dose calculations between YUTREPIA and Tyvaso DPI. This is a red hearing. Patients and physicians don't care about admitted dose calculations. They only care about the actual dose received. As confirmed in our registration studies and validated by the FDA and their granting of tentative approval, YUTREPIA reliably and precisely delivers doses to patients that are comparable to all of the treprostinil doses in the Tyvaso DPI level as well as doses above and beyond those that are in the Tyvaso DPI label.

(57) Recent stock price trends further demonstrate the competitive relationship between United and Liquidia. Around December 20, 2023, when the Federal Circuit affirmed a PTAB decision that would hold all claims of the '793 patent are not patentable, United's stock price dropped significantly and Liquidia's stock price increased significantly.[114] From an economic

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TD Cowen, "Tyvaso '793 Patent PTAB Decision Affirmed in Appeals Court as Expected," 12/20/2023, at 1. ("When we asked our surveyed physicians about their views on the overall safety/efficacy profiles of Tyvaso and Yutrepia in our most recent PAH survey, 72% of our respondents indicated that they see the two products as likely interchangeable, while 24% indicated that they see Tyvaso as the superior product, and only 4% saw Yutrepia as the superior product.")

Zacks, "United Therapeutics (UTHR)," 12/8/2023, at 4. ("We believe competition will continue to increase with several companies working on bringing additional therapies to the market. Several investigational PAH therapies are in the later stages of development. Yutrepia, a DPI formulation of treprostinil developed by Liquidia Technologies, was granted tentative approval by the FDA in November 2021. The final FDA approval is pending until the Tyvaso patent expires, which is in May 2027.")

UBS, "3Q Wrap: Headline Risk of Competitive Threat Overrated," 11/1/2023, at 1. ("UTHR's strong commercial execution against competitor LQDA has been demonstrated in the Remodulin genericization: we believe Tyvaso is a similar set-up.")

112 Needham, "Top Pick for 2024; Yutrepia Opportunity in PAH/PH-ILD Markets Comes Into Focus," 1/5/2024, at 1. ("Yutrepia will compete directly against UTHR's Tyvaso franchise, which now generates >$1.3B in annualized sales (3Q23 sales of $316MM, +26%Y/Y). Growth of the Tyvaso franchise has been driven by a PH-ILD label expansion in Apr. 2021 and approval of Tyvaso DPI in May 2022.")

113 Refinitiv Eikon, "Q1 2023 Liquidia Corp Earnings Call," 5/4/2023.

114 Liquidia Press Release, "U.S. Federal Circuit Affirms Earlier PTAB Decision to Invalidate All Claims of United Therapeutics Patent No. 10,716,793 ('793 Patent)," 12/20/2023, https://liquidia.com/news-releases/news-release-details/us-federal-circuit-affirms-earlier-ptab-decision-invalidate-all.

United's stock price dropped over 11% from $246.40 on December 18, 2023, to $218.93 on December 22, 2023. Liquidia's stock price jumped over 57% from $7.47 to $11.77 over the same period.

($218.93 - $246.40) / $246.40 = -11.15%.

($11.77 - $7.47) / $7.47 = 57.56%.

perspective, United's stock price decreasing and Liquidia's stock price increasing around this event demonstrate that the market views Yutrepia and the Tyvaso products to be close competitors. This stock price behavior is indicative of investor expectations of direct competition between Yutrepia and the Tyvaso products.

4.2. Price erosion

4.2.1. Overview

(58) Given the similarities between Yutrepia and the Tyvaso products, absent a stay, United will have to offer discounts and price concessions due to Yutrepia's infringement and entry into the PAH and PH-ILD marketplaces. Accordingly, Liquidia's entry will cause lasting price erosion. This harm is infeasible to fully quantify and thereby compensate with monetary damages. However, price erosion effects on the Tyvaso products from Yutrepia entry are a near certainty. [redacted].[115] As I explain below, comparable pharmaceutical markets experienced price erosion of up to 30% to 40% or more.[116]

(59) Price competition in this marketplace is likely to be driven by the unique position of insurers and pharmacy benefit managers in the healthcare market. Insurers and PBMs have strong financial incentives to balance access to beneficial treatments and keep costs low. PBMs act as "intermediaries between pharmacies, plan sponsors (insurance companies and employers), pharmaceutical manufacturers, and drug wholesalers."[117] An important service provided by PBMs is the development of a drug formulary.[118] Formularies specify what drugs are covered

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Yahoo Finance, United Therapeutics Corporation Historical Data, https://finance.yahoo.com/quote/UTHR/history?period1=1701388800&period2=1703980800&interval=1d&filter=history&frequency=1d&includeAdjustedClose=true (accessed 2/14/2024).

Yahoo Finance, Liquidia Corporation Historical Data, https://finance.yahoo.com/quote/LQDA/history?period1=1701388800&period2=1703980800&interval=1d&filter=history&frequency=1d&includeAdjustedClose=true (accessed 2/14/2024).

115 Interview with David Barton, 2/14/2024.

116 This is based on the rebates observed in analogous market situations (Hepatitis C and PCSK9 inhibitors).

117 Mattingly, T. Joseph, David A. Hyman, and Ge Bai (2023), "Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy," *JAMA Health Forum* 4(11): 1–14, at 1.

118 Mattingly, T. Joseph, David A. Hyman, and Ge Bai (2023), "Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy," *JAMA Health Forum* 4(11): 1–14, at 3.

and the associated costs to patients when a drug is dispensed.[119] Drugs on a formulary are organized into tiers, based on clinical assessments and negotiated prices obtained by the plans, with higher priced products appearing on higher tiers and carrying the highest coinsurance rates.[120] Formularies allow payors to steer patients to the lowest cost option among a range of substitutes.[121] Formularies provide "substantial leverage to purchasers in negotiations with manufacturers" and "[t]hat leverage is the primary cost-control mechanism in Medicare Part D (the drug benefit portion of Medicare) and in most private insurance plans."[122] Favorable formulary placement stimulates demand for a drug, both by reducing the effective cost to the patient and by inducing substitution away from competing drugs with less favorable placement.[123] Because payors will place the lower-priced drug on the formulary,

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119 Mattingly, T. Joseph, David A. Hyman, and Ge Bai (2023), "Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy," *JAMA Health Forum* 4(11): 1–14, at 3.

120 Health Affairs Health Policy Brief, "Formularies," 9/2017, at 2–3, available at: https://www.healthaffairs.org/do/10.1377/hpb20171409.000177/full/hpb_2017_09_14_formularies-1687871374910.pdf.

As an example, formulary tiers could be structured as follows:

Tier 1. Generic drugs: Typically the most affordable and are equal to their brand-name counterparts in quality, performance characteristics, and intended use.

Tier 2. Preferred brand-name drugs: Proven to be safe, effective, and favorably priced compared to nonpreferred brands.

Tier 3. Nonpreferred brand-name drugs: These drugs have either a generic or preferred brand available; therefore, patients' cost share will be higher.

Tier 4. Preferred specialty drugs: Proven to be safe, effective, and favorably priced compared to nonpreferred specialty drugs.

Tier 5. Nonpreferred specialty drugs: These drugs typically have a preferred brand available; therefore, patients' cost share will be higher.

121 Berndt, Ernst R. and Joseph P. Newhouse (2012), "Pricing and Reimbursement in US Pharmaceutical Markets," in Patricia M. Danzon and Sean Nicholson eds., *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, Oxford, UK: Oxford University Press, at 210. ("By insuring a drug—that is, by requiring a co-payment of *c* rather than requiring the consumer to pay the uninsured market price—the insurer has a bargaining chip to trade with the manufacturer. With a formulary, the insurer controls access to the added quantity demanded at the insured price. In exchange for being able to make these sales, manufacturers are willing to discount off the uninsured price.")

122 Health Affairs Health Policy Brief, "Formularies," 9/2017, at 1, available at: https://www.healthaffairs.org/do/10.1377/hpb20171409.000177/full/hpb_2017_09_14_formularies-1687871374910.pdf.

See also: Berndt, Ernst R. and Joseph P. Newhouse (2012), "Pricing and Reimbursement in US Pharmaceutical Markets," in Patricia M. Danzon and Sean Nicholson eds., *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, Oxford, UK: Oxford University Press, at 210. ("By insuring a drug—that is, by requiring a co-payment of c rather than requiring the consumer to pay the uninsured market price—the insurer has a bargaining chip to trade with the manufacturer. With a formulary, the insurer controls access to the added quantity demanded at the insured price. In exchange for being able to make these sales, manufacturers are willing to discount off the uninsured price.")

123 Berndt, Ernst R. and Joseph P. Newhouse (2012), "Pricing and Reimbursement in US Pharmaceutical Markets," in Patricia M. Danzon and Sean Nicholson eds., *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, Oxford, UK: Oxford University Press, at 209–210. ("Suppose now that drug insurance becomes available and that the insurer solicits price bids from the two firms, promising the firm with the lowest bid price that its drug will be on the formulary with a small co-payment, whereas the firm with the losing bid will not have its drug on the formulary, and the consumer will pay a full price for that uninsured product. This favorable formulary placement stimulates own-demand for the winning bidder's

manufacturers are forced to price compete, offering greater discounts and rebates in exchange for favorable or equivalent formulary placement.[124]

(60) [redacted]

drug and induces substitution away from the firm with the losing price bid. Each firm will assess its profits with and without placement on the formulary and will bid a lower price provided that, if it wins, its profits will not be lower than if it did not lower its price to the insurer. . . . In sum, with a tiered formulary, prices of both drugs fall and the quantity sold of the drug on the formulary increases.")

124 Berndt, Ernst R. and Joseph P. Newhouse (2012), "Pricing and Reimbursement in US Pharmaceutical Markets," in Patricia M. Danzon and Sean Nicholson eds., *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, Oxford, UK: Oxford University Press, at 208. ("Instead of a patent-protected, truly unique drug in a monopoly situation, envisage two patent-protected drugs in the same therapeutic class that compete to be on the formulary; the insurer will place the lower-priced drug on the formulary. . . . It is somewhat tedious but not difficult to generalize this simple model to the case of several drugs, multiple-tier formularies, and positive marginal production costs, but the qualitative results we report here would still hold.")

See also:

Borrell, Joan-Ramon (2003), "Drug Price Differentials Caused by Formularies and Price Caps," *International Journal of the Economics of Business* 10(1): 35–48, at 46. ("This paper shows that drug firms are willing to offer discounts to health care providers when formulary and price caps are implemented. The model shows that discounts offered by pharmaceutical companies to major purchasers are competitive responses to health-care providers implementing price-sensitive formularies.")

Wall Street Journal, "For Prescription Drug Makers, Price Increases Drive Revenue," 10/5/2015, https://www.wsj.com/articles/for-prescription-drug-makers-price-increases-drive-revenue-1444096750. ("In competitive markets such as asthma and diabetes therapy, which have multiple drugs that can be substituted for one another, manufacturers often give especially large rebates as they seek better positioning on insurers' 'formularies' of covered drugs.")

AMA, "How Are Prescription Drug Prices Determined?," 4/9/2019, available at: https://www.ama-assn.org/print/pdf/node/20881. ("Working on behalf of health insurance companies or employers, PBMs negotiate upfront discounts on the prices of prescription drugs with pharmaceutical companies, as well as rebates, which reward favorable coverage of a particular drug (and the resulting increase in utilization by a health plan's patients).")

125 Interview with David Barton, 2/14/2024.

126 Interview with David Barton, 2/14/2024.

127 Interview with David Barton, 2/14/2024.

128 Interview with David Barton, 2/14/2024.

[redacted]

(61) Aside from formulary placement or exclusion of certain products from the formulary entirely, there are other levers that payors can use to incentivize price competition. These include utilization management via step therapy and prior authorization.

(62) Step therapy requires a patient to try "less expensive options before 'stepping up' to drugs that cost more."[131] In other words, a patient needs to experience treatment failure with the preferred medication before being approved for a non-preferred medication.[132] Step therapy "encourages the use of less costly yet effective medications before more costly medications are approved for coverage."[133] Drugs that are part of a step therapy program "are typically considered therapeutic alternatives to each other for their respective step therapy group."[134] [redacted]

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129 Interview with David Barton, 2/14/2024.

130 Interview with David Barton, 2/14/2024.

131 Blue Cross Blue Shield Blue Care Network of Michigan Website, How Does Step Therapy Work, https://www.bcbsm.com/individuals/help/pharmacy/what-is-step-therapy/ (accessed 1/30/2024).

132 Mattingly, T. Joseph, David A. Hyman, and Ge Bai (2023), "Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy," *JAMA Health Forum* 4(11): 1–14, at 4.

133 Cigna Healthcare Website, Step Therapy, https://static.cigna.com/assets/chcp/resourceLibrary/pharmacyResources/pharmSteptherapy.html (accessed 1/30/2024).

134 Cigna Healthcare Website, Step Therapy, https://static.cigna.com/assets/chcp/resourceLibrary/pharmacyResources/pharmSteptherapy.html (accessed 1/30/2024).

One example of step therapy requirements relates to proton pump inhibitors (PPIs) where patients have to try cheaper therapies before stepping up to more expensive ones. For example, under United Healthcare's step therapy program for PPIs, patients are required to try lower cost PPIs before coverage will be provided for Nexium suspension, Prevacid SoluTab and Zegerid suspension. Nexium suspension and Prevacid SoluTabs will only be approved if one of three conditions is met. First, a patient can be approved if they have a history of failure, contraindication, or intolerance to a prescription formulation of omeprazole, pantoprazole, and rabeprazole. Second, a patient can be approved if they are unable to swallow a tablet or capsule dosage form due to either age, oral/motor difficulties, or dysphagia. Third, a patient can be approved if they utilize a feeding tube for medical administration. The step program also dictates that Zegerid suspension will only be approved if a patient has a history of failure, contraindication, or intolerance to both Nexium Suspension (esomeprazole) and generic Prevacid SoluTabs.

See: UnitedHealthcare, "Clinical Pharmacy Programs," 6/1/2023, at 1, 2, available at: https://www.uhcprovider.com/content/dam/provider/docs/public/resources/pharmacy/step-therapy/Step-Therapy-Nexium.pdf.

See also: Cigna, "Cigna National Formulary Coverage Policy," 12/13/2023, available at: https://static.cigna.com/assets/chcp/pdf/coveragePolicies/cnf/cnf_070_coveragepositioncriteria_proton_pump_inhibitors_st.pdf.

[redacted][135]

(63) Prior authorization on the other hand "refers to a prospective utilization review focusing on evaluating the appropriateness of the prescribed therapy."[136] Payors will not cover treatments requiring prior authorization until they have reviewed and approved the request.[137] Often, a prescribing physician is required to submit additional information before payment is approved.[138] Medications that may require prior authorization include treatments that have lower cost yet equally effective alternatives available, treatments that should only be used for certain health conditions, treatments that are often misused or abused, and drugs used for cosmetic purposes.[139] I understand that Tyvaso and Tyvaso DPI typically require prior authorization before coverage will be provided.[140] The existing prior authorization process is what will enable payors to set requirements that patients try one medication or therapy and fail it before agreeing to reimburse the alternative medication or therapy.

(64) Both step therapy and prior authorization requirements create greater hurdles for patients and prescribers. A physician will be less likely to prescribe a drug that is in a higher step tier if there is an effective drug in a lower step tier available. Similarly, a physician will be less likely to prescribe a drug requiring prior authorization if there is an effective option that does not require prior authorization. Recognizing the disincentives to prescribe a non-preferred drug, manufacturers such as United will be forced to price compete to achieve preferred

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135 Interview with David Barton, 2/14/2024.

136 Mattingly, T. Joseph, David A. Hyman, and Ge Bai (2023), "Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy," *JAMA Health Forum* 4(11): 1–14, at 4.

137 Cigna Website, What is Prior Authorization, https://www.cigna.com/knowledge-center/what-is-prior-authorization (accessed 1/30/2024).

138 Mattingly, T. Joseph, David A. Hyman, and Ge Bai (2023), "Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy," *JAMA Health Forum* 4(11): 1–14, at 4.

139 Cigna Website, What is Prior Authorization, https://www.cigna.com/knowledge-center/what-is-prior-authorization (accessed 1/30/2024). ("What types of medical treatments and medications may need prior authorization? Medications that may be unsafe when combined with other medications[;] Medical treatments that have lower-cost, but equally effective, alternatives available[;] Medical treatments and medications that should only be used for certain health conditions[;] Medical treatments and medications that are often misused or abused[;] Drugs often used for cosmetic purposes[.]")

140 See, for example: United Healthcare, "Prior Authorization / Medical Necessity – PAH Agents," 6/1/2023, available at: https://www.uhcprovider.com/content/dam/provider/docs/public/prior-auth/drugs-pharmacy/commercial/h-p/PA-Med-Nec-PAH.pdf.

status. Dr. Nathan confirmed that, for drugs that are considered to be alternatives, it is reasonable that physicians will make prescribing decisions based on insurance mandates.[141]

(65) The magnitude of rebates and/or discounts a PBM can negotiate depends on "both the PBM's ability to shift patients and prescribers to specific drugs and on the availability of close substitutes."[142] When there are no close alternatives available, "PBMs have little leverage to negotiate discounts."[143] Conversely, when there are alternatives available, PBMs will have greater leverage to negotiate discounts. Thus, United will have to offer significantly greater discounts to payors absent a stay (i.e., following Yutrepia entry for the PAH and PH-ILD indications) compared to if a stay is granted.

(66) Further, the costs associated with the Tyvaso products are likely to further incentivize payors to encourage price competition from United and Liquidia.[144] As of 2022, the Wholesale Acquisition Cost for Tyvaso DPI was $186.66 per cartridge for the 48 mcg and 64 mcg cartridges, yielding estimated costs of $20,905.92 per 28-day month or $271,776.96 per year.[145] The Medicare part B payment limit for a 1.74 mg dose of Tyvaso, which represents the dosage for a full day of treatment,[146] has grown from $418.17 in 2011 (the first year that included Tyvaso) to $733.64 in 2023.[147] Medicare part B payment limits are calculated at 106%

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141 Interview with Dr. Steven Nathan, 2/9/2024.

142 RAND Corporation Research Report, "Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships," 2021, at 19, available at: https://aspe.hhs.gov/sites/default/files/documents/0a464f25f0f2e987170f0a1d7ec21448/RRA328-1-Rxsupplychain.pdf.

143 RAND Corporation Research Report, "Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships," 2021, at 19, available at: https://aspe.hhs.gov/sites/default/files/documents/0a464f25f0f2e987170f0a1d7ec21448/RRA328-1-Rxsupplychain.pdf.

144 Although payors may bear significant costs for Tyvaso, as I discuss in Section 7.2, United offers reimbursement policies and co-pay assistance programs such that patients do not have to pay high prices for the Tyvaso products.

145 Oklahoma Health Care Authority, "Drug Utilization Review Board Meeting," 3/8/2023, at pdf 81, available at: https://oklahoma.gov/content/dam/ok/en/okhca/docs/about/boards-and-committees/dur/2023/march/DUR%20Packet%2003082023.pdf. ("The Wholesale Acquisition Cost (WAC) of Tyvaso DPI is $186.66 per cartridge for either the 48mcg or 64mcg cartridge, resulting in an estimated cost of $20,905.92 per 28 days and $271,776.96 per year based on the recommended target maintenance dose of 48mcg or 64mcg administered 4 times daily.")

146 A 1.74 mg dose corresponds to one ampule of Tyvaso, which "contains a sufficient volume of medication for all 4 treatment sessions in a single day." See:

United, Tyvaso Label, 5/2022, at 1, 3, available at: https://www.tyvaso.com/pdf/TYVASO-PI.pdf.

147 Centers for Medicare and Medicaid Services, October 2011 ASP Pricing File, https://www.cms.gov/license/ama?file=/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/downloads/April_2011_NOC_Pricing_File.zip.

The HCPCS code for Tyvaso is J7686. See, for example:

of the ASP for a drug.[148] Therefore, the average selling price has risen from $394.50 per day of treatment to $692.11 per day of treatment.[149] Under 2023 prices, this reflects costs of $19,379.08 per 28-day month or $251,928.04 per year.[150] These costs create strong incentives for payors to negotiate on price, thereby causing United to have to lower its prices to compete with Liquidia.

(67) Liquidia will have an economic incentive to offer payors favorable pricing or discounts and rebates relative to Tyvaso and Tyvaso DPI. In exchange for these discounts, payors can steer utilization away from the Tyvaso products and towards Yutrepia through step therapy requirements (which would be imposed during the prior authorization process) as well as lower co-insurance amounts. In turn, United will have to counter these discounts to avoid being disadvantaged by payors.

(68) [redacted] A stay will remove this pressure experienced by United. A stay would allow United additional time to recover the costs of its investments through its pricing power.

(69) Furthermore, if a stay is not granted and Yutrepia is allowed to enter the market, a subsequent ruling may force Liquidia to withdraw Yutrepia from the market. In this case, it is unlikely that eroded prices will return to pre-entry prices as prices for the Tyvaso products are likely to be downward sticky. [redacted]

Point32Health, "Medical Necessity Guidelines: Tyvaso (treprostinil inhalation solution)," 12/12/2023, at 2, available at: https://www.carepartnersct.com/cpct-pdoc-tyvaso.

Centers for Medicare and Medicaid Services, October 2023 ASP Pricing File, https://www.cms.gov/files/zip/october-2023-asp-pricing-file.zip.

148 Centers for Medicare and Medicaid Services Website, Medicare Part B Drug Average Sales Price, https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price (accessed 1/11/2024).

149 $394.50 = $418.17 / 106%.

$692.113 = $733.64 / 106%.

150 Calculations: $19,379.08 = $692.11 × 28 days. $251,928.04 = $19,379.08 × 13. Monthly costs scaled to annual costs consistent with Tyvaso DPI WAC estimates. ($271,776.96 / $20,905.92 = 13.)

151 Interview with David Barton, 2/14/2024.

152 Interview with David Barton, 2/14/2024.

[redacted].[153]

(70) Given the considerations described above and the examples described in Section 4.2.2, absent a stay precluding the use of Yutrepia for treating PAH or PH-ILD, United would suffer significantly reduced lifecycle revenues for its Tyvaso products due to price erosion.

4.2.2. Analogous product experiences

(71) The experience of other branded pharmaceuticals that have faced entry of a head-to-head competitor can illustrate the negative impact that Yutrepia will have on the price of the Tyvaso products. These examples are informative and analogous in the sense that the head-to-head competition manifested in the form of different molecules but were seen by the payors as alternatives. As such, the trends in price and market share erosion observed in these markets serve as an indication for how the Tyvaso products are likely to experience the same from Yutrepia's infringement and entry in the PAH and PH-ILD marketplaces.

Hepatitis C treatments

(72) In 2013 Gilead Sciences, Inc. ("Gilead") received FDA approval for their new chronic hepatitis C virus ("HCV") treatment, Sovaldi.[154] Sovaldi was the first oral treatment of hepatitis C that did not require interferon injections for two of the six forms of HCV.[155] Additionally, Sovaldi

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153 Interview with David Barton, 2/14/2024.

One potential future indication for the Tyvaso products is idiopathic pulmonary fibrosis. There are two Phase 3 studies being conducted for this indication and the FDA has granted orphan designation for Treprostinil to treat idiopathic pulmonary fibrosis. See: United, Form 10-K, 2023, at 8–9.

154 Gilead Sciences, Inc., Form 10-K, 2013, at 4. ("In December 2013, we received FDA approval for sofosbuvir under the brand name Sovaldi for the treatment of HCV as a component of a combination antiviral treatment regimen.")

155 Before Sovaldi was approved, HCV patients were typically treated with interferon injections. Interferon injections had limited effectiveness and could lead to severe side effects such as hair loss, anemia, fatigue, and depression. See:

The New York Times, "F.D.A. Approves Pill to Treat Hepatitis C," 12/6/2013, https://www.nytimes.com/2013/12/07/business/fda-approves-pill-to-treat-hepatitis-c.html. ("Until two years ago, the treatment for hepatitis C consisted of 24 to 48 weeks of weekly injections of interferon alfa combined with daily tablets of ribavirin. Neither drug was developed specifically to treat hepatitis C. The combination cured about half of patients, but the side effects, including flulike symptoms, anemia and depression, could be severe.")

The New Yorker, "A Better Treatment for Hepatitis C," 12/9/2013, https://www.newyorker.com/tech/annals-of-technology/a-better-treatment-for-hepatitis-c. ("The existing treatment regimen involves weekly injections of a substance called interferon combined with other drugs. Interferon is naturally produced by the body to combat viral infections; it's what makes you feel tired, feverish, and generally miserable when you have the flu. In the treatment of hepatitis C, it boosts the immune system. But the injections have brutal side effects: reduced appetite and hair loss, and, over long periods of

worked faster than other treatments and had exceptionally high cure rates with fewer side effects.[156] For genotype 1 HCV, which accounted for 70 percent of cases in the United States and had historically been the most difficult type of HCV to treat, Sovaldi reduced the treatment time from 24 or 48 weeks to only 12 weeks and had a cure rate of about 90 percent.[157] However, patients with genotype 1 still needed to take ribavirin and have interferon injections while taking Sovaldi.[158]

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time, anemia, fatigue, and depression. If the side effects of interferon don't sound bad enough, the other drugs often cause more anemia, fatigue, chills, nausea, vomiting, diarrhea, hair loss, and rash.")

There are six genotypes of hepatitis C, and Sovaldi was the first oral treatment for genotypes 2 and 3. See:

The New York Times, "F.D.A. Approves Pill to Treat Hepatitis C," 12/6/2013, https://www.nytimes.com/2013/12/07/business/fda-approves-pill-to-treat-hepatitis-c.html. ("For genotypes 2 and 3, which together account for about 20 to 25 percent of cases in the United States, Sovaldi's label recommends the drug be used with ribavirin. This will constitute the first all-oral, interferon-free treatment for hepatitis C. Genotype 2 will require 12 weeks of treatment and genotype 3 will need 24 weeks.")

Gilead Sciences, Inc. Press Release, "U.S. Food and Drug Administration Approves Gilead's Sovaldi (Sofosbuvir) for the Treatment of Chronic Hepatitis C," 12/6/2013, https://www.gilead.com/news-and-press/press-room/press-releases/2013/12/us-food-and-drug-administration-approves-gileads-sovaldi-sofosbuvir-for-the-treatment-of-chronic-hepatitis-c. ("First Ever Oral Treatment Regimen for Genotypes 2 or 3")

156 Scientific American, "Inventor of Hepatitis C Cure Wins a Major Prize—and Turns to the Next Battle," 9/13/2016, https://www.scientificamerican.com/article/inventor-of-hepatitis-c-cure-wins-a-major-prize-and-turns-to-the-next-battle/. ("Just three years ago patients suffering from hepatitis C faced some bleak treatment options. The main drug employed against this viral disease was only available via injection. It also came with serious side effects and—for too many patients—was not even effective. Then a transformative new pill called sofosbuvir hit the market. Better known as Sovaldi, the drug managed to recast hepatitis C from a hard-to-treat illness into an easily managed one that can be cured in just a few months. When used alongside other drugs it also worked much faster than any other hepatitis C treatments and had both fewer side effects and much higher success rates. About 90 percent of patients with a common form of the virus are cured with the medicine.")

157 See:

The New York Times, "F.D.A. Approves Pill to Treat Hepatitis C," 12/6/2013, https://www.nytimes.com/2013/12/07/business/fda-approves-pill-to-treat-hepatitis-c.html. ("For genotype 1, which accounts for more than 70 percent of American cases, Sovaldi is supposed to be used with injected interferon and ribavirin. But the treatment is for only 12 weeks instead of 24 or 48, and the cure rate is about 90 percent for newly treated patients.")

The New Yorker, "A Better Treatment for Hepatitis C," 12/9/2013, https://www.newyorker.com/tech/annals-of-technology/a-better-treatment-for-hepatitis-c. ("The first genotype of hepatitis C has always been the most difficult to treat, and remains so, even with the advent of sufosbuvir.")

Scientific American, "Inventor of Hepatitis C Cure Wins a Major Prize—and Turns to the Next Battle," 9/13/2016, https://www.scientificamerican.com/article/inventor-of-hepatitis-c-cure-wins-a-major-prize-and-turns-to-the-next-battle/. ("Better known as Sovaldi, the drug managed to recast hepatitis C from a hard-to-treat illness into an easily managed one that can be cured in just a few months. When used alongside other drugs it also worked much faster than any other hepatitis C treatments and had both fewer side effects and much higher success rates. About 90 percent of patients with a common form of the virus are cured with the medicine.")

158 The New York Times, "F.D.A. Approves Pill to Treat Hepatitis C," 12/6/2013, https://www.nytimes.com/2013/12/07/business/fda-approves-pill-to-treat-hepatitis-c.html. ("For genotype 1, which accounts for more than 70 percent of American cases, Sovaldi is supposed to be used with injected interferon and ribavirin.")

(73) In October 2014, the FDA approved Gilead's Harvoni for the treatment of chronic genotype 1 HCV infection in adults.[159] Harvoni "completely eliminat[ed] the need for interferon and ribavirin" was "the first once-daily single tablet regimen for the treatment of HCV genotype 1 infection in adults."[160] Harvoni combined Sovaldi and the NS5A inhibitor ledipasvir and achieved 94-99% cure rates in eight or twelve weeks.[161]

(74) Gilead's Sovaldi and Harvoni were extremely successful in 2014.[162] Gilead sold $10.3 billion of Sovaldi in 2014, "a figure that brought it close to being the best-selling drug in the world in only its first year on the market."[163] Harvoni generated sales of $2.1 billion from its approval in October through December 2014, leading to $12.5 billion in combined global sales of

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159 Gilead Sciences, Inc., Form 10-K, 2014, at 3. ("In the liver diseases area, we received approval from the U.S. Food and Drug Administration (FDA) and the European Commission of Harvoni, the first once-daily single tablet regimen for the treatment of HCV genotype 1 infection in adults.")

Gilead Sciences, Inc. Press Release, "U.S. Food and Drug Administration Approves Gilead's Harvoni (Ledipasvir/Sofosbuvir) he First Once-Daily Single Tablet Regimen for the Treatment of Genotype 1 Chronic Hepatitis C," 10/10/2014, https://www.gilead.com/news-and-press/press-room/press-releases/2014/10/us-food-and-drug-administration-approves-gileads-harvoni-ledipasvirsofosbuvir-the-first-oncedaily-single-tablet-regimen-for-the-treatment-of. ("Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the U.S. Food and Drug Administration (FDA) has approved Harvoni (ledipasvir 90 mg/sofosbuvir 400 mg), the first once-daily single tablet regimen for the treatment of chronic hepatitis C genotype 1 infection in adults.")

160 Gilead Sciences, Inc., Form 10-K, 2014, at 3. ("In the liver diseases area, we received approval from the U.S. Food and Drug Administration (FDA) and the European Commission of Harvoni, the first once-daily single tablet regimen for the treatment of HCV genotype 1 infection in adults.")

Gilead Sciences, Inc. Press Release, "U.S. Food and Drug Administration Approves Gilead's Harvoni (Ledipasvir/Sofosbuvir), the First Once-Daily Single Tablet Regimen for the Treatment of Genotype 1 Chronic Hepatitis C," 10/10/2014, https://www.gilead.com/news-and-press/press-room/press-releases/2014/10/us-food-and-drug-administration-approves-gileads-harvoni-ledipasvirsofosbuvir-the-first-oncedaily-single-tablet-regimen-for-the-treatment-of. ("'By providing very high cure rates in as little as eight weeks and completely eliminating the need for interferon and ribavirin, which are challenging to take and tolerate, Harvoni significantly advances treatment for patients with the most common form of hepatitis C in the United States,' said Nezam Afdhal, MD, Director of Hepatology at Beth Israel Deaconess Medical Center, Professor of Medicine at Harvard Medical School and a principal investigator in the Harvoni clinical trials.")

161 Gilead Sciences, Inc., Form 10-K, 2014, at 3. ("In clinical studies, Harvoni demonstrated very high cure rates of 94% to 99% in eight or twelve weeks.")

162 The New York Times, "Sales of Sovaldi, New Gilead Hepatitis C Drug, Soar to $10.3 Billion," 2/3/2015, https://www.nytimes.com/2015/02/04/business/sales-of-sovaldi-new-gilead-hepatitis-c-drug-soar-to-10-3-billion.html. ("Gilead Sciences sold $10.3 billion of its new hepatitis C drug Sovaldi in 2014, a figure that brought it close to being the best-selling drug in the world in only its first year on the market. The sales figure, announced on Tuesday in Gilead's earnings report for the fourth quarter, falls short of the $12.5 billion in sales recorded in 2014 by AbbVie's autoimmune disease drug Humira, which is believed to be the world's top-selling pharmaceutical. But sales of Sovaldi were lower than they might have been because of Gilead's introduction of an even newer hepatitis C drug, Harvoni, which recorded $2.1 billion in sales since its approval in October. Together Sovaldi and Harvoni achieved $12.4 billion in sales, just short of Humira's total.")

163 The New York Times, "Sales of Sovaldi, New Gilead Hepatitis C Drug, Soar to $10.3 Billion," 2/3/2015, https://www.nytimes.com/2015/02/04/business/sales-of-sovaldi-new-gilead-hepatitis-c-drug-soar-to-10-3-billion.html. ("Gilead Sciences sold $10.3 billion of its new hepatitis C drug Sovaldi in 2014, a figure that brought it close to being the best-selling drug in the world in only its first year on the market.")

Sovaldi and Harvoni of which $10.5 billion were in the United States.[164] Then, in December 2014 the FDA approved AbbVie's Viekira Pak for the treatment of genotype 1 HCV.[165] At $83,000 for a 12 week supply, Viekira Pak had a lower, but similar, list price as Sovaldi and Harvoni.[166] However, competition quickly led Gilead and AbbVie to compete by offering large discounts to payors intent on inducing competition and effectively lowering the average sale

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164 2014 Global Sales: $10.283 billion + $2.127 billion = $12.41 billion.

2014 U.S. Sales: $8.5 billion + $2 billion = $10.5 billion.

See:

Gilead Sciences, Inc., Form 10-K, 2014, at 59. ("In 2014, sales of Sovaldi and Harvoni (HCV products) were $12.4 billion. . . . HCV product sales were $10.5 billion in the United States and $1.6 billion in Europe in 2014.")

Gilead Sciences, Inc., Form 10-K, 2016, at 51. ("In 2014, [Harvoni] sales were $2.0 billion in the United States and $103 million in Europe. . . . In 2014, [Sovaldi] sales were $8.5 billion in the United States, $1.5 billion in Europe and $230 million in other international locations.")

The New York Times, "Sales of Sovaldi, New Gilead Hepatitis C Drug, Soar to $10.3 Billion," 2/3/2015, https://www.nytimes.com/2015/02/04/business/sales-of-sovaldi-new-gilead-hepatitis-c-drug-soar-to-10-3-billion.html. ("But sales of Sovaldi were lower than they might have been because of Gilead's introduction of an even newer hepatitis C drug, Harvoni, which recorded $2.1 billion in sales since its approval in October. . . . Almost all of those sales were in the United States.")

165 AbbVie Press Release, "AbbVie Receives U.S. FDA Approval of VIEKIRA PAK (Ombitasvir/Paritaprevir/Ritonavir Tablets; Dasabuvir Tablets) for the Treatment of Chronic Genotype 1 Hepatitis C," 12/19/2014, https://news.abbvie.com/2014-12-19-AbbVie-Receives-U-S-FDA-Approval-of-VIEKIRA-PAK-TM-Ombitasvir-Paritaprevir-Ritonavir-Tablets-Dasabuvir-Tablets-for-the-Treatment-of-Chronic-Genotype-1-Hepatitis-C. ("The U.S. Food and Drug Administration (FDA) has approved AbbVie's (NYSE:ABBV) VIEKIRA PAK, an all-oral, interferon-free treatment, with or without ribavirin (RBV), for the treatment of patients with chronic genotype 1 (GT1) hepatitis C virus (HCV) infection, including those with compensated cirrhosis.")

166 The New York Times, "Sales of Sovaldi, New Gilead Hepatitis C Drug, Soar to $10.3 Billion," 2/3/2015, https://www.nytimes.com/2015/02/04/business/sales-of-sovaldi-new-gilead-hepatitis-c-drug-soar-to-10-3-billion.html. ("Harvoni is a combination of Sovaldi and a second drug in a single pill taken once a day. It has a list price of $94,500 for the typical 12-week course of therapy. Sovaldi, also a once-a-day pill, has a list price of $84,000 for a 12-week treatment course, but it must be taken with at least one other drug. Viekira Pak from AbbVie is four pills a day and has a list price of about $83,000 for 12 weeks.")

price.[167] Many health plans began "trying to control costs by pitting Gilead against AbbVie" by "offering to pay for only one company's drugs as a way to get them to offer bigger discounts."[168]

(75) Gilead and AbbVie vied for market share after Viekira Pak's release by competing for contracts with PBMs, insurance companies, and government insurance programs through lower prices driven by discounts and rebates.[169] Twenty-five states entered into a purchasing consortium in early 2015 to secure rebate and discount offers for Gilead and AbbVie's HCV drugs before deciding which drugs would become "the preferred option[] for their state's Medicaid recipients."[170] In an earnings call at the beginning of February 2015, Gilead announced that it expected the 2015 gross-to-net adjustments for its HCV product to be approximately 46%,

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167 See:

Medicaid and CHIP Payment and Access Commission, "High-Cost HCV Drugs in Medicaid: Final Report," 1/2017, at 4, available at: https://www.macpac.gov/wp-content/uploads/2017/03/High-Cost-HCV-Drugs-in-Medicaid-Final-Report.pdf. ("Harvoni was followed by Abbvie's Viekira Pak (ombitasvir-paritaprevir-ritonavir tablets; dasabuvir tablets), approved by the FDA in December 2014 to treat genotype 1 patients, including those with compensated cirrhosis (Figure 1). . . . However, it made the HCV market competitive, leading to significant discounts from manufacturers to major insurers and pharmacy benefit managers (PBMs).")

The New York Times, "Sales of Sovaldi, New Gilead Hepatitis C Drug, Soar to $10.3 Billion," 2/3/2015, https://www.nytimes.com/2015/02/04/business/sales-of-sovaldi-new-gilead-hepatitis-c-drug-soar-to-10-3-billion.html. ("Many health plans are now trying to control costs by pitting Gilead against AbbVie, which introduced a hepatitis C treatment called Viekira Pak in December. Many of the plans are offering to pay for only one company's drugs as a way to get them to offer bigger discounts.")

168 The New York Times, "Sales of Sovaldi, New Gilead Hepatitis C Drug, Soar to $10.3 Billion," 2/3/2015, https://www.nytimes.com/2015/02/04/business/sales-of-sovaldi-new-gilead-hepatitis-c-drug-soar-to-10-3-billion.html. ("Many health plans are now trying to control costs by pitting Gilead against AbbVie, which introduced a hepatitis C treatment called Viekira Pak in December. Many of the plans are offering to pay for only one company's drugs as a way to get them to offer bigger discounts.")

169 The Wall Street Journal, "States Work to Strike Deals for Hep C Drug Discounts," 1/29/2015, https://www.wsj.com/articles/states-work-to-strike-deals-for-hep-c-drug-discounts-1422492687. ("The battle for market share in the booming business for hepatitis C drugs is shifting to state Medicaid programs, which are busy negotiating discounts and supply deals with pharmaceutical companies. . . . The state deals follow a series of high-profile supply contracts that drug makers Gilead Sciences Inc. and AbbVie Inc. have signed in recent weeks with insurance companies and pharmacy-benefit managers, in exchange for undisclosed discounts. This week, one of the biggest insurers, UnitedHealth Group, notified plan members that Gilead's Harvoni would be the preferred option for hepatitis C treatment, meaning it would carry lower out-of-pocket costs for members than AbbVie's Viekira Pak. Meanwhile, Blue Shield of California selected Viekira Pak as the preferred treatment for most members with hepatitis C, a Blue Shield spokesman said Thursday.")

170 The Wall Street Journal, "States Work to Strike Deals for Hep C Drug Discounts," 1/29/2015, https://www.wsj.com/articles/states-work-to-strike-deals-for-hep-c-drug-discounts-1422492687. ("Missouri and Connecticut are among the states that are either negotiating or securing discounts on expensive new hepatitis C drugs in exchange for making them the preferred options for their state's Medicaid recipients. . . . In a statement on its website, Missouri said it entered the agreement 'as part of a 25-state purchasing consortium' that includes Connecticut, Michigan, Pennsylvania and other states. It added that AbbVie has 'agreed to provide a rebate to states participating in the consortium.' A spokeswoman for the Missouri Department of Social Services said the pricing offer from AbbVie was available to all 25 states in the consortium, but she declined to provide further details. . . . A spokesman for Connecticut's department of social services said the state is 'awaiting further information on costs and rebate amounts, and will make a decision on which product to prefer in several weeks.'")

more than double the value at the end of 2014, which was approximately 22%.[171] Gilead's Vice President of Commercial Operations noted that this was a "result of the recent and ongoing round of negotiations with payers and PBMs and includes the shift towards a higher proportion of public payers and higher prescribing of Harvoni amongst those payers with rebates to payers such as the Medicaid's and the VA's exceeding 50%."[172] The discounts offered were significantly higher than expected and this news was followed by about a 5% drop in share price in after-hours trading which dipped to a 9% drop the following morning.[173]

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171 Refinitiv Eikon, "Q4 2014 Gilead Sciences Inc Earnings Call," 2/3/2015, at 5. ("We expect our 2015 gross-to-net adjustments for our HCV product in the United States to be approximately 46%, or a little more than double of that where we ended 2014, which was around 22%. This increase is the result of the recent and ongoing round of negotiations with payers and PBMs and includes the shift towards a higher proportion of public payers and higher prescribing of Harvoni amongst those payers with rebates to payers such as the Medicaid's and the VA's exceeding 50%.")

The New York Times, "Sales of Sovaldi, New Gilead Hepatitis C Drug, Soar to $10.3 Billion," 2/3/2015, https://www.nytimes.com/2015/02/04/business/sales-of-sovaldi-new-gilead-hepatitis-c-drug-soar-to-10-3-billion.html. ("The depth of the discounting has been confidential and a matter of great Wall Street speculation. But in the conference call on Tuesday, Gilead executives revealed some numbers. They said that they expected the gross-to-net adjustment, a measure of discounting from list price, would average 46 percent for their hepatitis C drugs in the United States in 2015, more than double the 22 percent in 2014. For certain Medicaid programs and the Department of Veterans Affairs, they said, rebates exceeded 50 percent.")

172 Refinitiv Eikon, "Q4 2014 Gilead Sciences Inc Earnings Call," 2/3/2015, at 5. ("We expect our 2015 gross-to-net adjustments for our HCV product in the United States to be approximately 46%, or a little more than double of that where we ended 2014, which was around 22%. This increase is the result of the recent and ongoing round of negotiations with payers and PBMs and includes the shift towards a higher proportion of public payers and higher prescribing of Harvoni amongst those payers with rebates to payers such as the Medicaid's and the VA's exceeding 50%.")

173 See:

The Wall Street Journal, "What the 'Shocking' Gilead Discounts on its Hepatitis C Drugs Will Mean," 2/4/2015, https://www.wsj.com/articles/BL-270B-1426. ("The guidance on the discount is 'meaningfully worse than expectations,' which were in the 25% to 30% range, writes R.W. Baird analyst Brian Skorney. 'A discount of this magnitude brings our net price down per [prescription] significantly, resulting in about a 20% decline in our total estimated hepatitis C revenues for 2015. 'We can only imagine how far AbbVie has to go on price with their pack of pills to have any [market] share. Depending on patient mix, we believe Harvoni will net about $45,000 per patient in 2015 and Sovaldi will net about $54,000… We think investors would suffer the discount happily if assure of price stability beyond 2015, but the bigger concern will be around how much further price can go' as other drug makers enter the market.")

CNBC, "Pricing Wars Heating Up Over Hepatitis C Drugs," 2/4/2015, https://www.cnbc.com/2015/02/04/pricing-wars-heat-up-over-hepatitis-c-drugs.html. ("Yet the magnitude of the discounts surprised the market: A day after the conference call, Gilead's stock was down almost 9 percent Wednesday morning—even after its hepatitis C drugs Sovaldi and Harvoni drew a combined $3.8 billion in revenue in the fourth quarter, topping analysts' estimates.")

The New York Times, "Sales of Sovaldi, New Gilead Hepatitis C Drug, Soar to $10.3 Billion," 2/3/2015, https://www.nytimes.com/2015/02/04/business/sales-of-sovaldi-new-gilead-hepatitis-c-drug-soar-to-10-3-billion.html. ("The depth of the discounting has been confidential and a matter of great Wall Street speculation. But in the conference call on Tuesday, Gilead executives revealed some numbers. They said that they expected the gross-to-net adjustment, a measure of discounting from list price, would average 46 percent for their hepatitis C drugs in the United States in 2015, more than double the 22 percent in 2014. For certain Medicaid programs and the Department of Veterans Affairs, they said, rebates exceeded 50 percent. Gilead's shares fell about 5 percent in after-hours trading, perhaps because the extent of the discounting was greater than some investors had expected.")

(76) The competition from Viekira Pak had a substantial impact on Gilead's HCV drugs' market share and prices.[174] Gilead's sales of HCV products declined from $19.1 billion in 2015[175] to $2.9 billion in 2019.[176] In the United States specifically, Gilead's HCV product sales declined from $12.5 billion in 2015[177] to $1.5 billion in 2019.[178] In a 2017 earnings call, Gilead's Executive Vice President of Worldwide Commercial Operations explained that in the HCV market "the arrival of new competition has further eroded Gilead's market share and net pricing."[179] The price of Sovaldi, for example, has continued to decrease and has not rebounded as of 2023 the national average price of a 12-week course of treatment was $23,412, compared to an initial launch price of $84,000.[180]

PCSK9 Inhibitors

(77) In July, 2015 the FDA approved Praluent, a PCSK9 inhibitor manufactured by Regeneron and Sanofi.[181] PCSK9 inhibitors are a class of drugs that reduce low-density lipoprotein (LDL), also

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174 BioPharma Dive, "Gilead Forecasts Steep Slide in 2018 Hepatitis C Revenues," 2/6/2018, https://www.biopharmadive.com/news/gilead-hepatitis-c-revenues-slide-fourth-quarter-earnings/516494/. ("After Gilead's Sovaldi (sofosbuvir) and Harvoni (ledipasvir/sofosbuvir) were first launched, tens of thousands of new patients began treatment — pushing annual revenues from the drugs to nearly $20 billion in 2015. That bolus of patients has ebbed considerably, while new competition both stole market share and brought down net prices.")

175 2015 Global Sales: $5.276 billion + $13.864 billion = $19.14 billion.

See: Gilead Sciences, Inc., Form 10-K, 2016, at 50–51.

176 Gilead Sciences, Inc., Form 10-K, 2019, at 33-35. ("HCV product sales decreased by 20% to $2.9 billion in 2019, compared to $3.7 billion in 2018, primarily due to lower average net selling price, including a decline in U.S. Medicare prices in 2019.")

177 2015 U.S. Sales: $2.4 billion + $10.1 billion = $12.5 billion.

See: Gilead Sciences, Inc., Form 10-K, 2016, at 51. ("In 2015, [Harvoni] sales were $10.1 billion in the United States, . . . [i]n 2015, [Sovaldi] sales were $2.4 billion in the United States[.]")

178 Gilead Sciences, Inc., Form 10-K, 2019, at 35.

179 Refinitiv Eikon, "Q3 2017 Gilead Sciences Inc Earnings Call," 10/26/2017, at 6. ("While patient starts have exceeded our expectations in 2017, the arrival of new competition has further eroded Gilead's market share and net pricing, which is now similar across genotypes.")

180 PCMA, "PBMs Use Competition to Negotiate Lower Net Costs for Hepatitis C Treatments," c. 2021, available at: https://www.pcmanet.org/wp-content/uploads/2021/06/hcvdrugs_Infographic.pdf.

Hepatitis C: State of Medicaid Access, "The Actual Cost of HCV Treatment," c. 2023, at 2, available at https://stateofhepc.org/wp-content/uploads/2023/02/State-of-Hep-C-Treatment-Costs-Fact-Sheet.pdf.

181 Regeneron Press Release, "Regeneron and Sanofi Announce FDA Approval of Praluent (alirocumab) Injection, the First PCSK9 Inhibitor in the U.S., for the Treatment of High LDL Cholesterol in Adult Patients," 7/24/2015, https://investor.regeneron.com/news-releases/news-release-details/regeneron-and-sanofi-announce-fda-approval-praluentr-alirocumab.

known as "bad" cholesterol.[182] They do so by preventing PCSK9 proteins from breaking down the body's LDL receptors, which help facilitate the removal of LDL via the liver.[183]

(78) One month after Praluent's approval, the FDA approved Repatha, a competing PCSK9 inhibitor manufactured by Amgen.[184] The two drugs also launched with similar prices, with an annual supply costing $14,100 and $14,600 for Repatha and Praluent respectively.[185]

(79) Shortly after launch, both manufacturers began offering steep rebates to PBMs and insurers in order to stimulate demand and incentivize favorable coverage for their respective drugs. By January, 2016 Amgen had reached a deal with Harvard Pilgrim Health Care to provide enhanced discounts for Repatha if the reduction in LDL cholesterol levels in the health plan's members were less than what was seen during clinical trials and if drug utilization on the plan exceeded certain levels.[186] Similarly, Sanofi and Regeneron, in May 2018, agreed to a deal

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182 Hajar, Rachel (2019), "PCSK 9 Inhibitors: A Short History and a New Era of Lipid-lowering Therapy," *Heart Views* 20(2): 74–75, at 75.

183 Cleveland Clinic Website, "PCSK9 Inhibitors," https://my.clevelandclinic.org/health/drugs/22550-pcsk9-inhibitors (accessed 2/2/2024).

Although statins are the most commonly used drugs for treating high cholesterol, they are not effective for all patients and may lead to certain side effects. PCSK9 inhibitors can serve as a complement to statins, or as an alternative therapy for patients who are statin-intolerant.

See: Hajar, Rachel (2019), "PCSK 9 Inhibitors: A Short History and a New Era of Lipid-lowering Therapy," *Heart Views* 20(2): 74–75, at 74–75. ("Statins are the most common drug that lowers cholesterol, but they do not work for everyone. Statins are effective at lowering cholesterol and protecting against a heart attack and stroke, but they may lead to side effects for some people[.] . . . Guideline recommendations and consensus statements now endorse the use of PCSK9 inhibitors as appropriate second- or third-line agents or as an alternative therapy in cases of complete statin intolerance, for patients with established atherosclerotic CVD or familial hypercholesterolemia with persistent hypercholesterolemia.")

184 Both Repatha and Praluent were approved by the FDA for treatment of heterozygous familial hypercholesterolemia (HeFh) and clinical atherosclerotic cardiovascular disease (ASCVD), and, consequently, the two competed in that marketplace.

See:

Amgen Press Release, "FDA Approves Amgen's New Cholesterol-Lowering Medication Repatha (evolocumab)," 8/27/2015, https://www.amgen.com/newsroom/press-releases/2015/08/fda-approves-amgens-new-cholesterollowering-medication-repatha-evolocumab.

Regeneron Press Release, "Regeneron and Sanofi Announce FDA Approval of Praluent (alirocumab) Injection, the First PCSK9 Inhibitor in the U.S., for the Treatment of High LDL Cholesterol in Adult Patients," 7/24/2015, https://investor.regeneron.com/news-releases/news-release-details/regeneron-and-sanofi-announce-fda-approval-praluentr-alirocumab.

185 Barlas, Stephen (2016), "Health Plans and Drug Companies Dip Their Toes Into Value-Based Pricing: The Pressure Is on P&T Committees to Monitor Utilization," *P&T* 41(1): 39–53, at 39. ("Repatha costs $14,100 and Praluent $14,600, respectively, for a year's supply.")

186 Barlas, Stephen (2016), "Health Plans and Drug Companies Dip Their Toes Into Value-Based Pricing: The Pressure Is on P&T Committees to Monitor Utilization," *P&T* 41(1): 39–53, at 39. ("The Harvard Pilgrim health plan opened a new front in the battle to contain drug prices in November when it announced a pioneering contract with Amgen. Amgen agreed to provide two 'pay for performance' rebates if its evolocumab (Repatha), one of the two new proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors, failed to meet two separate thresholds. . . . To help control costs, Amgen agreed

with PBM Express Scripts to lower the price of Praluent to between $4,500 and $8,000 per year in exchange for being the only drug in its class covered on Express Scripts' National Preferred Formulary Plan.[187] After Regeneron and Sanofi announced their deal with Express Scripts, Amgen responded by lowering the list price of Repatha from $14,523 to $5,850 in October, 2018.[188] Regeneron and Sanofi quickly followed suit, announcing that Praluent would be made available at a new list price of $5,850, a 60% reduction, in February, 2019.[189]

4.3. Lost unit sales and market share

(80) In addition to price erosion, United will also suffer from lost unit sales and market share due to Liquidia's infringement. The pricing dynamics discussed in Section 4.2 suggest that at least some payors will likely have favorable formulary placement for Yutrepia over the Tyvaso products. Favorable placement means that Yutrepia would be the preferred treatment for those payors, so Yutrepia would earn sales from those payors. Part of this will be due to the increased burden physicians will face if they prefer to keep their patient(s) on the Tyvaso products, but the payor prefers Yutrepia on the formulary. Physicians will face increased effort costs in seeking to attain authorization for the Tyvaso products and many physicians will default to Yutrepia because of these costs.[190] Given the direct competition and product similarities between the Tyvaso products and Yutrepia, it is likely that a provider considering

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to provide Harvard Pilgrim with an enhanced discount if the reduction in LDL-C levels for the health plan's members is less than that seen during clinical trials. The agreement also provides for additional discounts if utilization of the drug exceeds certain levels.")

187 CNBC, "A $14,000 Cholesterol Drug Gets a Price Cut as Regeneron, Sanofi Strike Deal With Express Scripts," 5/1/2018, https://www.cnbc.com/2018/05/01/regeneron-sanofi-chop-cholesterol-drug-price-in-express-scripts-pact.html.

188 BioPharma Dive, "Amgen Cuts US Repatha Price 60% Amid Market Pressure," 10/24/2018, https://www.biopharmadive.com/news/amgen-cuts-us-repatha-price-60-amid-market-pressure/540517/. ("Amgen has cut the annual list price for its cholesterol-lowering medicine Repatha in the U.S. from $14,523 to $5,850, a decision the company said was to secure broader insurance coverage and lower out-of-pocket costs for patients on Medicare. It's a significant reduction, and a rare move for a branded product just three years removed from an initial U.S. approval. Amgen, though, has faced considerable pushback from payers on the drug's price, and remains locked in competition with Sanofi and Regeneron, makes of a rival drug called Praluent. That Amgen chose to lower Repatha's list price is notable. Earlier this year, Sanofi and Regeneron announced they would offer greater rebates in a deal with Express Scripts that lowered Praluent's net price to between $4,500 and $8,000 a year.")

189 Regeneron Press Release, "Regeneron and Sanofi Offer Praluent (alirocumab) at a New Reduced U.S. List Price," 2/11/2019, https://investor.regeneron.com/node/21811/pdf. ("Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) and Sanofi today announced that Praluent (alirocumab) will be made available at a new reduced U.S. list price of $5,850 annually, a 60% reduction from the original price, for both the 75 mg and 150 mg doses, beginning in early March.")

190 Epstein, Andrew and Jonathan Ketcham (2014), "Information Technology and Agency in Physicians' Prescribing Decisions," *The Rand Journal of Economics* 45(2): 422–448, at 423. ("Similarly, formularies often include 'prior authorization' (PA) requirements for some drugs as determined by prescription drug insurers, commonly known as pharmacy benefits managers (PBMs). PAs impose administrative burdens on health care providers, typically physicians, by requiring them or their staffs to provide patient-specific clinical information to the insurer as a prerequisite for insurance coverage for a given drug.")

Yutrepia also considered the Tyvaso products, meaning that at least some degree of Yutrepia sales likely would have been sales of one of the Tyvaso products absent Yutrepia's entry. Moreover, since the but-for world is one without Yutrepia's entry, Yutrepia sales would likely come at the expense of one of the Tyvaso products. Thus, Yutrepia entering the market and receiving favorable placement over the Tyvaso products will result in lost sales for the Tyvaso products. Because Yutrepia entering the PAH and PH-ILD markets will not decrease total sales in the markets, lost sales also implies lost market share for United.

(81) Even assuming similar coverage for the Tyvaso products and Yutrepia, sales that Yutrepia earns are likely to reflect at least some lost sales for the Tyvaso products. As discussed in Section 4.1, the Tyvaso products and Yutrepia will directly compete in the PAH and PH-ILD markets and Liquidia is positioning Yutrepia as an alternative to the Tyvaso products. I [redacted][191] Given the similarities between the Tyvaso products and Yutrepia, it is likely that physicians that choose to prescribe Yutrepia will have also considered the Tyvaso products (and vice versa). In other words, if a provider is choosing between Yutrepia and the Tyvaso products and decides on Yutrepia, it is reasonable to assume that the provider would have chosen one of the Tyvaso products in a market without Yutrepia as an option. As such, at least some portion of Yutrepia sales represent lost sales for the Tyvaso products.

(82) Harm to sales is also likely to be significant because Yutrepia's market entrance places United in the position of having to choose between maintaining its marketing efforts for the Tyvaso products, which will likely also aid Liquidia as inadvertent marketing for Yutrepia given the drug similarities,[192] or reducing its marketing efforts in order to avoid that outcome. Either situation is likely to reduce United's sales in comparison to the but-for world where Yutrepia does not enter the PAH or PH-ILD markets.[193]

(83) Moreover, Yutrepia entry is unlikely to expand the addressable markets for either PAH or PH-ILD. Multiple treatment options have been available for PAH for many years, including nebulized Tyvaso since 2009, such that material market growth would be unlikely due to the

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191 Interview with Greg Bottorff, 2/14/2024.

192 For example, the website for Tyvaso DPI highlights that "TYVASO DPI FITS IN THE PALM OF YOUR HAND." This benefit is also likely to be provided by Yutrepia (see Section 3.3.2). See:

Tyvaso DPI Website, Home Page, https://www.tyvaso.com/dpi/ (accessed 2/20/2024).

193 Any alleged benefit to United from Liquidia's marketing efforts is likely to be minimal and overshadowed by the significant harms to United resulting from Yutrepia's market entrance.

introduction of one additional treatment (especially one with similar characteristics to the existing Tyvaso products). While the nascent PH-ILD marketplace is likely to expand over time, the introduction of Yutrepia (separate and apart from other factors) is unlikely to expand the addressable PH-ILD market in a significant way. As a result, Yutrepia sales are more likely to come at the expense of the Tyvaso products. Untreated PH-ILD patients largely remain untreated because they are not diagnosed—diagnosis of PH-ILD is difficult (as discussed in Sections 3 and 5.2)—not because there is a lack of available treprostinil treatments. The introduction of Yutrepia to the market, separate and apart from other factors, will not change diagnosis rates such that the addressable market of PH-ILD patients increases in a meaningful way because of Yutrepia's efforts. While the PH-ILD marketplace is likely expanding due to United's efforts, I have not seen evidence that Liquidia is investing heavily in improving methods for screening PH-ILD patients. Said differently, any marketplace expansion that is occurring would likely occur at a similar rate but for Liquidia's infringement. Accordingly, in light of the likely lack of Yutrepia-driven expansion for either PAH or PH-ILD, sales made by Liquidia are likely to come at the expense of United, even if those sales are part of an expanding market.

(84) In addition, the population of patients in the United States with PH-ILD is relatively small and as such, even with market expansion, there is unlikely to be a scenario where Yutrepia can make infringing sales without taking sales away from the Tyvaso products. Both Tyvaso and Tyvaso DPI received orphan drug designation, a designation used for treatments of conditions with patient populations lower than 200,000 in the United States.[194] As discussed in Section 3, United has estimated that PH-ILD affects approximately 30,000 patients in the United States with PH-ILD, whereas Liquidia has estimated that there are around 60,000 PH-ILD patients in the United States.

(85) The extent of lost unit sales and market share for the Tyvaso products due to Liquidia's infringement will be significant in two aspects, namely (1) in the PH-ILD market because it is in its early stages and expected to grow (see Section 5.2) and (2) for Tyvaso DPI generally, which is a relatively new product for both PAH and PH-ILD. As such, without Yutrepia in the market, there is still a significant market opportunity for Tyvaso and Tyvaso DPI to continue

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[194] FDA Website, Orphan Drug Designations and Approvals, Tyvaso, https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=189104 (accessed 1/5/2024).

FDA Website, Rare Diseases at FDA, https://www.fda.gov/patients/rare-diseases-fda (accessed 1/5/2024). ("The Orphan Drug Act defines a rare disease as a disease or condition that affects less than 200,000 people in the United States. … The Orphan Drug Act is a law passed by Congress in 1983 that incentivizes the development of drugs to treat rare diseases. Companies and other drug developers can request orphan drug designation and FDA will grant such designation if the drug meets specific criteria.")

earning United revenue and profit in the relatively untapped PH-ILD market. For example, a Wedbush analyst report discusses how, "[a]lthough there remains an immense opportunity for Tyvaso DPI in PAH as a result of its first mover-advantage, we see an even greater opportunity for Tyvaso DPI in PH-ILD where there are no other inhaled therapies are approved to our knowledge with the exception of nebulized Tyvaso."[195] As another example, an analyst report from BTIG estimates that "Tyvaso DPI is currently at a $820 million run rate, 5 quarters into launch, and the total DPI treprostinil market estimated to be in excess of $3 billion at maturity (PAH and PH-ILD)[.]"[196] The BTIG report also states: "We expect YUTREPIA to emerge as the preferred DPI treprostinil Tx option in PAH and PH-ILD . . . the upside potential for LQDA looks significant to us. . . . We are now modeling 50% odds of PH-ILD launch in 2024, 40% odds in 2026, and 10% odds in 2041[.]"[197]

(86) As discussed with price erosion in Section 4.2, competitive entry also had a significant impact on sales and market share in the Hepatitis C and PCSK9 inhibitor marketplaces, further demonstrating the significant likelihood for lost sales and market share erosion in this case. For Gilead's Sovaldi and Harvoni in the HCV market, the entry of AbbVie's Viekira Pak led not only to price competition as described in Section 4.2 but also to competition for unit sales, with many patients steered towards AbbVie's product.[198] In December 2014, the same month that Viekira Pak was approved by the FDA, "AbbVie signed an exclusive deal for placement on Express Scripts' largest formulary plan—the pharmacy benefits manager's plan that includes

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195 Wedbush, "Don't Call It a Comeback...Initiating at OP and $10 PT," 10/9/2023, at 4.

196 BTIG, "'793 IPR Decisions Affirmed on Appeal, Leaving YUTREPIA Launch On Track for Mid-2024 or Earlier. Increasing PT to $29 from $18," 12/20/2023, at 1.

197 BTIG, "'793 IPR Decisions Affirmed on Appeal, Leaving YUTREPIA Launch On Track for Mid-2024 or Earlier. Increasing PT to $29 from $18," 12/20/2023, at 1.

198 See:

AbbVie Press Release, "AbbVie Receives U.S. FDA Approval of VIEKIRA PAK (Ombitasvir/Paritaprevir/Ritonavir Tablets; Dasabuvir Tablets) for the Treatment of Chronic Genotype 1 Hepatitis C," 12/19/2014, https://news.abbvie.com/2014-12-19-AbbVie-Receives-U-S-FDA-Approval-of-VIEKIRA-PAK-TM-Ombitasvir-Paritaprevir-Ritonavir-Tablets-Dasabuvir-Tablets-for-the-Treatment-of-Chronic-Genotype-1-Hepatitis-C. ("The U.S. Food and Drug Administration (FDA) has approved AbbVie's (NYSE:ABBV) VIEKIRA PAK, an all-oral, interferon-free treatment, with or without ribavirin (RBV), for the treatment of patients with chronic genotype 1 (GT1) hepatitis C virus (HCV) infection, including those with compensated cirrhosis.")

Fierce Pharma, "Sorry, Gilead. AbbVie Cuts Exclusive Hep C Deal with Express Scripts," 12/22/2014, https://www.fiercepharma.com/sales-and-marketing/sorry-gilead-abbvie-cuts-exclusive-hep-c-deal-express-scripts. ("The proud new parent of Viekira, a highly anticipated hepatitis C cocktail, AbbVie now has exclusive access to millions of the pharmacy benefits manager's patients in return for a "significant discount" off its $85,000 list price. . . . Under the deal, patients infected with genotype 1--the most common strain of hepatitis C--will be steered to AbbVie's cocktail beginning January 1. Patients already in treatment with Gilead's drugs can continue. Because AbbVie's drugs are only approved for genotype 1 disease, Express Scripts will cover Gilead's meds in patients with other genotypes. The deal applies to the 25 million people covered under Express Scripts' National Formulary.")

the most patients—at a significant discount[.]"[199] Express Scripts is "the largest prescription-management company in the U.S." and the deal both essentially cut Gilead off from "the 25 million people covered under the Express Script's National Formulary" and led to increased competition to obtain exclusive deals with other PBMs.[200]

(87) The same trend occurred in the PCSK9 inhibitor market. By March, 2018, nearly 3 years after launch, Repatha had captured an estimated 60% market share in the market for PCSK9 drugs.[201] Evidence suggests that this trend has continued, as both Repatha and Praluent have continued to each capture significant shares of the market as of April, 2022.[202]

4.4. Lost first mover advantages

(88) United has spent considerable time, resources, and efforts developing and commercializing its products.[203] Through its investments in the Tyvaso products, United has engaged in effort to

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199 CNBC, "Pricing Wars Heating Up Over Hepatitis C Drugs," 2/4/2015, https://www.cnbc.com/2015/02/04/pricing-wars-heat-up-over-hepatitis-c-drugs.html. ("Yet the magnitude of the discounts surprised the market: A day after the conference call, Gilead's stock was down almost 9 percent Wednesday morning—even after its hepatitis C drugs Sovaldi and Harvoni drew a combined $3.8 billion in revenue in the fourth quarter, topping analysts' estimates.")

200 Yahoo News, "Gilead Falls on AbbVie and Express Scripts Deal: 3 Biotech ETFs to Watch - ETF News And Commentary," 12/23/2014, https://news.yahoo.com/gilead-falls-abbvie-express-scripts-170205245.html. ("Express Scripts (ESRX), the largest prescription-management company in the U.S., said that it has secured a lower price for a newly approved hepatitis C drug produced by AbbVie Inc.(ABBV) and that it will no longer cover Gilead's drug. In exchange for securing the drug at a lower price, Express Scripts has struck a deal with AbbVie to provide its drug as the sole option for treating hepatitis C.")

See also:

Fierce Pharma, "Sorry, Gilead. AbbVie Cuts Exclusive Hep C Deal with Express Scripts," 12/22/2014, https://www.fiercepharma.com/sales-and-marketing/sorry-gilead-abbvie-cuts-exclusive-hep-c-deal-express-scripts. ("The proud new parent of Viekira, a highly anticipated hepatitis C cocktail, AbbVie now has exclusive access to millions of the pharmacy benefits manager's patients in return for a "significant discount" off its $85,000 list price. . . . Under the deal, patients infected with genotype 1--the most common strain of hepatitis C--will be steered to AbbVie's cocktail beginning January 1. Patients already in treatment with Gilead's drugs can continue. Because AbbVie's drugs are only approved for genotype 1 disease, Express Scripts will cover Gilead's meds in patients with other genotypes. The deal applies to the 25 million people covered under Express Scripts' National Formulary.")

CNBC, "Pricing Wars Heating Up Over Hepatitis C Drugs," 2/4/2015, https://www.cnbc.com/2015/02/04/pricing-wars-heat-up-over-hepatitis-c-drugs.html. ("It's a price war that's been brewing for some time, and flared even more when competitor AbbVie signed an exclusive deal for placement on Express Scripts' largest formulary plan—the pharmacy benefits manager's plan that includes the most patients—at a significant discount in December. Weeks later, Gilead struck back, signing an exclusive deal with CVS.")

201 Fierce Pharma, "Amgen Faces Tough One-Two Blow as Competition Mounts for Repatha and Sensipar," 3/13/2018, https://www.fiercepharma.com/corporate/amgen-faces-tough-one-two-blow-as-competition-mounts-for-repatha-and-sensipar.

202 SVB, "IQVIA Script Trends for the Week Ended April 15, 2022," 4/22/2022, at 67.

203 See, for example: United, Form 10-K, 2023, at 55. ("We devote substantial resources to our various clinical trials and other research and development efforts, which are conducted both internally and through third parties. From time to time, we also license or acquire additional technologies and compounds to be incorporated into our development pipeline.")

increase its brand recognition for the Tyvaso products among both physicians and patients. With the Tyvaso products as the first inhaled treprostinil-based therapies in the PAH market, and the only FDA-approved therapies in the PH-ILD market, United has also benefited from first mover advantages in both markets, including brand recognition and stickiness due to patient familiarity. Economic literature explains that the first mover generally will benefit from positive economic profits, typically from maintaining a high market share.[204] According to Lieberman and Montgomery (1988), one such example is the pharmaceutical market, due to the strength of patent protections and the costly process of regulatory approvals.[205]

(89) Liquidia's premature entry will irreparably harm United through negating United's first mover advantage benefits including brand recognition. United has expended time and expense developing the Tyvaso products and obtaining approval for the Tyvaso products to treat PAH and PH-ILD, and in doing so effectively created the PH-ILD market segment. As such, United is establishing the brand name of Tyvaso as synonymous with innovation for both PAH and PH-ILD and with filling the unmet need for a treatment for PH-ILD. If Yutrepia enters the market, United will lose its unique positioning with the Tyvaso products as the only treatments of their kind for PAH and PH-ILD. In other words, these markets will become more commoditized. Yutrepia entering the market will effectively eliminate United's ability to continue developing and benefitting from its first mover advantage, as well as any ability to further develop its reputation as an innovator. The sales trajectories of the Tyvaso products if

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See also: Section 6.

204 Lieberman, Marvin B. and David B. Montgomery (1988), "First-Mover Advantages," *Strategic Management Journal* 9: 41–58, at 41.

There is evidence of a strong empirical association between market share and profitability, suggesting that market pioneers who maintain a high market share also tend to have higher profitability. See:

Robinson, William T., Gurumurthy Kalyanaram, and Glen L. Urban (1994), "First-Mover Advantages from Pioneering New Markets: A Survey of Empirical Evidence," *Review of Industrial Organization* 9: 1–23, at 1–2.

Note here that economic profit differs from accounting profit. Economic profit is defined as a firm's total revenue minus all opportunity costs (both explicit and implicit costs), while accounting profit is defined as a firm's total revenue minus only the firm's explicit costs. This means that accounting profit is usually larger than economic profit. Economic profit is an important measure, as it motivates firms to supply goods and services. See, for example:

Mankiw, N. Gregory (2018), *Principles of Economics*, 8th ed., Boston, MA: Cengage Learning, at 250.

205 Lieberman, Marvin B. and David B. Montgomery (1988), "First-Mover Advantages," *Strategic Management Journal* 9: 41–58, at 43.

For additional examples of the theoretical economics literature relating to this topic, see:

Gilbert, Richard J. and David M. G. Newbery (1982), "Preemptive Patenting and the Persistence of Monopoly," *The American Economic Review* 72(3): 514–526.

Fudenberg, Drew et al. (1983), "Preemption, Leapfrogging and Competition in Patent Races," *European Economic Review* 22: 3–31.

United is able to retain its first mover advantage will be very different from the sales trajectories of the Tyvaso products if Yutrepia prematurely enters.

(90) The patent process fosters innovation and helps inventors like United protect large investments in innovative technology.[206] Exclusivity enables United to continue to build recognition and patient trust in the market. Yutrepia's entry will cause United to lose valuable first mover advantages (the Tyvaso products are the first therapies of their kind in PAH and the first approved therapies for PH-ILD), hampering United's ability to further develop brand recognition. Liquidia is positioning Yutrepia as an alternative to the Tyvaso products. [redacted][207] Indeed, I understand from Dr. Nathan that many providers will view the Tyvaso products and Yutrepia as alternatives.[208] This commoditization will eliminate United's first mover advantages of being viewed as an innovator for PAH and PH-ILD treatments and being able to continue distinguishing itself in the market.

(91) The impact of a lost or disrupted first-mover advantage will be magnified in the market segment of inhaled dry powder formulation drugs for PAH and PH-ILD as Tyvaso DPI represents a breakthrough technology. Indeed, Tyvaso DPI has been described as "next-generation" and "a groundbreaking advancement for PAH and PH-ILD patients[.]"[209] Compared to Tyvaso, which is administered via a nebulizer (as discussed in Section 3.3.1), the benefits of inhaled dry powder formulation products are ease of use and convenience.[210] As the first

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206 See, for example:

Lemley, Mark A. and Carl Shapiro (2005), "Probabilistic Patents," *Journal of Economic Perspectives* 19(2): 75–98, at 77. ("Patents are rewards for those who have contributed to economic growth through their inventions. Any resulting market power enjoyed by a patent holder is typically considered a social cost that is necessary to stimulate innovation and provide a return on R&D expenditures.")

207 Interview with Greg Bottorff, 2/14/2024.

208 Interview with Dr. Steven Nathan, 2/9/2024.

209 United Press Release, "United Therapeutics Announces FDA Acceptance of Tyvaso DPI New Drug Application for Priority Review," 6/16/2021, https://ir.unither.com/press-releases/2021/06-16-2021-145947051. ("Tyvaso DPI is a next-generation dry powder formulation of Tyvaso. If approved, Tyvaso DPI is expected to provide a more convenient method of administration as compared with traditional nebulized Tyvaso therapy.")

United Press Release, "United Therapeutics Provides an Update on the Progress of the Tyvaso DPI New Drug Application," 10/18/2021, https://ir.unither.com/press-releases/2021/10-18-2021-151607305. ("'Tyvaso DPI will be a groundbreaking advancement for PAH and PH-ILD patients[.]'")

210 United Press Release, "United Therapeutics Announces FDA Acceptance of Tyvaso DPI New Drug Application for Priority Review," 6/16/2021, https://ir.unither.com/press-releases/2021/06-16-2021-145947051. ("Tyvaso DPI is a next-

and only product in the market with this convenience benefit, Tyvaso DPI has a significant first mover advantage and is the default choice for potential patients.[211] However, Yutrepia, as another inhaled dry powder formulation, also offers this same convenience benefit—a Liquidia news release discusses "[t]he attributes of YUTREPIA including ease-of-use [and] convenience[.]"[212] Thus, if Yutrepia enters the market, Tyvaso DPI would lose its first mover advantage as the only product with this benefit in the PAH and PH-ILD markets and instead have to compete directly against its own technology. Furthermore, United is likely to lose at least some degree of its brand recognition as a pioneer in the PAH and PH-ILD markets due to Yutrepia's premature entry and infringement.

4.5. Reduced pipeline investment

(92) In addition to the direct harm to United arising from price erosion, lost unit sales, and lost market share, the reduced revenues from these harms will inhibit United's ability to invest in ongoing development efforts for its pipeline drug candidates and products, which include novel drugs to treat PAH as well as organ manufacturing projects for treating end-stage organ

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generation dry powder formulation of Tyvaso. If approved, Tyvaso DPI is expected to provide a more convenient method of administration as compared with traditional nebulized Tyvaso therapy.")

Tyvaso Website, Frequently Asked Questions, https://www.tyvasohcp.com/pah/inhaled-prostacyclin/faqs/ (accessed 1/5/2024). ("TYVASO DPI provides your patients with the benefits of TYVASO in a convenient delivery device, which is a simple-to-use option for the treatment of PAH.")

Ladenburg Thalmann, "Liquidia Prevails in '793 PTAB CAFC Appeal; PH-ILD PDUFA 1/24/24; Buy & $30 PT," 12/21/2023, at 11. ("We note that dry powder inhalers (DPI) offer several points of differentiation over current options: Portability - In contrast to the Tyvaso nebulizer, which requires setup and cleaning, Yutrepia DPI uses a convenient cartridge delivery that can improve compliance with target dosing. …")

211 See, for example:

Wedbush, "Federal Circuit Affirms '793 PTAB Decision; Tyvaso DPI's Dominance to Persist," 12/21/2023, at 1. ("While YUTREPIA could still receive approval in PAH and/or PH-ILD, we see the confluence of several factors impacting the success of a potential launch including: Tyvaso DPI's ~1.6yr first-mover advantage in PAH and PH-ILD, YUTREPIA's lack of meaningful differentiation from Tyvaso DPI according to our prior conversations with experts [] and Liquidia's cash position limiting the ability to support a competitive launch ($76.2M as of Q3:23 and ~$25M in gross proceeds from Dec. 2023 offering provide runway into Q1:25 by our calculation). As such, we think Tyvaso DPI is well-positioned to remain physicians' first choice DPI treprostinil and to continue along its growth trajectory with MannKind's increased manufacturing capacity (~25K-35K in 2024 from ~7K-10K in 2023) providing United with the capability to sufficiently fulfill growing patient demand especially in PH-ILD (~30K U.S. patients) where Tyvaso DPI is the only approved product other than Tyvaso.")

TD Cowen, "Tyvaso '793 Patent PTAB Decision Affirmed in Appeals Court as Expected," 12/20/2023, at 1. ("While the launch of Yutrepia would introduce an additional player into the PAH commercial landscape, and we do expect Yutrepia to take a minority share of the overall market, our KOLs have emphasized the importance of UTHR's first-to-market position and established sales organization as important advantages for Tyvaso.")

212 Liquidia Press Release, "FDA Grants Tentative Approval for Liquidia's YUTREPIA (Treprostinil) Inhalation Powder," 11/8/2021, https://www.liquidia.com/news-releases/news-release-details/fda-grants-tentative-approval-liquidias-yutrepiatm-treprostinil.

disease.[213] This will, in turn, result in reduced future revenue streams. This harm is infeasible to fully quantify and hence to compensate through monetary damages.

(93) Cash flows from sales of established products is a preferred method for financing development efforts.[214] United has reported it "[devotes] substantial resources to [] various clinical trials and other research and development efforts[.]"[215] United's "research and development expenses primarily include costs associated with the research and development of products and post-marketing research commitments."[216] United's research and development projects include "new indications and delivery devices for [] existing products, as well as new products to treat PAH and other conditions."[217] United is also developing new products to treat PAH, and is "heavily engaged in research and development of a number of organ transplantation-related technologies including xenotransplantation, regenerative medicine, bio-artificial organs, 3-D organ bioprinting, and *ex vivo* lung perfusion."[218]

(94) United's research and development efforts would be harmed by reduced revenues of Tyvaso and Tyvaso DPI. United has reported, "[w]e rely heavily on sales of our treprostinil-based therapies to generate revenues and support our operations. Sales of our treprostinil-based therapies—Tyvaso DPI, nebulized Tyvaso, Remodulin, and Orenitram—comprise the vast majority of our revenues. Substantially decreased sales of any of these products could have a

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213 United Website, Complete Pipeline, https://pipeline.unither.com/ (accessed 1/26/2024).

214 Nicholson, Sean (2012), "Financing Research and Development," in Patricia M. Danzon and Sean Nicholson, eds., *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, New York, NY: Oxford University Press, Inc., at 47, 50. ("Even with patents there could still be underinvestment if firms have insufficient internal funds to finance all economically viable investments and the cost of external funds exceeds the cost of internal funds. Pharmaceutical firms with established products are able to finance all their economically viable projects with retained earnings[.] . . . Firms finance their R&D differently depending on where they are in their life cycle. Large firms with established products have traditionally relied on retained earnings.")

See also:

L.E.K. Consulting, "Financial Ecosystem of Pharmaceutical R&D: Annex A," 9/2021, at 44, available at: https://www.rand.org/content/dam/rand/pubs/external_publications/EP60000/EP68954/RAND_EP68954.annexa.pdf. ("Summary of key R&D funders . . . Pharma/biotech with revenue stream . . . Reinvestment of drug revenue into internal R&D pipeline[.]")

215 United, Form 10-K, 2023, at 55.

216 United, Form 10-K, 2023, at 55.

217 United, Form 10-K, 2023, at 3.

218 United, Form 10-K, 2023, at 54.

material adverse impact on our operations."[219] Sales of the Tyvaso products are important to United, representing 53% of United's total revenue in 2023.[220]

4.6. Reputational harm from subsequent withdrawal

(95) If a stay is not granted but a subsequent permanent injunction is granted, Yutrepia may be allowed to enter the market and then be forced to withdraw. Subsequent removal of Yutrepia due to the outcome of this litigation may cause external stakeholders to view United negatively for having removed an additional product from the market for PAH and PH-ILD patients.

(96) United reports that it is the "first publicly-traded biotech or pharmaceutical company to take the form of a public benefit corporation (PBC)."[221] United's public benefit purpose is "to provide a brighter future for patients through (a) the development of novel pharmaceutical therapies; and (b) technologies that expand the availability of transplantable organs."[222] Furthermore, United was founded to develop therapies to treat a condition suffered by the founder's family.[223] If United is viewed as responsible for removing what could be perceived as a "novel pharmaceutical therapy" (i.e., Yutrepia) from the marketplace, it may be claimed that United is operating counter to its mission and purpose to help patients, which would cause reputational harm. Harm to reputation can negatively impact financial performance, investor

219 United, Form 10-K, 2023, at 36.

220 See Attachment B-2.

221 United, Form 10-K, 2023, at 3.

222 United, Form 10-K, 2023, at 3.

223 United Website, United Therapeutics Corporation History, https://www.unither.com/about-us/history (Accessed 1/5/2024). ("United Therapeutics founded by Martine Rothblatt to find a cure for her daughter's life- threatening condition, now known as pulmonary arterial hypertension")

recognition/shareholder value, and the ability to attract high-quality applicants, among other things.[224] United has noted the importance of its reputation as a PBC to many of these areas.[225]

[224] See, for example:

Cao, Ying, et al. (2015), "Company reputation and the cost of equity capital," *Review of Accounting Studies* 20: 42–81, at 44–45. ("We use two approaches to estimate the cost of equity. . . . We find that companies with better reputations enjoy a lower cost of equity using either cost of equity estimation approach and the difference in the cost of equity between companies with higher reputations and companies with lower reputations is significant even after controlling for a large set of variables previously documented to affect the cost of equity. . . . Second, we examine whether company reputation increases investor recognition of the company's stock. We use the number of institutional investors to proxy for investor recognition (Chen et al. 2002; Lehavy and Sloan 2008) and find that changes in reputation are positively associated with subsequent changes in investor recognition. This is consistent with high reputation reducing the cost of equity by increasing investor recognition and allowing for more efficient risk sharing.")

Roberts, Peter W. and Grahame R. Dowling (2002), "Corporate Reputation and Sustained Superior Financial Performance," *Strategic Management Journal* 23: 1077–1093, at 1077. ("Good corporate reputations are critical because of their potential for value creation, but also because their intangible character makes replication by competing firms considerably more difficult. Existing empirical research confirms that there is a positive relationship between reputation and financial performance. This paper complements these findings by showing that firms with relatively good reputations are better able to sustain superior profit outcomes over time.")

Turban, Daniel B. and Daniel M. Cable (2003) "Firm Reputation and Applicant Pool Characteristics," *Journal of Organizational Behavior* 24: 733–751 at 746. ("We theorized that reputable firms would have higher-quality interviewees because they would receive more applicants and/or higher-quality applicants; either or both of these effects could lead to higher-quality interviewees. Our results provided only limited support for the hypothesis that lower-quality applicants are less likely to apply to firms with positive reputations, perhaps because such applicants have a low expectancy of receiving a job offer. Interestingly, however, our results provide strong evidence that employers with positive reputations attract more applicants and thus can be more selective in choosing higher-quality applicants to interview. More broadly, our results provide stronger support for signaling theory and social identity theory, which led to the prediction that firm reputation would result in more positive perceptions of the firm as an employer and therefore lead to more applicants.")

[225] United, 2022 Corporate Responsibility and Public Benefit Report, at 6. ("Our shareholders overwhelmingly approved our PBC conversion in September 2021. . . . We view United Therapeutics' PBC conversion as a virtuous cycle where our mission and strategic objectives benefit a wide range of stakeholders, which in turn, creates long-term shareholder value: . . . Employees: We compete for the best global talent with many other employers, and we believe that converting to a PBC helps us attract and retain Unitherians who are genuinely, and fiercely, committed to advancing our treatments and furthering our mission. . . . Investors: We are encouraged by the growth of long-term investors who care not only about how well we do financially, but also about *how we do well*. We want to make clear that we share the same long-term focus and values.")

5. Reasons Harms Cannot be Fully Compensated

5.1. Overview

(97) As discussed in Section 4, United will suffer harms due to Liquidia's infringement because Yutrepia will directly compete with the Tyvaso products. The harms that United will face due to Liquidia's infringement include lost profits due to price erosion, lost profits due to lost unit sales and market share, lost profits due to lost first mover advantages, reduced pipeline investments, and reputational harms.

(98) I understand that the Federal Circuit and district courts have considered harms that are difficult to quantify with reasonable certainty as sufficient for establishing irreparable harm. See Section 1.3. As explained in this section, the full extent of the financial losses United will suffer due to Liquidia's infringement cannot be isolated from the financial impacts of other factors, making it infeasible to fully quantify damages and compensate United for the full extent of harm due to Liquidia's infringement. In other words, Liquidia's infringement will cause United harm that cannot be compensated via an award of monetary damages.

5.2. The complexity of the marketplaces makes it infeasible to fully quantify and compensate harms

(99) Due to the complexity of the PAH and PH-ILD marketplaces, it will be infeasible to fully quantify and compensate the harms suffered by United in the absence of a stay. Calculating the full extent of harms from Yutrepia's infringement if a stay is not granted requires knowledge of (1) the marketplaces in the presence of infringement and (2) the ability to accurately predict the state of the marketplaces but for the infringement. While the state of the marketplaces in the presence of infringement will be observable, the complexities of the marketplaces make it difficult to predict what the marketplaces would have been but for the infringement.

(100) One source of complexity in evaluating harms arises from the use of the Tyvaso products and, if approved, Yutrepia, for the treatment of two different indications, PAH and PH-ILD. The indications each have complex competitive environments that make evaluating harms infeasible.

(101) The PAH market is relatively more established, with nebulized Tyvaso obtaining FDA approval in 2009[226] and multiple other treatment options available for treatment of PAH. See Section 3.2.2. As discussed in Section 3.2.2, PAH is treated in various ways, including treatment of underlying conditions, treatments to improve breathing or address blood pressure, and more targeted therapies delivered through numerous forms including oral, intravenous/subcutaneous, and inhaled. The substitution patterns and competition dynamics among these various types of therapies are complex. Namely, these different types of treatments may be substitutes in certain cases but are not necessarily interchangeable. The degree to which Yutrepia and the Tyvaso products would compete with the various types of treatments is uncertain. In addition, as discussed in Section 3.2.2., the different types of therapies may be used as complementary products. In a market with such competitive dynamics, proving the degree of reduced prices or lost sales and lost market share attributable to Yutrepia's entry is difficult. As a result, it is unlikely that United would be fully compensated for harms arising from Yutrepia's entry into PAH.

(102) The PH-ILD market is complex and unique because it is essentially a new market. Tyvaso and Tyvaso DPI—the only products approved to treat PH-ILD—were approved in March 2021 and May 2022, respectively (see Section 3.3.1); as such, this indication remains a nascent market. Prior to the addition of the PH-ILD indication for Tyvaso, there were no available FDA-approved treatments indicated for PH-ILD.[227] There is also a wide spectrum of ILD patients that also have PH.[228] As a result, existing estimates of PH-ILD incidence and prevalence are highly uncertain.[229] I understand that the prevalence of PH-ILD is unknown because (1) the diagnosis of PH-ILD is difficult and there is currently no standard or optimal method for screening patients for PH-ILD and (2) the need to specify the diagnosis was hampered by the lack of available treatments.[230] Liquidia Corporation has reported that "[c]urrent estimates of

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226 United, Form 10-K, 2023, at 4.

PR Newswire, "United Therapeutics Announces FDA Approval and Launch of Tyvaso for the Treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease," 4/1/2021, https://www.prnewswire.com/news-releases/united-therapeutics-announces-fda-approval-and-launch-of-tyvaso-for-the-treatment-of-pulmonary-hypertension-associated-with-interstitial-lung-disease-301260212.html.

227 Interview with Greg Bottorff, 2/14/2024.

228 Interview with Greg Bottorff, 2/14/2024.

229 Liquidia Corporation, Form 10-K, 2022, at 4. ("Current estimates of diagnosed and undiagnosed prevalence of PH-ILD range between 30,000 to 70,000, depending on the growth on the underlying lung diseases. The prevalence of PH in many of these underlying ILD diseases is not yet known due to factors including underdiagnosis and lack of approved treatments until recently.")

230 See:

diagnosed and undiagnosed prevalence of PH-ILD range between 30,000 to 70,000, depending on the growth on the underlying lung diseases."[231] This uncertainty surrounding the size of the market, current and future efforts to educate providers, and the anticipated entry of other medications makes forecasting this market difficult.[232]

(103) The expansion of the patient population treated for PH-ILD is expected to grow the estimated market for treprostinil-based inhalation products. For example, a BTIG analyst report states "[t]here is some small amount of overlap between PAH and ILD prescribers, but we believe it is generally accepted that this label expansion opportunity for inhaled treprostinil represents a new pool of prescribing physicians."[233] [redacted]

Parikh, Raj, et al. (2022), "Pulmonary Hypertension in Patients With Interstitial Lung Disease: A Tool For Early Detection," *Pulmonary Circulation* 12(4): 1–11, at Abstract. ("However, no standard currently exists regarding which patients to screen for PH-ILD nor the optimal method to do so. Furthermore, the diagnosis of PH in the context of ILD is often difficult because of the overlap in symptoms and diagnostic testing.")

Dhont, Sebastiaan, et al. (2022), "Pulmonary Hypertension in Interstitial Lung Disease: An Area of Unmet Clinical Need," *ERJ Open Research* 8: 1–9, at 4. ("There is no validated screening tool for PH in the setting of ILD.")

Rahaghi, Farbod and Franck Rahaghi (2021), "PH-ILD: Identification, Evaluation, and Monitoring: A Diagnostic View From Both Sides," *Advances in Pulmonary Hypertension* 20(4): 103–108, at 104. ("The estimation of the prevalence of PH-ILD is difficult given the variable admixture of causes of ILD, and the inherent bias of the presence of retrospective hemodynamic data only in those patients already suspected of having PH or undergoing transplant work-up. As a result, a wide range of estimates of prevalence of PH in ILD exist. For example, a review of 126 studies in IPF revealed a range of prevalence of PH between 3% and 86%.")

United, Marketing Brand Plans, c. 2021 (Consolidated Marketing Plan 2021_11302020.pptx, at slide 69). ("Current Belief": "Since there is no treatment, there is no benefit in diagnosing PH-ILD. I do as much as I can to treat my patients' ILD, but there isn't much that can be done to treat the PH itself.")

231 Liquidia Corporation, Form 10-K, 2022, at 4.

Liquidia Press Release, "Liquidia Provides Update on Clinical Pipeline Targeting PAH and PH-ILD," 1/5/2024, https://www.liquidia.com/news-releases/news-release-details/liquidia-provides-update-clinical-pipeline-targeting-pah-and-ph. ("A current estimate of PH-ILD prevalence in the United States is greater than 60,000 patients, though population growth in many of these underlying ILD diseases is not yet known due to factors including underdiagnosis and lack of approved treatments until March 2021, when inhaled treprostinil was first approved for this indication.")

232 Indeed, Oppenheimer described some of the "complex dynamics" associated with the entry of Yutrepia. See:

Oppenheimer, "Inhaled Treprostinil Battle Heats Up; Tyvaso Still in Driver Seat," 12/20/2023, at 1.

233 BTIG, "793 IPR Decisions Affirmed on Appeal, Leaving YUTREPIA Launch On Track for Mid-2024 or Earlier. Increasing PT to $29 from $18," 12/20/2023, at 3.

234 United, "Treprostinil Marketing: 2022 Business Plan," c. 2021, at 28.

[redacted][235]

(104) United has made significant investments in developing the PH-ILD market for the Tyvaso products, including marketing efforts to increase awareness of the Tyvaso products and education about screening for PH-ILD.[236] As a result of these efforts, United has seen sales growth in the market with physicians increasingly prescribing the Tyvaso products.[237] The Tyvaso products have experienced significant growth over the last couple of years[238] and this trend is likely to continue. [redacted]

(105) Yutrepia's entry will necessarily muddy the long-term trajectory of the PH-ILD market and make it difficult to distinguish between sales resulting from United's marketing efforts separate and apart from price competition from Yutrepia. Disentangling the price erosion, lost sales, and lost market share and computing harms as a result of Yutrepia's infringement would require making this distinction.

(106) Another factor that will complicate the assessment of harms from infringement is the potential entry of other treatments for PAH and PH-ILD. United's 2023 Form 10-K acknowledges that there are "a wide variety of investigational PAH therapies in development," identifying sotatercept, imatinib, MK-5475, L606, TPIP, and various other therapies as under development for PAH.[241] United also stated that "[s]everal PAH drug candidates are also being

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235 United, "Treprostinil Marketing: 2022 Business Plan," c. 2021, at 29.

236 Interview with Greg Bottorff, 2/14/2024.
See also the discussion in Section 6.

237 Interview with Greg Bottorff, 2/14/2024.

238 See Attachment B-1.

239 United, "2023 Business Planning," c. 2022, at 6.

240 United, "Treprostinil Marketing: 2022 Business Plan," c. 2021, at 23.

241 United, Form 10-K, 2023, at 19-20.

developed for PH-ILD (*e.g.*, Yutrepia, L606, sotatercept, imatinib, and TPIP). Other companies are now developing, or may in the future develop, other therapies to treat PH-ILD. In addition, the use of antifibrotic therapies to treat underlying lung disease (such as the IPF therapies discussed below) could delay the onset of group 3 pulmonary hypertension."[242] New products entering the market will have an impact on the price and sales of the Tyvaso products. However, the impact on the market of each new entrant is uncertain because substitution patterns and competitive dynamics in the marketplace will depend on the entrant's currently unobservable characteristics and the degree to which these characteristics will drive payor and prescriber behavior. One potential entrant to the PAH and PH-ILD marketplace that is currently preparing for Phase 3 trials is Pharmosa Biopharm's L606, an inhaled, sustained-release formulation of treprostinil.[243] According to a Liquidia press release from June 2023, Liquidia exclusively licensed the North American rights to L606, which is being evaluated for PAH and PH-ILD indications.[244] Another potential entrant is Aerami Therapeutics' AER-901 (inhaled imatinib), a drug device combination using a nebulizer indicated for PH-ILD that is currently between Phase 1 and Phase 2 clinical trials.[245]

(107) It is especially difficult to calculate the impact of a loss of first mover advantage with certainty. The benefits associated with a first mover advantage can take various forms—such as increased market share, stickiness, brand recognition, etc.—and it is hard to precisely tease out which benefits and the extent to which those benefits are attributable solely to the first mover advantage, separate and apart from other factors. Full estimation of the erosion of United's first-mover advantage would require accurate forecasts of addressable patients, coverage determinations, and market shares, among other information. However, the PAH and PH-ILD markets are complex, dynamic, and characterized by uncertainty. These unique dynamics make the potential impact on United's first-mover advantage variable and subject

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242 United, Form 10-K, 2023, at 20.

243 Pharmosa Website, Pipeline, https://www.pharmosa.com.tw/phases (accessed 1/22/2024).

Liquidia Press Release, "Liquidia Corporation and Pharmosa Biopharm Announce Collaboration for Sustained-Release Inhaled Treprostinil Product in North America," 6/28/2023, https://www.liquidia.com/news-releases/news-release-details/liquidia-corporation-and-pharmosa-biopharm-announce.

244 Liquidia Press Release, "Liquidia Corporation and Pharmosa Biopharm Announce Collaboration for Sustained-Release Inhaled Treprostinil Product in North America," 6/28/2023, https://www.liquidia.com/news-releases/news-release-details/liquidia-corporation-and-pharmosa-biopharm-announce.

245 Aerami Therapeutics Press Release, "Aerami Therapeutics Announces Expansion of the AER-901 (inhaled imatinib) Development Program in Pulmonary Hypertension Supported by Phase 1 Clinical Trial Data and Continued Progress," 2/23/2023, https://www.aerami.com/news-media/press-releases/detail/20/aerami-therapeutics-announces-expansion-of-the-aer-901.

Aerami Therapeutics Website, Pipeline, https://www.aerami.com/pipeline (accessed 1/22/2024).

to many evolving and interacting factors. In addition, with the PH-ILD market being in its early stages and continuing to grow, the competitive dynamics between United and Liquidia—as well as potential future competitors—are also uncertain and likely to continue to change.

(108) Similarly, the impacts of reduced pipeline investment are not feasible to fully quantify and compensate with precision. It would be difficult to determine what opportunities United could have invested in absent Yutrepia's entry and the ultimate outcome of those investments. The drug development process is characterized by uncertainty[246] and it is extremely difficult to determine these outcomes but for Yutrepia's infringing entry.

(109) The full extent of the reputational harm if Yutrepia enters the market and is then subsequently withdrawn is also not fully compensable with monetary damages because the damages caused are uncertain and impossible to quantify with precision. To do so would require detailed data about all factors that could impact United's reputation over time (which may not exist) and the impacts of all of those factors, separate and apart from the impact of Yutrepia's infringing entry.

(110) As I discuss in Section 5.3, standard methodologies that are typically used to quantify harms are deficient in this case because of the complexity of the marketplaces.

5.3. Standard methodologies are deficient

5.3.1. Overview

(111) There are many marketplace complexities that are not fully quantifiable but will impact United's financial performance. Observed changes in United's business will be a result of Liquidia's infringement as well as other factors described in Section 5.2. Due to the complexity of the PH-ILD market, standard methodologies and/or benchmarks for evaluating but-for sales—such as sales forecasts, other products and comparables, and imputed market shares—are deficient. The quantification of harm is further complicated by an endogeneity problem.

246 See: DiMasi, Joseph A., Henry G. Grabowski, and Ronald W. Hansen (2016), "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," *Journal of Health Economics* 47: 20–33, at Figure 1. (The figure provides probabilities of transitioning to each subsequent phase in the drug development process.)

5.3.2. Forecasts

(112) Forecasts—whether internal United forecasts, Liquidia forecasts, or analyst forecasts—of metrics such as unit sales, prices, and revenues, are deficient for evaluating United's financial performance in the absence of infringement for several reasons.

(113) First, as discussed in Section 5.2, the PAH and PH-ILD markets are complex and evolve over time. Changes to the market landscape are likely to have substantial impacts on United's product sales and likely cannot be fully accounted for in sales forecasts, especially if the changes are unexpected or are more significant than anticipated. Furthermore, given the ongoing evolution of the market, historical market data is not necessarily predictive of future market outcomes.[247]

(114) Second, more recent forecasts may already attempt to incorporate the effects of the infringement, and thereby do not provide a benchmark that could be used to determine the full extent of harm. For example, analyst forecasts for future sales may already capture United's expected sales in the presence of infringing competition.[248]

(115) Third, for forecasts to be accurate and reliable, it is necessary to know enough about the market such that the inputs and equations informing the forecasts are correctly specified. Markets with multiple evolving factors that affect that information, such as the PAH and PH-ILD markets, significantly complicate the forecasting process. Indeed, economists have noted that if the process generating the observed data changes, it becomes very difficult to construct a reliable forecast.[249] Elliott and Timmermann (2016) note:[250]

> Whenever a forecast is being constructed or evaluated, an overriding concern revolves around the practical problem that the best forecasting model is not only unknown but also unlikely to be known well enough to even correctly specify forecasting equations up to a set of unknown parameters. . . . Moreover, in many situations the data generating process changes over time, further emphasizing the difficulty in obtaining very large samples of observations on which to base a model. These foundations using misspecified [*sic*] models to

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247 See: *Veeco Instruments Inc. v. SGL Carbon, LLC*, No. 17-CV-2217 (PKC), (E.D.N.Y. 2017), at 22. ("[T]he medium- and long-term effects of [patentee's] lost market share and other competitive harms will be especially difficult to quantify at trial because the [infringed technology] market is entering an expansionary period, making historical market data less predictive of future results.")

248 See, for example: Wedbush, "Don't Call It a Comeback...Initiating at OP and $10 PT," 10/9/2023, at 5. (Figure 3 show "PAH Projected DPI Market Share" with "Gross Peak Sales in 2030 ($000)" that includes in the market Tyvaso DPI and Yutrepia. Thus, Tyvaso DPI's projected sales reflect Yutrepia in the market.)

249 Elliot, Graham and Allan Timmermann (2016), *Economic Forecasting*, Princeton, New Jersey: Princeton University Press, at 3.

250 Elliot, Graham and Allan Timmermann (2016), *Economic Forecasting*, Princeton, New Jersey: Princeton University Press, at 3.

> forecast outcomes generated by a process that may be evolving over time–generate many of the complications encountered in forecasting. . . . Without knowing the true data-generating process, the problem of constructing a good forecasting method becomes much more difficult.

(116) United and Liquidia annual reports note the difficulty in forecasting outcomes. For example, United has stated that there are "numerous evolving risks and uncertainties that we may not be able to accurately predict or assess, and that may cause our actual results to differ materially from anticipated results[.]"[251] Similarly, Liquidia has stated: "[w]e are subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, the impact of the COVID-19 pandemic, and the ability to secure additional capital to fund operations."[252]

5.3.3. Other products or comparables

(117) As discussed in Section 5.2, the PAH and PH-ILD markets are unique and complex. While the outcome of direct competition between products in other markets (*e.g.,* PCSK9 inhibitors or Hepatitis C treatments) may provide insight as to the types of harm that United is likely to suffer absent a stay on Yutrepia's approval and entry (i.e., price erosion, lost sales, and lost market share), as well as demonstrating that such harms can be significant, the PAH and PH-ILD markets are unique such that the experience of other products is a deficient benchmark for quantifying the full extent of the impact of Liquidia's infringement on United.

(118) To use products outside of the PAH and PH-ILD markets as comparable benchmarks for Tyvaso and Tyvaso DPI, one would have to adjust for the differences between the PAH and PH-ILD markets and the benchmark marketplace. However, the information necessary to make such adjustments (*e.g.*, the related market features, players, products, relationship to the market, size of the market, rate of growth, etc.) is incomplete, and those adjustments cannot be made with complete accuracy. Other markets are unlikely to have the same unique dynamics as the PAH and PH-ILD markets. For example, there are likely to be different competitive dynamics, different reimbursement dynamics, and different pricing dynamics, among others. These effects are accentuated by the fact that the PH-ILD marketplace is nascent and growing.

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251 United, Form 10-K, 2023, at 53.

252 Liquidia Corporation, Form 10-K, 2022, at 28.

(119) For example, Repatha and Praluent are considered alternatives similar to Tyvaso DPI and Yutrepia, and the resulting effects observed in that market suggest that the Tyvaso products will experience price erosion, lost sales, and lost market share. However, the exact pricing and sales trends for the Tyvaso products cannot be predicted based on the trends experienced by Repatha and Praluent because the markets have different patient populations, different reimbursement dynamics, different available treatment options, different prices, etc. A similar logic applies to other potential benchmarks. There is no comparable that is a close enough comparator to the circumstances of Tyvaso and Tyvaso DPI.

5.3.4. Imputed market shares

(120) Imputed market shares absent the presence of Liquidia's Yutrepia product are a deficient benchmark to evaluate the full impact of Liquidia's infringement on United's business.

(121) A commonly used methodology for determining the market share that would be enjoyed by the patentee in the absence of the infringer is described in *State Industries v. Mor Flo*.[253] Under this methodology, it is assumed that absent the infringement, remaining market participants would make the infringer's sales in proportion to their relative shares.[254] As an example, suppose the patentee, infringer, and a third competitor have shares of 40%, 40%, and 20%, respectively. In this scenario, the patentee and the third party will split the infringer's share as follows: patentee will gain 40%/60% or 2/3 of the infringer's sales, whereas the third party will gain 20%/60% or 1/3 of the infringer's sales.

(122) In the case of the PAH and PH-ILD markets, a methodology such as the one described in *State Industries v. Mor-Flo* ("*Mor-Flo*") cannot be used to fully capture United's sales but for Liquidia's infringement for several reasons. Regarding the nascent PH-ILD market, as it grows, disputes would arise as to how much of that growth should be credited to Liquidia rather than United, rendering it difficult to identify counterfactual United sales and complicating the use of a *Mor-Flo* approach. More generally, should other potential treatments enter the PAH or PH-ILD markets (see Section 5.2), the increasingly complicated market dynamics would render such an approach impossible to implement with accuracy.

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253 *State Industries, Inc. v. Mor-Flo Industries*, 883 F.2d 1573, 1576–1580 (Fed. Cir. 1989).

254 *State Industries, Inc. v. Mor-Flo Industries*, 883 F.2d 1573, 1576 (Fed. Cir. 1989). ("Finding that [plaintiff] had approximately 40% of the gas water heater market nationwide, the court awarded State the profits it lost on 40% of the sales of 754,181 infringing [defendant] water heaters.")

(123) Product choice will also be dictated by complex payor and PBM preferences and reimbursement dynamics and cannot be simply divided according to proportional shares. Said differently, the Tyvaso products will experience declines in price due to complex negotiations with payors and PBMs as discussed in Section 4.2. At the same time, demand for the Tyvaso products will be predicated on price, formulary placement, step therapy requirements, and prior authorization requirements. It is extremely difficult to predict all these inputs with certainty in the but-for world, let alone the impacts of the complex interactions between them.

(124) More complex demand estimation models used by economists to analyze demand in differentiated markets, such as the one presented by Barry, Levinsohn, and Pakes (1995), are also deficient because they cannot be effectively applied when the market is evolving significantly. These models are sometimes referred to as discrete-choice models or structural models of demand estimation and, under certain circumstances, allow powerful analyses of demand and substitution between products. However, these models can only provide a conditional analysis of each issue and the model's performance can deteriorate if the primitives of the model change in response to a change in the environment.[255] As such, changes in market dynamics, such as changes in reimbursement dynamics, formulary placement, etc., will affect the reliability of the analysis.

5.3.5. Endogeneity

(125) An endogeneity problem further complicates the process of measuring the impact of Liquidia's infringement on United's price, sales, and market share. Endogeneity arises, for example, when a third variable affects both the independent and dependent variable,[256] such that the distinct effect of the independent variable on the dependent variable cannot be appropriately

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255 Berry, Steven, James Levinsohn, and Ariel Pakes (1995), "Automobile Prices in Market Equilibrium," *Econometrica* 63(4): 841–890, at 885–886. ("On the other hand, all of the models, including our own, are limited in that they provide only a 'conditional' analysis of each issue. That is, to do policy analysis we will have to perturb a small number of parameters and compute new equilibria conditional on the other primitives of the model remaining unchanged. In fact in many cases these other 'primitives' will change in response to a change in policy or in the environment. For example, Pakes, Berry, and Levinsohn (1993) used our model's estimates to predict the effect of the 1973 gas price hike on the average MPG of new cars sold in subsequent years. We found that our model predicted 1974 and 1975 average MPG almost exactly. This is because the characteristics of cars, treated as fixed in our predictions, did not change much in the first two years after the gas price hike and our model did well in predicting responses conditional on the characteristics of cars sold. However, by 1976 new small fuel efficient models began to be introduced and our predictions, based on fixed characteristics, became markedly worse and deteriorated further over time.")

256 Many econometric analysis models begin with the premise that *y* and *x* are two variables, and the economist is interested in explaining how *y* changes in response to *x*. *y* is often referred to as the dependent variable and *x* is often referred to as the independent variable.

See: Wooldridge, Jeffrey M. (2006), *Introductory Econometrics: A Modern Approach*, 3rd ed., Mason, OH: Thomson South-Western, at 24–25.

measured.[257] In this case, there is an endogeneity problem because Liquidia's infringement affects United's business decisions, and United's infringement-impacted business decisions affect Tyvaso and Tyvaso DPI sales.

(126) To fully quantify harms to United, one would need to compare United's financial performance in the world with infringement to a world without infringement. However, United's business decisions are dependent on whether there is infringement. As an illustrative example, the PH-ILD market is in its early stages and United's investments into developing the market are likely to differ in the worlds with and without infringement—thereby affecting United's financial performance. The differences in these investments cannot be accurately measured because it is uncertain what they would have been absent infringement. Said differently, United has likely made and will likely continue to make business decisions to mitigate the harm caused by the market entry of infringing products. That is, faced with the option of selling Tyvaso and Tyvaso DPI as if there were no infringing entry, or selling Tyvaso and Tyvaso DPI to compete most efficiently in the new market that includes the infringing products, United will likely opt for the latter.

(127) Moreover, any potential mitigation approaches employed by United may not have necessarily been optimal, but rather were based on the best available information known at the time. Even with hindsight, lack of a perfect control group makes it extremely difficult to isolate the impact of Liquidia's products separate and apart from other factors.

(128) Since Liquidia's infringement likely will impact United's behavior and product marketing activities, it is very difficult to determine with certainty what sales would have been but for the infringement, because the infringement has likely affected United's marketing, commercialization, and development efforts.

5.4. Harm to United is disproportionate to gain to Liquidia

(129) As I discuss in this section, the lost profits to United arising from Liquidia's entry are likely to be significantly larger than the profits gained by Liquidia from entry. Accordingly, it is unlikely that a damages amount United could reasonably recover at trial would be capable of simultaneously (1) providing adequate compensation to United for harm due to Liquidia's infringement, while (2) allowing Liquidia to profitably sell Yutrepia. In other words, any

[257] Wooldridge, Jeffrey M. (2006), *Introductory Econometrics: A Modern Approach*, 3rd ed., Mason, OH: Thomson South-Western, at 552.

damages United can recover at trial would not adequately compensate United for Liquidia's infringement.

(130) For illustrative purposes only, suppose one dose of Yutrepia is sold at parity with the Tyvaso products at $21,000 for a one-month supply.[258] Further, suppose that the costs to produce a one-month supply for the Tyvaso products and Yutrepia is $1,000. Under these pricing and cost assumptions, United would lose $20,000 in gross profits per sale lost to Yutrepia.

(131) From a royalty perspective, the only economically reasonable royalty that United would agree to would be one that compensates United for the full extent of losses from Yutrepia entry. On the other hand, this royalty would mean that Yutrepia would not earn any profits from sales of its products.[259]

(132) However, the above example rests on the untenable assumption that prices would remain the same after Yutrepia entry. As I described at length above, it is entirely reasonable to expect Liquidia to offer discounts to gain share in the PAH and PH-ILD markets. In response, United would need to offer similar discounts to maintain a favorable or parity formulary position in order to mitigate market share erosion. As a result, United would lose profits not only on each unit sale lost to Liquidia, but also on each unit sale it retains. This is because United would be making a lower profit per unit sold in the presence of infringement than it would have made but for the infringement. In this case, suppose both manufacturers arrive at an eroded $10,000 net price for the Tyvaso products and Yutrepia. Each sale made by United would represent $11,000[260] in price erosion damages (i.e., in reduced gross profits) for United *in addition to* lost profits due to unit sales lost to Yutrepia. Any royalty aimed at addressing this loss necessarily exceeds the revenue generated by Yutrepia ($10,000 per dose), making it economically infeasible that any royalty that United can recover at trial would make United whole.[261]

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258 This figure and the rest of the figures in this Section 5.4 are for illustrative purposes only and not intended to reflect actual prices or costs for the Tyvaso products or Yutrepia.

259 Consideration of sales and marketing expenses would make this determination more complex. However, as discussed immediately following, this calculation overlooks the role that price competition and erosion would play.

260 But for the infringement, United would make profits of $21,000 – $1,000 = $20,000 per unit. However, due to the infringement it only makes $10,000 – $1,000 = $9,000 per unit. The difference of $20,000 – $9,000 = $11,000 would be the lost profits per unit due to price erosion.

261 Potential PH-ILD market expansion does not resolve these issues. As an initial observation, this would not address these losses for sales associated with Yutrepia entry to the PAH market. Moreover, even if the PH-ILD market expands to some degree, thereby increasing the overall quantity sold, it is unlikely that such expansion would be the result of Yutrepia's entry, but rather the efforts United has engaged in to increase screening and treatment for PH-ILD. Furthermore, even with market expansion, the patient populations for PH-ILD will likely remain relatively small, given it is an orphan disease.

5.5. Liquidia has limited ability to properly compensate United due to its financial condition

(133) Even if the full extent of harm to United could be quantified (which as discussed above, is very difficult to accomplish with precision), Liquidia has limited ability to properly compensate United for the full extent of harm caused by its infringement in this case.

(134) While no measure of monetary damages in this case could sufficiently capture the extent of harm from Liquidia's infringement due to the challenges I have described above, it is likely that even an understated estimate of damages would be significantly higher than the revenue that Liquidia currently generates. Tyvaso and Tyvaso DPI together generated net revenues of $607.5 million in 2021, $873.0 million in 2022, and $1.23 billion in 2023.[262] [redacted][263]

(135) United reported that "[t]he increase in quantities sold [from 2021 to 2022] was driven by the commercial launch of Tyvaso DPI in June 2022 and continued growth in the number of patients following the PH-ILD label expansion in March 2021."[264] United later reported that "continued growth in utilization by PH-ILD patients" helped drive increases in product sales from 2022 to 2023.[265] United also has estimated that around 40% to 50% of new prescriptions are PH-ILD.[266]

Thus, it is unlikely that Yutrepia can expand the market to such a degree that it can remain profitable while simultaneously compensating United for the full extent of harms suffered.

262 United, Form 10-K, 2023, at 57.

263 United, Tyvaso DPI and Nebulized Tyvaso Gross Margins, c. 2024 (Tyvaso DPI and Nebulized Tyvaso Gross Margins.xlsx, at tab "Gross Margin Analysis").

264 United, Form 10-K, 2022, at 49. ("Tyvaso net product sales increased in 2022, as compared to 2021, primarily due to an increase in quantities sold and, to a lesser extent, the impact of a price increase and lower gross-to-net deductions. The increase in quantities sold was driven by the commercial launch of Tyvaso DPI in June 2022 and continued growth in the number of patients following the PH-ILD label expansion in March 2021.")

265 United, Form 10-K, 2023, at 57. ("Total Tyvaso net product sales grew 41% to $1,233.7 million in 2023, compared to $873.0 million for 2022. This growth was primarily due to an increase in quantities sold, driven by the commercial launch of Tyvaso DPI in June 2022 and continued growth in utilization by PH-ILD patients.")

266 Refinitiv StreetEvents, "United Therapeutics Corp at JPMorgan Healthcare Conference," 1/8/2024, at 8. (Q. "And what's your latest thinking about the Tyvaso revenue breakdown between PAH and PH-ILD. And how is that kind of shifting over time?" A. "Yes. From a -- it's a little difficult to answer that from a revenue standpoint right now, just because we have so many legacy patients on there on product and are being reflected in the revenue numbers. What I can tell you is that in terms of new prescriptions that are coming in, we have decent, though not perfect visibility into the breakout between PAH and PH-ILD. If I look at just purely what's written on the referral form, it's roughly 40%, a little bit above 40% of the referrals coming in are PH-ILD. I think in reality, it's probably closer to 50%, a little bit -- or a little bit more. And the reason for that is there's -- depending on how the doctors write on the referral form, a PH-ILD patient could come in looking like a PAH patient and vice versa.")

(136) In contrast, Liquidia has a limited array of available treatments and limited revenues at present (see Section 3.1.2). Liquidia Corporation has reported that it currently generates revenue "pursuant to a Promotion Agreement between Liquidia PAH and Sandoz Inc. [] sharing profit derived from the sale of Sandoz's substitutable generic treprostinil injection [] in the United States."[267] Liquidia Corporation reported revenue of $12.9 million in 2021 and $15.9 million in 2022, as well as loss from operations of -$33.8 million in 2021 and -$38.8 million in 2022.[268] Liquidia Corporation also reported that "[w]e have a history of losses and our future profitability remains uncertain. . . . We may continue to incur losses and negative cash flow and may never transition to profitability or positive cash flow."[269] A Wedbush analyst report from December 2023 also discusses "Liquidia's cash position limiting the ability to support a competitive launch[.]"[270]

(137) The profits that Liquidia makes from sales of Yutrepia are unlikely to be sufficient to compensate for the significant harm that United will suffer in the absence of a stay. As discussed in Section 4.2, Yutrepia is likely to enter the market at a lower price than the Tyvaso products, especially after accounting for discounts and rebates that Liquidia is likely to offer to gain market share. Accordingly, the profit gained by Liquidia is likely to be smaller than the profit lost by United for each unit sale made by Yutrepia that United would have captured but for Yutrepia's premature entry. Absent a stay, United will also suffer significant price erosion (see Section 4.2) and any profits Liquidia makes are unlikely to be sufficient to cover harms due to price erosion.

(138) Given the magnitude of Tyvaso sales, the high gross margins that United earns on those Tyvaso sales, and the significant harm that United will suffer due to infringement, even a damages estimate that does not account for the full extent of harm will be a significant amount.

(139) To demonstrate Liquidia's likely inability to compensate United for its infringement (even if damages could be calculated), I have prepared an illustrative analysis that estimates an approximate low-end magnitude of lost revenues that United is likely to suffer if Yutrepia enters the market. This analysis assumes the losses stem only from price erosion and lost sales (as discussed in Sections 4.2 and 4.3). [redacted]

267 Liquidia Corporation, Form 10-K, 2022, at 3.

268 Liquidia Corporation, Form 10-K, 2022, at 72.

269 Liquidia Corporation, Form 10-K, 2022, at 29.

270 Wedbush, "Federal Circuit Affirms '793 PTAB Decision; Tyvaso DPI's Dominance to Persist," 12/21/2023, at 1.

[redacted][274] In contrast, Liquidia Corporation's market capitalization—a measure of how much the entire company is worth as determined by the stock market[275]—was $1.054 billion as of April 17, 2024.[276]

(140) As such, given Liquidia's financial position compared with the magnitude of damages that would likely apply in this case, it is unlikely that Liquidia would be able to adequately compensate United for lost profits or other damages. As a result, even if they could be calculated with certainty, monetary damages are not able to fully compensate United for the harms arising from Yutrepia's infringement.

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271 United, United Therapeutics Tyvaso Forecast (2023–2035), 9/6/2023 (UTHR Forecast 2023–2035 09-06-2023.xlsx, at tab "forecast").

This forecast was generated prior to Liquidia's announcement on September 25, 2023 that the FDA had accepted for review Liquidia's submission to add the PH-ILD indication to the label for Yutrepia. See: Liquidia Press Release, "FDA Accepts Submission to Add PH-ILD to Yutrepia Label," 9/25/2023, https://www.liquidia.com/news-releases/news-release-details/fda-accepts-submission-add-ph-ild-yutrepiatm-label.

272 See Attachment C-1.

273 I note that this figure is intended only to illustrate the point that Liquidia has limited ability to properly compensate United. The figures in Attachment C-1 do not represent estimates of damages for Liquidia's infringement. For the reasons discussed throughout my report, the full extent of harms are not feasible to quantify with precision.

274 See Attachment C-1.

275 Investopedia, "Market Capitalization: How Is It Calculated and What Does It Tell Investors?," 12/14/2023, https://www.investopedia.com/terms/m/marketcapitalization.asp.

276 Yahoo Finance, Liquidia Corporation (LQDA), https://finance.yahoo.com/quote/LQDA/ (accessed 4/17/2024).

Furthermore, as discussed in Section 5.4, the lost profits suffered by United from Liquidia's entry in the PAH and PH-ILD marketplaces are likely to be significantly larger than the profits gained by Liquidia.

6. Balance of Equities

(141) United's investments in the Tyvaso products and in developing the PH-ILD market exceed Liquidia's investments. The harms to United if a stay is not granted exceed the harms that Liquidia may suffer if the stay is granted. From an economic perspective, the balance of equities in this case favors United.

(142) As an initial matter, United's total research and development expenses have far exceeded Liquidia's. United has confirmed: "We devote substantial resources to our various clinical trials and other research and development efforts, which are conducted both internally and through third parties. From time to time, we also license or acquire additional technologies and compounds to be incorporated into our development pipeline."[277] In terms of total research and development, United has spent approximately $2.95 billion on research and development projects from 2017 through 2022.[278] By comparison, Liquidia has spent approximately $166.1 million in research and development over the same period.[279] Further, United spent $1.1 billion from inception through 2014 on cardiopulmonary disease programs alone.[280]

(143) From a business and economic perspective, United made significant upfront investments with the expectation that those investments would ultimately yield significant returns and lead to

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277 United, Form 10-K, 2023, at 55.

278 United, Form 10-K, 2018, at 68. (Research and development projects expenses are $256.4 million in 2017 and $370.0 million in 2018.)

United, Form 10-K, 2021, at 54. (Research and development projects expenses are $1,182.2 million in 2019, $328.2 million in 2020, and $515.7 million in 2021.)

United, Form 10-K, 2023, at 59. (External research and development expenses are $168.8 million in 2022. Internal research and development expenses are $131.4 million in 2022. Other research and development expenses are -$1.1 million in 2022.)

$256.4M + $370.0M + $1,182.2M + $328.2M + $515.7M + ($168.8M + $131.4M - $1.1M) = $2,951.6M.

279 Liquidia, Form 10-K, 2018, at 102–103.

Liquidia, Form 10-K, 2019, at 104.

Liquidia Corporation, Form 10-K, 2020, at 56.

Liquidia Corporation, Form 10-K, 2021, at 70.

Liquidia Corporation, Form 10-K, 2022, at 72.

$19.435M + $20.517M + $32.222M + $40.491M + $28.700M + $24.754M = $166.119M

280 United, Form 10-K, 2014, at 67. ("From inception to December 31, 2014, we have spent $1.1 billion on all of our current and former cardiopulmonary disease programs.")

long-term success in the marketplace.[281] To date, its investments in Tyvaso and Tyvaso DPI have collectively generated $6.92 billion in revenue and $6.32 billion in gross profit beginning with Tyvaso's launch in 2009.[282] The Tyvaso franchise is an important contributor to United's financial performance, averaging 34.6% of United's total revenues from 2010 to 2023.[283] The percentage has increased annually since 2017 from 21.6% to 53.0% in 2023.[284]

(144) In contrast to United's efforts and investments toward developing the Tyvaso products, Liquidia has spent less to bring Yutrepia to the market. As discussed in Section 3.4, Liquidia submitted Yutrepia for approval via the 505(b)(2) pathway, which allows a drug developer pursuing approval of a new product to make use of clinical evidence from a reference product that already has been reviewed and approved by the FDA.[285] In the case of Yutrepia, Liquidia made use of Tyvaso (in nebulized form) as the reference product in order to rely on FDA findings of efficacy and safety for the active ingredient, treprostinil.[286] In addition, a Liquidia press release from July 2023 states that "[t]he U.S. Food and Drug Administration (FDA) has previously confirmed in writing that the addition of the PH-ILD indication [to Yutrepia] will

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281 See: Levin, Richard, et al. (1987), "Appropriating the Returns from Industrial Research and Development," *Brookings Papers on Economic Activity* 1987(3): 783-831, at 783. ("To have the incentive to undertake research and development, a firm must be able to appropriate returns sufficient to make the investment worthwhile.")

Hsieh, Ping-Hung, Chandra S. Mishra and David H. Gobeli (2003), "The Return on R&D Versus Capital Expenditures in Pharmaceutical and Chemical Industries," *IEEE Transactions on Engineering Management* 50(2): 141–150, at Abstract. ("The impact of research and development (R&D) on firm performance is generally agreed to be positive, but the nature and extent of this impact share little agreement in the previous research. Using an improved, time series, cross-sectional regression model that accounts for both contemporaneous and firm-specific serial correlation, as well as the feedback between firm profitability and investments, our study compares the rate of return from a dollar investment on R&D to a dollar investment on fixed assets in pharmaceutical and chemical industries. We find positive associations of R&D intensity and all variables of firm performance (net margin, operating margin, sales growth, and market value). We find that an investment in R&D earns an operating margin return much higher than the industry cost of capital. We also find that the effect of an investment in R&D on the firm's market value is about twice as much the effect of an investment in fixed assets. These findings have implications for corporate investment strategies, indicating that additional R&D investment is more likely to provide a firm with a unique and sustainable competitive advantage.")

282 See Attachment B-1.

283 See Attachment B-2.

284 See Attachment B-2.

285 FDA, "Determining Whether to Submit an ANDA or a 505(b)(2) Application: Guidance for Industry," 5/2019, at 4, available at: https://www.fda.gov/media/124848/download. ("As discussed in section II above, an application submitted through the pathway described in section 505(b)(2) of the FD&C Act contains full reports of investigations of safety and effectiveness, where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use (e.g., the Agency's finding of safety and/or effectiveness for a listed drug, published literature). A 505(b)(2) applicant may rely on FDA's finding of safety and/or effectiveness for a listed drug only to the extent that the proposed product in the 505(b)(2) application shares characteristics (e.g., active ingredient, dosage form, route of administration, strength, indication or other conditions of use) in common with the relied-upon listed drug(s).")

286 Liquidia Corporation, Form 10-K, 2022, at 5.

not require any new clinical information."[287] By relying on Tyvaso as the reference product for Yutrepia to earn approval, Liquidia is freeriding on United's efforts to bring the Tyvaso products to market without incurring the significant costs that United had to spend and risks that United had to take on the development and commercialization of the Tyvaso products. Indeed, United has invested significantly into the drug development process by way of conducting multiple clinical trials, which are expensive and inherently risky.[288] For example, United performed the *INCREASE* study to establish safety and efficacy of Tyvaso for PH-ILD and the *BREEZE* study to establish safety and pharmacokinetics of switching PAH patients from Tyvaso to Tyvaso DPI.[289] From an economic perspective, performing the *INCREASE* study was a significant risk that United took to develop a new segment of the market that others had tried and failed to develop (i.e., PH-ILD).[290] If Yutrepia is not prevented from entry, United will be harmed by losing the ability to recoup its significant research and development expenses and earn the rewards it should be able to earn from successfully taking the risk to develop the first drug in a new indication. Conversely, if Liquidia is prevented from launching Yutrepia, any lost investments into drug development that Liquidia will incur will be small compared to what United will experience; Liquidia currently does not have any clinical study results available for PH-ILD.[291]

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287 Liquidia Press Release, "Liquidia Submits Amendment to Add PH-ILD Indication to Tentatively Approved NDA for YUTREPIA (treprostinil) Inhalation Powder," 7/27/2023, https://www.liquidia.com/news-releases/news-release-details/liquidia-submits-amendment-add-ph-ild-indication-tentatively.

288 See, for example: DiMasi, Joseph A., Henry G. Grabowski, and Ronald W. Hansen (2016), "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," *Journal of Health Economics* 47: 20–33.

289 See: Section 3.3.1.

290 See, for example:

Baughman, Robert P., et. al. (2022), "Riociguat for Sarcoidosis-Associated Pulmonary Hypertension: Results of a 1-Year Double-Blind, Placebo-Controlled Trial," *Chest* 161(2): 448–457, at 449. ("Riociguat is a soluble guanylate cyclase stimulator that has been shown to be a successful treatment for WHO group 1 pulmonary arterial hypertension (PAH) and WHO group 4 chronic thromboembolic pulmonary hypertension. Unfortunately, riociguat did not meet with success when studied in PH resulting from interstitial lung disease, with the Riociguat for idiopathic interstitial pneumonia-associated pulmonary hypertension (RISE-IIP) study being stopped early because of observed increased harm in the active treatment arm.")

Behr, Jürgen (2022), "Inhaled Treprostinil in Pulmonary Hypertension in the Context of Interstitial Lung Disease: A Success, Finally," *American Journal of Respiratory and Critical Care Medicine* 205(2): 144–145, at 144. ("Pulmonary hypertension in the context of interstitial lung disease (PH-ILD) is one of the most fatal medical conditions patients and doctors are faced with. The vascular component of advanced ILD is difficult to tackle and obviously differs from pulmonary arterial hypertension (PAH), as multiple high-quality clinical trials failed to convincingly demonstrate a clinical benefit of pulmonary vasoactive drugs in various PH-ILD populations, whereas those drugs are effective and approved in PAH. Some drugs like ambrisentan and riociguat even showed harmful effects in PH-ILD populations and were consequently banned from treatment in this indication.")

291 Yutrepia announced on January 5, 2024 that "the first PH-ILD patient was enrolled in December 2023 in the Open-Label Prospective Multicenter Study to Evaluate Safety and Tolerability of Dry Powder Inhaled Treprostinil in Pulmonary

(145) In addition to benefiting from United's clinical evidence, Liquidia benefits from United's prior investments and efforts to develop and establish the PAH and PH-ILD markets. As an example, an analyst report from Ladenburg Thalmann states: "The PAH market is well established, which will allow Yutrepia to launch without a significant educational effort. We believe that pricing and convenience will allow Yutrepia to compete with the prostacyclin-based drugs in the market."[292] An analyst report from BTIG echoes a similar sentiment: "PAH is a commercially well-established market that should be highly receptive to YUTREPIA. Despite the relatively low prevalence of PAH patients (45k in US, ~35k on Tx), the established commercial market for the indication is large."[293] While these sources speak to the PAH market, it is reasonable that Yutrepia will also benefit from United's efforts to develop the PH-ILD market.

(146) United is the innovator in the markets for nebulized and dry powder formulations of treprostinil. By infringing and entering the market, Yutrepia will be circumventing the protections granted by United's intellectual property and gaining unfair competitive advantages in the market, freeriding off of United's efforts as an innovator. Liquidia has not made the substantial investments in research and development, market penetration, and education that United has had to make. Liquidia did not have to validate the use of treprostinil for PAH and PH-ILD or validate the DPI reformulation of treprostinil for PAH and PH-ILD. Liquidia did not have to do the due diligence that United had to do in order to gain approval and enter the market. Yutrepia entering the market as another inhaled dry powder formulation drug for PAH and PH-ILD places United in the position of having to compete directly against its own technology, reducing the return on the valuable investments United has made.

(147) In sum, United's growth and success as a company is predicated on the success of the Tyvaso products, its reputation as a market leader, and the reputation of the Tyvaso products as

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Hypertension, referred to as the ASCENT study." However, this study is still recruiting and is only expected to be completed in 2026. See:

Liquidia Press Release, "Liquidia Provides Update on Clinical Pipeline Targeting PAH and PH-ILD," 1/5/2024, https://www.liquidia.com/news-releases/news-release-details/liquidia-provides-update-clinical-pipeline-targeting-pah-and-ph.

ClinicalTrials.gov Website, An Open-Label ProSpective MultiCENTer Study to Evaluate Safety and Tolerability of Dry Powder Inhaled Treprostinil in PH (ASCENT), https://clinicaltrials.gov/study/NCT06129240 (accessed 2/19/2024).

292 Ladenburg Thalmann, "Liquidia Prevails in '793 PTAB CAFC Appeal; PH-ILD PDUFA 1/24/24; Buy & $30 PT," 12/21/2023, at 11.

293 BTIG, "793 IPR Decisions Affirmed on Appeal, Leaving YUTREPIA Launch On Track for Mid-2024 or Earlier. Increasing PT to $29 from $18," 12/20/2023, at 3.

high-performing and reliable. Due to Liquidia's infringement, United's opportunity to recoup its investments and earn a positive economic profit is smaller than it would have been absent the infringement. Liquidia's entry threatens not only the success of the Tyvaso products, but also United's company-wide success. Should a stay not be granted, Liquidia will continue benefitting from United's investments, putting at risk United's ability to recoup its return on those investments and continuing the harm that United has already experienced due to Liquidia's infringement. A stay would allow United to grow in accordance with its pioneering efforts and developments, uninhibited by Liquidia's infringement that weakens the Tyvaso products' positioning in the PAH and PH-ILD markets. As such, the economic factors relating to the balance of equities in this case are in favor of a stay.

7. Public Interest

7.1. Overview

(148) As discussed in Section 1.3, I understand that one of the factors courts consider in deciding whether to grant a stay is the public interest. It is more likely than not that a stay of Liquidia's use of the asserted patents is in the public interest. United's Tyvaso and Tyvaso DPI products are alternatives for Liquidia's Yutrepia product, and United has sufficient capacity to meet market demand in the event a stay is granted. In addition, as I explain below, a stay will protect intellectual property rights and foster innovation.

7.2. Alternatives

(149) A stay would not disserve the public interest in terms of the ability to find replacement products. United's Tyvaso and Tyvaso DPI products are acceptable and available to customers, and are reasonable alternatives for Liquidia's Yutrepia product.

(150) First, I understand that Tyvaso and Tyvaso DPI can be used in place of Yutrepia.[294] I further understand that providers will see virtually no clinical differences between Tyvaso DPI and Yutrepia.[295] I understand that, if Yutrepia is prevented from entering the market, patients that would have used Yutrepia could instead use Tyvaso or Tyvaso DPI without any adverse impact.[296] I further understand that there might even be an advantage to the Tyvaso products over Yutrepia; for example, if a patient would respond better to a nebulized form of Tyvaso, they can be easily switched from Tyvaso DPI to Tyvaso whereas Yutrepia does not offer a nebulized formulation.[297] I understand that, for patients preferring a dry powder inhaler over a nebulizer, Tyvaso DPI can be used in place of Yutrepia.[298]

294 Interview with Dr. Steven Nathan, 2/9/2024.
See also Sections 3 and 4.1.

295 Interview with Dr. Steven Nathan, 2/9/2024.

296 Interview with Dr. Steven Nathan, 2/9/2024.

297 Interview with Dr. Steven Nathan, 2/9/2024.

298 Interview with Dr. Steven Nathan, 2/9/2024.
See also Section 3.

(151) Second, reimbursement will not pose obstacles for patients using Tyvaso or Tyvaso DPI instead of Yutrepia. Tyvaso is covered under Medicare Part B and Medicaid whereas Tyvaso DPI is covered under Medicare Part D and Medicaid.[299] United works with two major contracted specialty pharmaceutical distributors — Accredo and CVS Specialty — that are "responsible for assisting patients with obtaining reimbursement for the cost of [United's] treprostinil-based products and providing other support services."[300] United also has patient-assistance programs in the United States where it provides its "treprostinil-based products to eligible uninsured or under-insured patients at no charge."[301]

7.3. Capacity

(152) United has sufficient manufacturing capacity to supply market demand if a stay is granted. According to United's 2023 10-K filing, United maintains, at minimum, a two-year inventory of nebulized Tyvaso.[302] Accordingly, there are unlikely to be any supply issues associated with nebulized Tyvaso.

(153) United has also indicated during healthcare conferences and earnings calls that it has made the necessary investments in its manufacturing capacity so that there are no supply issues for Tyvaso DPI. For example, during a presentation at a UBS BioPharma conference in

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299 United, Form 10-K, 2023, at 29. ("Tyvaso DPI, Orenitram, and Adcirca are reimbursed under Medicare Part D, and we pay rebates to Part D plans that cover these products. Remodulin and nebulized Tyvaso are reimbursable under Medicare Part B. The Medicare Part B contractors who administer the program cover Remodulin and nebulized Tyvaso under local coverage determinations and provide reimbursement according to statutory guidelines. Medicaid also covers Remodulin, Tyvaso DPI, nebulized Tyvaso, Adcirca, Orenitram, and Unituxin, and, as noted above, we must pay Medicaid rebates on this utilization.")

300 United, Form 10-K, 2023, at 12.

Assist Website, Product Distribution, https://www.utassist.com/tyvaso-pah/product-distribution (accessed 1/16/2024). ("United Therapeutics has contracted with a limited distribution network of authorized specialty distributors and wholesalers that have made a commitment to product integrity and patient safety [including Accredo Health Group, Inc., CVS Specialty, and CuraScript SD.")

301 United, Form 10-K, 2023, at 12.

Assist Website, Financial Support, https://www.utassist.com/tyvaso-pah/financial-support (accessed 1/16/2024). ("Most eligible patients on commercial, non-government plans may pay as little as a $0.00 co-pay for each prescription of TYVASO or TVYASO DPI and may receive up to $8,000 per year toward their co-pay. . . . If your patient does not have insurance, their insurance does not cover the medication, or they are underinsured, United Therapeutics offers medication free of charge to eligible patients.")

302 United, Form 10-K, 2023, at 18–19. ("We maintain, at a minimum, a two-year inventory of nebulized Tyvaso, Remodulin, and Orenitram based on expected demand, and we contract with third-party contract manufacturers to supplement our capacity for some products, in order to mitigate the risk that we might not be able to manufacture internally sufficient quantities to meet patient demand. For example, Simtra BioPharma Solutions (formerly known as Baxter Pharmaceutical Solutions, LLC) is approved by the FDA, the EMA, and various other international regulatory agencies to manufacture Remodulin for us. We rely on Woodstock Sterile Solutions to serve as an additional manufacturer of nebulized Tyvaso drug product.")

November 2023, United indicated that "once [it] gained approval for -- to treat ILD with Tyvaso, [it] immediately moved to make some pretty significant capital investments in the MannKind facility to increase [MannKind's] capacity for future production."[303] United indicated that these investments included the "purchase of high speed and high capacity equipment to produce the dry powder product."[304]

(154) Market analysts have also noted United's increased manufacturing capacity. For example, a Wedbush analyst report from October 2023 states: "we are confident in the potential for Tyvaso DPI to continue along its growth trajectory for the remainder of 2023 and beyond with: 1) the normalization of ordering patterns for Tyvaso DPI specifically the SKU mix between naïve and experienced patients and doses being taken by patients, 2) the 'exponential' expansion of MannKind's production capacity 'every quarter from here on out' (recent efforts completed in Q2 are expected to increase capacity by +250% with further expansion planned to come online in 2024 including a $60M scale-up facility currently being built in Danbury, CT), 3) the construction of a new Tyvaso DPI manufacturing facility on United's North Carolina campus[.]"[305] Another Wedbush analyst report from January 2024 notes that "MannKind's increased manufacturing capacity (~25K-35K in 2024 from ~7K-10K in 2023) provid[es] United with the capability to sufficiently fulfill growing patient demand especially in PH-ILD (~30K U.S. patients) where Tyvaso DPI is the only approved product other than Tyvaso[.]"[306] In

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303 Refinitiv StreetEvents, "United Therapeutics Corp at UBS BioPharma Conference," 11/8/2023, at 4–5.

304 Refinitiv StreetEvents, "United Therapeutics Corp at UBS BioPharma Conference," 11/8/2023, at 4–5. ("So there's been multiple efforts that have taken place, really culminating in 2021 with the ILD approval. And this was pre-approval of Tyvaso DPI. But once we gained approval for -- to treat ILD with Tyvaso, we immediately moved to make some pretty significant capital investments in the MannKind facility to increase their capacity for future production. Now those investments involved purchase of high speed and high capacity equipment to produce the dry powder product. Now that equipment is very specialized and have a very long lead time, and we knew it was going to take some time to get it built and get it in place. Now in the meantime, while we were waiting for that, we did get approval of Tyvaso DPI and we launched it very quickly after approval. And again, we recognized immediately that the interest in the product and the uptake, which was very strong, we were very pleased with, was going to require us to make some interim changes at MannKind to make sure we could supply the specialty pharmacies with their minimum inventory levels. And so we did that, and we were able to double really on the bulk side -- the bulk powder side, we were able to double their capacity and implement that in Q2 of this year. And the result of that is we've strengthened inventory levels and really addressed that concern. And now we're moving into trying to smooth out shipments and in order frequencies with the SPs. But in parallel with that, of course, the equipment that we -- we purchased 2 years ago is now in place and is being qualified at their facility. And we expect that to come online in, say, the next 4 to 6 months. And at that time, once that's done, we'll be able to support 25,000 patients out of the Danbury facility. So all that's happening in the next, say, 4 to 6 months, we'll have that capability. Now beyond that, of course, we have to prepare for TETON outcomes with pulmonary fibrosis. Now these -- these studies could bring upwards of 160,000 patients into use of Tyvaso DPI or Tyvaso nebulized, which is a significant increase over what we have today. So in preparation for that, we have begun construction of our own facility in on -- our North Carolina campus to support those additional patients. So design has been completed and we expect to break ground on that early in '24.")

305 Wedbush, "Don't Call It A Comeback...Initiating at OP and $10 PT," 10/9/2023, at 4.

306 Wedbush, "Tyvaso DPI Royalty Deal Pads Balance Sheet, Underscores Blockbuster Potential," 1/3/2024, at 1.

addition, in November 2023, United discussed its plans for constructing its own facility in North Carolina to support a "significant increase" in additional patients, stating: "Now beyond that, of course, we have to prepare for TETON outcomes with pulmonary fibrosis. Now these -- these studies could bring upwards of 160,000 patients into use of Tyvaso DPI or Tyvaso nebulized, which is a significant increase over what we have today. So in preparation for that, we have begun construction of our own facility in on -- our North Carolina campus to support those additional patients. So design has been completed and we expect to break ground on that early in '24."[307]

(155) To my knowledge, no patient has ever been unable to access Tyvaso DPI due to supply issues. For example, during a presentation at the JPMorgan Healthcare conference in January 2024, United stated that "historically, no patient has not had the ability to get Tyvaso DPI or for that matter, any of [its] therapies[.]"[308] In January 2024, United indicated that it did not anticipate any inventory issues.[309]

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307 Refinitiv StreetEvents, "United Therapeutics Corp at UBS BioPharma Conference," 11/8/2023, at 4–5. ("So there's been multiple efforts that have taken place, really culminating in 2021 with the ILD approval. And this was pre-approval of Tyvaso DPI. But once we gained approval for -- to treat ILD with Tyvaso, we immediately moved to make some pretty significant capital investments in the MannKind facility to increase their capacity for future production. Now those investments involved purchase of high speed and high capacity equipment to produce the dry powder product. Now that equipment is very specialized and have a very long lead time, and we knew it was going to take some time to get it built and get it in place. Now in the meantime, while we were waiting for that, we did get approval of Tyvaso DPI and we launched it very quickly after approval. And again, we recognized immediately that the interest in the product and the uptake, which was very strong, we were very pleased with, was going to require us to make some interim changes at MannKind to make sure we could supply the specialty pharmacies with their minimum inventory levels. And so we did that, and we were able to double really on the bulk side -- the bulk powder side, we were able to double their capacity and implement that in Q2 of this year. And the result of that is we've strengthened inventory levels and really addressed that concern. And now we're moving into trying to smooth out shipments and in order frequencies with the SPs. But in parallel with that, of course, the equipment that we -- we purchased 2 years ago is now in place and is being qualified at their facility. And we expect that to come online in, say, the next 4 to 6 months. And at that time, once that's done, we'll be able to support 25,000 patients out of the Danbury facility. So all that's happening in the next, say, 4 to 6 months, we'll have that capability. Now beyond that, of course, we have to prepare for TETON outcomes with pulmonary fibrosis. Now these -- these studies could bring upwards of 160,000 patients into use of Tyvaso DPI or Tyvaso nebulized, which is a significant increase over what we have today. So in preparation for that, we have begun construction of our own facility in on -- our North Carolina campus to support those additional patients. So design has been completed and we expect to break ground on that early in '24.")

308 Refinitiv StreetEvents, "United Therapeutics Corp at JPMorgan Healthcare Conference," 1/8/2024, at 5.

309 Refinitiv StreetEvents, "United Therapeutics Corp at JPMorgan Healthcare Conference," 1/8/2024, at 5. ("So going into 2024, we don't expect any inventory issues going forward. As we talked about back in the third quarter earnings call, we did make and MannKind did make some changes to their manufacturing processes. And we think going forward that there won't be any issues with respect to making sure that patients have the inventory that they need or -- and the specialty pharmaceutical distributors are able to build our inventories in accordance with their contractual requirements. And we can say, historically, no patient has not had the ability to get Tyvaso DPI or for that matter, any of our therapies, but specifically to your question on inventory build related to DPI, no issues going forward in that regard.")

7.4. Innovation

(156) I understand that courts have long recognized the strong public interest in enforcing and protecting intellectual property rights.[310] A stay protects United's intellectual property rights. The short-term gains to customers in terms of additional choice of allowing Yutrepia to compete in the market do not outweigh the long-term harms to innovation that would result from not granting a stay.

(157) The protection of intellectual property rights is in the public interest because it provides incentives for firms to invest resources in research and development efforts and promotes innovation. Innovation is also a key driver of competition.[311] Additionally, innovation in one

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310 See, for example:

Hypbritech, Inc. v. Abbott Laboratories, 849 F.2d 1446, 1458 (Fed. Cir. 1988). ("[T]he public interest in enforcing valid patents outweighed any other public interest considerations.")

E.I. du Pont de Nemours & Co. v. Polaroid Graphics Imaging, Inc., 706 F. Supp. 1135, 1146 (D. Del.1989). ("Moreover, . . . we find . . . that the public has an interest in protection of rights found in valid patents. . . . One of the bases of intellectual property law is to give inventors an incentive to practice their talents by allowing them to reap the benefits of their labor. One of these benefits is the right to prevent others from practicing what they have invented. Otherwise, if inventors cannot depend on their patents to exclude others, we fear that research and development budgets in the science and technology based industries would shrink, resulting in the public no longer benefitting from the labors of these talented people.")

Amazon.com Inc. v. Barnesandnoble.com Inc., 73 F. Supp. 2d 1228, 1249 (W.D. Wash. 1999). ("The public has a strong interest in the enforcement of intellectual property rights. The purpose of the patent system is to reward inventors and provide incentives for further innovation by preventing others from exploiting their work. . . . Encouraging [the patent owner] to continue to innovate — and forcing competitors to come up with their own new ideas — unquestionably best serves the public interest.")

Abbott Laboratories v. Sandoz, Inc., 544 F.3d 1341, 1362 (Fed. Cir. 2008). ("To the extent that this Court has found a substantial likelihood that the . . . patent is valid and enforceable, there can be no serious argument that public interest is not best served by enforcing it.")

Apple, Inc. v. Samsung Elecs. Co., 809 F.3d 633, 642 (Fed. Cir. 2015). ("The right to exclude competitors from using one's property rights is important. And the right to maintain exclusivity — a hallmark and crucial guarantee of patent rights deriving from the Constitution itself — is likewise important.")

311 Lee, Yong-Gil, et al. (2008), "Technological Convergence and Open Innovation in the Mobile Telecommunication Industry," *Asian Journal of Technology Innovation* 16(1): 45-62, at 45. ("With more intense competition, firms that lack innovation will fail. Accordingly, innovation is one of the most important drivers of corporate survival and growth.")

Ziemnowicz, Christopher (2013), "Joseph A. Schumpeter and Innovation," *Encyclopedia of Creativity, Invention, Innovation and Entrepreneurship*, 1171-1176, at 1175. ("Schumpeter's creative destruction philosophy is the rule, rather than the exception: organizations survive by focusing on what will allow them to be, and stay, one step ahead of the competition. . . . Without innovation, business survival and success are unattainable.")

Yanadori, Yoshio and Victor Cui (2013), "Creating Incentives for Innovation? The Relationship Between Pay Dispersion in R&D Groups and Firm Innovation Performance," *Strategic Management Journal* 34(12): 1502-1511, at 1502. ("Innovation is a critical organizational outcome for its potential to generate competitive advantage. . . Innovation has long been recognized as a crucial component of competitive strategy.")

Banbury, Catherine and Will Mitchell (1995), "The Effect of Introducing Important Incremental Innovations on Market Share and Business Survival," *Strategic Management Journal* 16(S1): 161-182, at 178. ("The general conclusion of this study is that effective incremental product development and rapid product introduction are critically important to business

market or with respect to one set of products leads to knowledge spillovers to other markets and products, which can lead to further innovation in the future.[312]

(158) Modern growth theory, developed in part by models conceived by Joseph A. Schumpeter, includes innovation as a driver of economic growth.[313] For example, an analysis of the relationship between countries' research and development efforts and growth in innovation (as measured by patent stock), as well as the relationship between changes in innovation and per capita income, found a strong positive relationship between innovation and per capita GDP.[314] Schumpeter focused on the role of the entrepreneur as "the agent of innovation" and described entrepreneurs as "the pivot on which everything turns."[315] According to Schumpeter, innovation leads to "creative destruction," a process by which new technologies and

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performance. The results show that introducing incremental product innovations during its tenure as an industry incumbent strongly influences a business's market share and, indirectly, its survival in an established industry.")

Danneels, Erwin (2002), "The Dynamics of Product Innovation and Firm Competences," *Strategic Management Journal* 23(12): 1095-1121, at 1095. ("Organizations need to continuously renew themselves if they are to survive and prosper in dynamic environments. This renewal challenge is even more pronounced in the current business environment characterized by fast changes in customers, technologies, and competition. . . Underlying this strong interest [in innovation] is the notion that 'really new' products are crucial to firm survival in the current fast-changing business environment.")

312 Feldman, Maryann (1999), "The New Economics of Innovation, Spillovers and Agglomeration: A Review of Empirical Studies," *Economics of Innovation and New Technology* 8(1-2): 5-25, at 9–10. ("Persuasive evidence about the existence of knowledge spillovers is found by examining what may be termed the paper trails left by patent citations. . . Jaffe, Trajtenberg and Henderson (1991, p. 578) point out that, 'knowledge flows do sometimes leave a paper trail' - in particular, in the form of patented inventions and new product introductions.")

Scotchmer, Suzanne (1991), "Standing on the Shoulders of Giants: Cumulative Research and the Patent Law," *Journal of Economic Perspectives* 5(1): 29-41, at 29. ("Most innovators stand on the shoulders of giants, and never more so than in the current evolution of high technologies, where almost all technical progress builds on a foundation provided by earlier innovators.")

313 Ziemnowicz, Christopher (2013), "Joseph A. Schumpeter and Innovation," *Encyclopedia of Creativity, Invention, Innovation and Entrepreneurship*, 1171-1176, at 1171.

Federal Trade Commission (2003), "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy," *Federal Trade Commission*, at 1. ("An economy's capacity for invention and innovation helps drive its economic growth and the degree to which standards of living increase.")

Mazzucato, Mariana and Carlotta Perez (2015), "Innovation as Growth Policy: The Challenge for Europe," in Jan Fagerberg, Staffan Laestadius, and Ben R. Martin, eds., *The Triple Challenge for Europe: Economic Development, Climate Change, and Governance*, Oxford, UK: Oxford University Press, at 229. ("Our work has shown that investment is driven by innovation; specifically by the perception of where new technological opportunities lie[.]")

Katz, Michael L., and Carl Shapiro (1987), "R&D Rivalry with Licensing or Imitation," *The American Economic Review* 77(3): 402–420, at 402. ("Technological progress is the driving force behind long-run economic performance.")

314 Ulku, Hulya (2004), "R&D, Innovation, and Economic Growth: An Empirical Analysis," *International Monetary Fund Working Paper* at 27.

315 Ziemnowicz, Christopher (2013), "Joseph A. Schumpeter and Innovation," *Encyclopedia of Creativity, Invention, Innovation and Entrepreneurship*, 1171-1176, at 1172.

innovations lead to the obsolescence of existing ones.[316] According to Schumpeter's analysis, innovation is "[t]he strategic stimulus to economic development[.]"[317]

(159) Economists Michael Katz and Carl Shapiro note that the "pace of innovation in market economics depends … upon private firms' incentives to innovate."[318] Theorists including Schumpeter and economist Richard Gilbert have posited that potential increases in profit and market share provide the incentive to innovate.[319] Schumpeter also recognized that such gains could be fleeting in the presence of imitators that can copy the innovation.[320] Further, Gilbert notes that the "strength of intellectual property protection is an important determinant of the profit from invention because it determines the extent to which the inventor can exploit the potential of her discovery to add value."[321] Thus, early theories linking innovation and economic growth recognized the importance of preserving the incentives for innovation, such as those granted through intellectual property rights.

(160) From an economic point of view, intellectual property rights are essential to preserving incentives to invest in research and development and innovation. Those rights are the basis for that innovator to earn the return that makes that economic investment worthwhile. If intellectual property rights are not well-protected, meaning, for example, that the right under a patent to exclude others from using the patented technology is not well-protected, firms'

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316 Ziemnowicz, Christopher (2013), "Joseph A. Schumpeter and Innovation," *Encyclopedia of Creativity, Invention, Innovation and Entrepreneurship*, 1171-1176, at 1173.

317 Ziemnowicz, Christopher (2013), "Joseph A. Schumpeter and Innovation," *Encyclopedia of Creativity, Invention, Innovation and Entrepreneurship*, 1171-1176, at 1174.

318 Katz, Michael L., and Carl Shapiro (1987), "R&D Rivalry with Licensing or Imitation," *The American Economic Review* 77(3): 402–420, at 402.

319 Ziemnowicz, Christopher (2013), "Joseph A. Schumpeter and Innovation," *Encyclopedia of Creativity, Invention, Innovation and Entrepreneurship*, 1171-1176, at 1172–73. ("Schumpeter described that the entrepreneurs who initiate, create, and adopt innovations generally gain profits. The entrepreneur's original innovation produces increasing profits for them. . . Schumpeter's theory assumed that innovation originated market power could provide more effective results than pure price competition. He described that technological innovation often creates temporary monopolies that produce excessive profits.")

Gilbert, Richard (2006), "Looking for Mr. Schumpeter: Where Are We in the Competition-Innovation Debate?," in Adam B. Jaffe, Josh Lerner, and Scott Stern, eds., *Innovation Policy and the Economy, Volume 6*, Cambridge, MA: The MIT Press, at 162. ("As a general statement, the incentive to innovate is the difference in profit that a firm can earn if it invests in R&D compared to what it would earn if it did not invest.")

320 Ziemnowicz, Christopher (2013), "Joseph A. Schumpeter and Innovation," *Encyclopedia of Creativity, Invention, Innovation and Entrepreneurship*, 1171-1176, at 1173. ("Schumpeter argued that this profit disequilibrium would be eliminated by the introduction of rivals and imitators. He explained that just as competition drives innovation, it also brings about 'swarms' of imitators that want to capture the excessive profits and simply copy their rival's innovation")

321 Gilbert, Richard (2006), "Looking for Mr. Schumpeter: Where Are We in the Competition-Innovation Debate?," in Adam B. Jaffe, Josh Lerner, and Scott Stern, eds., *Innovation Policy and the Economy, Volume 6*, Cambridge, MA: The MIT Press, at 162.

incentives to invest in R&D and innovation are reduced. There would be little incentive for firms to make substantial investment to innovate if anyone would be free to copy the innovation.[322]

(161) The economic literature established that the existence and protection of intellectual property rights are effective for protecting incentives to innovate by deterring imitation. An academic study in the journal *Research Policy* found that average lag times for product or process imitation by rivals are longer in the case of patented products and processes relative to unpatented products and processes, respectively.[323] Another academic study in *Brookings Papers on Economic Activity* found that patents raise imitation costs by 40 percentage points for drugs, 30 points for new chemical products, 25 points for typical chemical products, and 7–15 percentage points for major electronics products.[324]

(162) The U.S. Department of Justice (DOJ) and the Federal Trade Commission (FTC) have acknowledged the role of intellectual property rights in promoting innovation. In their joint

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322 Greenhalgh, Christine and Mark Rogers (2010), *Innovation, Intellectual Property, and Economic Growth*, Princeton, NJ: Princeton University Press, at 32. ("[T]he basic justification for IPRs is that they give people an incentive to produce socially desirable new innovations. Without some guarantee of private ownership, innovators might not put resources into innovative activity, as their findings would rapidly be imitated, leaving them with little or no profit.")

Cohen, Wesley, et al. (2002), "R&D Spillovers, Patents and the Incentives to Innovate in Japan and the United States," *Research Policy* 31(8-9): 1349-1367, at 1349. ("The ability of firms to appropriate at least some of the value created by their innovations is essential if there is to be incentive to innovate.")

Scotchmer, Suzanne (1991), "Standing on the Shoulders of Giants: Cumulative Research and the Patent Law," *Journal of Economic Perspectives* 5(1): 29-41, at 30. ("The breadth of patent protection is a key consideration in the incentives to innovate.")

Gallini, Nancy (1992), "Patent Policy and Costly Imitation," *The RAND Journal of Economics* 23(1): 52-63, at 52. ("Two important goals underlie the patent system: to promote research and development and to encourage the disclosure of inventions so that others can use and build upon research results. The effectiveness of the patent system in achieving these goals depends in part on the ability of rival firms to imitate or 'invent around' patented innovations.")

Levin, Richard, et al. (1987), "Appropriating the Returns from Industrial Research and Development," *Brookings Papers on Economic Activity* 1987(3): 783-831, at 783. ("To have the incentive to undertake research and development, a firm must be able to appropriate returns sufficient to make the investment worthwhile.")

Joshi, Amol M., and Atul Nerkar (2011), "When Do Strategic Alliances Inhibit Innovation by Firms? Evidence From Patent Pools in the Global Optical Disc Industry," *Strategic Management Journal* 32(11): 1139-1160, at 1142. ("[P]atents appear to provide meaningful economic incentives for firms to engage in R&D.")

323 Cohen, Wesley, et al. (2002), "R&D Spillovers, Patents and the Incentives to Innovate in Japan and the United States," *Research Policy* 31(8-9): 1349-1367, at 1353 (Fig. 2).

324 Levin, Richard, et al. (1987), "Appropriating the Returns from Industrial Research and Development," *Brookings Papers on Economic Activity* 1987(3): 783-831, at 811.

2007 report "Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition," the DOJ and the FTC state:[325]

> Intellectual property laws create exclusive rights that provide incentives for innovation by "establishing enforceable property rights for the creators of new and useful products, more efficient processes, and original works of expression." These property rights promote innovation by allowing intellectual property owners to prevent others from appropriating much of the value derived from their inventions or original expressions. These rights also can facilitate the commercialization of these inventions or expressions and encourage public disclosure, thereby enabling others to learn from the protected property.

(163) For industries such as pharmaceutical sales, the costs to develop a drug can be significant because of the extensive FDA approval process.[326] Intellectual property protections guarantee a period of exclusivity in which innovators can recover those costs and earn profits from their products. If those protections are removed or weakened, and competing products infringing those intellectual property rights are allowed to enter the market, innovators would find it more difficult to profit from their R&D investments.

(164) Intellectual property protections are even more important for orphan drugs, as highlighted by the federal government's passing of the Orphan Drug Act in 1983.[327] As discussed in Section 4.3, both Tyvaso and Tyvaso DPI have received orphan drug designation. Orphan drugs treat rare diseases that by definition have a relatively small population of afflicted individuals, which may make conducting clinical trials difficult.[328] However, it is estimated that "[o]ver 7,000 rare diseases affect more than 30 million people in the United States[]" and

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325 U.S. Department of Justice and the Federal Trade Commission, "Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition," April 2007, at 1. (Quoting U.S. Department of Justice and the Federal Trade Commission, "Antitrust Guidelines for the Licensing of Intellectual Property, 1995.)

326 See: DiMasi, Joseph A., Henry G. Grabowski, and Ronald W. Hansen (2016), "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," *Journal of Health Economics* 47: 20–33, at 25, Table 4.

327 FDA Website, Rare Diseases at FDA, https://www.fda.gov/patients/rare-diseases-fda (accessed 1/5/2024). ("The Orphan Drug Act defines a rare disease as a disease or condition that affects less than 200,000 people in the United States. . . . The Orphan Drug Act is a law passed by Congress in 1983 that incentivizes the development of drugs to treat rare diseases. Companies and other drug developers can request orphan drug designation and FDA will grant such designation if the drug meets specific criteria.")

328 FDA Website, Rare Diseases at FDA, https://www.fda.gov/patients/rare-diseases-fda (accessed 1/5/2024). ("The Orphan Drug Act defines a rare disease as a disease or condition that affects less than 200,000 people in the United States. . . . The Orphan Drug Act is a law passed by Congress in 1983 that incentivizes the development of drugs to treat rare diseases. Companies and other drug developers can request orphan drug designation and FDA will grant such designation if the drug meets specific criteria. . . . Drug, biologic, and device development in rare diseases is challenging for many reasons, including the complex biology and the lack of understanding of the natural history of many rare diseases. The inherently small population of patients with a rare disease can also make conducting clinical trials difficult.")

for afflicted individuals, drug development provides a chance for survival.[329] The federal government passed the Orphan Drug Act to strengthen intellectual property protection in these small markets to incentivize innovation where there may otherwise be very little.[330] Removing or reducing United's intellectual property protections by allowing Yutrepia to enter would reduce incentives for other pharmaceutical companies to develop new treatments, which would have a larger and longer-run impact on public welfare than the (limited) benefits short-term competition with Yutrepia may yield.

* * * *

I, Frederic Selck, Ph.D., declare under penalty of perjury that the foregoing Declaration is true and correct.

Frederic Selck, Ph.D.
April 17, 2024

329 See:

FDA Website, Rare Diseases at FDA, https://www.fda.gov/patients/rare-diseases-fda (accessed 1/5/2024). ("Over 7,000 rare diseases affect more than 30 million people in the United States. Many rare conditions are life-threatening and most do not have treatments.")

U.S. Food & Drug Administration Website, Orphan Products: Hope for People With Rare Diseases, https://www.fda.gov/drugs/information-consumers-and-patients-drugs/orphan-products-hope-people-rare-diseases (accessed 2/2/2024). ("For rare disease patients, there may be no cures, but treatments of the symptoms can help. . . . Since 1983, the ODA has resulted in the development of more than 250 orphan drugs, which now are available to treat a potential patient population of more than 13 million Americans. In contrast, the decade before 1983 saw fewer than 10 such products developed without government assistance. As a result of the ODA, treatments are available to people with rare diseases who once had no hope for survival.")

330 U.S. Food & Drug Administration Website, Orphan Products: Hope for People With Rare Diseases, https://www.fda.gov/drugs/information-consumers-and-patients-drugs/orphan-products-hope-people-rare-diseases (accessed 2/2/2024). ("Before the passage of rare disease laws in the United States, patients diagnosed with a rare disease were denied access to effective medicines because prescription drug manufacturers rarely could make a profit from marketing drugs to such small groups. Consequently, the prescription drug industry did not adequately fund research for orphan product development. Other potential sources, such as research hospitals and universities, also lacked the capital and business expertise to develop treatments for small patient groups. Despite the urgent health need for these medicines, they came to be known as orphans because companies were not interested in adopting them. This changed in 1983 when Congress passed the Orphan Drug Act (ODA). The ODA created financial incentives for drug and biologics manufacturers, including tax credits for costs of clinical research, government grant funding, assistance for clinical research, and a seven-year period of exclusive marketing given to the first sponsor of an orphan-designated product who obtains market approval from the Food and Drug Administration for the same indication. . . . Since 1983, the ODA has resulted in the development of more than 250 orphan drugs, which now are available to treat a potential patient population of more than 13 million Americans. In contrast, the decade before 1983 saw fewer than 10 such products developed without government assistance."

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April 2024

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Ph.D., Applied Economics, Johns Hopkins University

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Professional Experience

Intensity, LLC. Managing Director, 2023 to present.

Bates White Economic Consulting. Partner, 2022 to 2023.

Bates White Economic Consulting. Principal, 2020 to 2022.

Bates White Economic Consulting. Manager, 2017 to 2019.

Bates White Economic Consulting. Senior Economist, 2015 to 2016.

Bates White Economic Consulting. Economist, 2014 to 2015.

Georgetown University, Adjunct Assistant Professor in Health Economics, 2024 to present.

Johns Hopkins University. Adjunct Faculty in Health Economics and Health Finance, 2013 to present.

National Center for Health Statistics Centers for Disease Control and Prevention. Senior Service Fellow, 2013 to 2014.

National Center for Health Statistics Centers for Disease Control and Prevention. Associate Service Fellow, 2012 to 2013.

National Center for Health Statistics. Expert, 2010 to 2011.

Center for Biosecurity. Contributing Scholar, 2008 to 2014.

City University of New York, Hunter College. Undergraduate Advisor, Economics, 2007 to 2008.

New York Organ Donor Network. Research Analyst, 2006 to 2008.

New York Organ Donor Network. Organ Placement Coordinator, 2004 to 2006.

Citigroup. Project Manager, Global Stock Options Group, 2002 to 2004.

Citigroup. Project Manager, Pilot Revenue Program, 2001 to 2002.

New York Organ Donor Network, Organ Placement Coordinator, 1999 to 2001

University of Maryland Medical System and the National Aquarium in Baltimore, Emergency Medical Technician, 1994 to 1998

Testimony

Authored expert report and provided deposition testimony in *Veeva Systems Inc., v. IQVIA Inc. and IMS Software Services, Ltd.,* No. 2:19-cv-18558-JXN-JSA, United States District Court for the District of New Jersey.

Authored expert report and provided deposition and trial testimony in *Himawan et al. v. Cephalon, Inc.*, No. 2018-0075-SG, Court of Chancery of the State of Delaware.

Authored expert report and provided deposition testimony in *AmerisourceBergen Drug Corporation et al. v. Ace American Insurance Company et al.*, No. 17-C-36, Circuit Court of Boone County, West Virginia.

Authored expert report and provided hearing testimony on pharmaceutical benchmark pricing in a hearing before Judge Derrick Coker, Pennsylvania Worker's Compensation Adjudication.

Authored expert reports and provided deposition testimony in *Jessica Julien v. Eric Lacefield et al.*, No. 1:17-cv-04045-MLB, U.S. District Court, Northern District of Georgia (Atlanta).

Authored expert report and provided deposition and hearing testimony in the *Mallinckrodt PLC, et al. bankruptcy*, No. 20-12522, U.S. Bankruptcy Court, District of Delaware (Wilmington).

Authored expert report and provided deposition testimony in *Forrest v. Van Eldik, M.D. and Gastroenterology Associates of Ocala*, No. 2017-CA-2122: 2021, Circuit Civil 5-D, Marion County, Florida.

Authored declaration and expert report in *Choker v. Pet Emergency Clinic, P.S.*, No. 2:20-CV-00417-SAB : 2021, U.S. District Court, Eastern District of Washington (Spokane).

Authored expert and rebuttal reports and provided deposition testimony in *Edward Lacey v. Visiting Nurse Service of New York*, No. 14-CV-5739-AJN: 2018, U.S. District Court, Southern District of New York (Foley Square).

Matters involving intellectual property (IP) and other commercial disputes

In *United Therapeutics Corporation v. Food and Drug Administration, Robert M. Califf, M.D., United States Department of Health and Human Services, and Xavier Becerra*, serving as a testifying expert in a matter involving preliminary injunction on behalf of United. Evaluated irreparable harm, balance of equities, and public interest.

In *United Therapeutics Corporation v. Liquidia Technologies, Inc.*, serving as a testifying expert in a matter involving preliminary injunction on behalf of United, alleging infringement of its patent by Liquidia. Evaluated irreparable harm, inadequacy of monetary damages, balance of equities, and public interest.

Serving as a testifying expert on behalf of a national pharmaceutical distributor involving the assessment of *bona fide* services used as part of a Foreign Direct Investment Income deduction.

Serving as a testifying expert in a German matter on behalf of a global biopharmaceutical manufacturer related to economic damages from an overturned biologic injunction.

Served as the arbitration expert on behalf of a global pharmaceutical manufacturer in estimating damages resulting from a licensee's delay in bringing a biologic to market. Matter was settled.

Led the consulting team advising the Special Committee to the Debtors in the Purdue Pharma bankruptcy in the U.S. Bankruptcy Court for the Southern District of New York.

Led the team advising a global pharmaceutical manufacturer on the value of their pharmaceutical IP portfolio. Advised the same manufacturer in a multibillion-dollar acquisition of another pharmaceutical innovator, focusing on the value of the target's IP portfolio and its potential royalty obligations to other parties.

Served as the consulting expert and led the consulting team on behalf of the Defendants in a class action alleging the participation of pharmacy benefit managers in the price inflation of a popular brand-name pharmaceutical product. Class certification was denied.

In *Amgen Inc. v. Sanofi Aventisub LLC and Regeneron Pharmaceuticals*, Inc., led the team supporting the testimony of Dr. Ernst R. Berndt regarding the eBay factors in a matter involving permanent injunction on behalf of Amgen, alleging infringement of its patents. Analyzed data and other materials relevant to the assessment of the four *eBay* factors: irreparable harm, inadequacy of monetary damages, balance of burdens, and public interest.

On behalf of the plaintiff in *Wells Fargo Bank et al. v. Merrimack Pharmaceuticals, Inc.*, co-led the team supporting the expert and performed a valuation of Merrimack's pipeline of oncology drugs that supported the opinion that the sale of Merrimack's sole commercial product constituted a fundamental change of the company.

Matters involving allegations of anticompetitive conduct

Serving as the consulting expert in a matter involving pharmaceutical "pay for delay" allegations on behalf of a large third-party payer. Analyzed physician prescribing and formulary data to define the relevant market. Analyzed pricing and rebate data to estimate damages associated with the alleged anticompetitive conduct.

In *State of Wisconsin et al. v. Indivior Inc. f/k/a Reckitt Benckiser Pharmaceuticals Inc. et al.*, led the team analyzing alleged anticompetitive conduct on behalf of more than 40 state attorneys general. Plaintiffs allege that Indivior, formerly a part of Reckitt Benckiser, engaged in anticompetitive "product hop" behavior in order to move prescribing from its Suboxone Tablets product to its Suboxone Film line extension to maintain profits in anticipation of generic tablet competition. Analyzed data and other material to estimate degree of foreclosed competition and disgorgement.

Matters involving allegations of false claims

In *United States v. Novartis Pharmaceuticals Corp. and BioScrip, Inc.*, provided consulting expertise for Novartis on the economics of pharmacy dispensing, government reimbursements, and adherence in connection with alleged FCA violations associated with alleged kickbacks concerning Novartis's distribution of two specialty brand-name pharmaceuticals: Myfortic and Exjade.

Publications (Peer-Reviewed)

Selck, Frederic and S.L. Decker: "Health Information Technology Adoption in the Emergency Department," (2016) *Health Services Research.* 51 (no. 1), 32-47.

Selck, Frederic, AM. Brown, and S.L. Decker: "Emergency Department Visits and Proximity to Patients' Residences," (2015) *NCHS Data Brief.* 192, 1-8.

Selck, Frederic, M. Schoch-Spana, and L. Goldberg: "A National Survey on Health Department Capacity for Community Engagement in Emergency Preparedness," (2015) *Journal of Public Health Management and Practice.* 21 (no. 2), 196-207.

Selck, Frederic, A. Adalja, and C. Franco: "An Estimate for the Global Costs of Dengue Fever," (2015) *Vector-borne and Zoonotic Diseases.* 14 (no. 11), 824-26.

Selck, Frederic, M. Watson, K. Rambhia, R. Morhard, C. Franco, and E.S. Toner: "Medical Reserve Corps Volunteers in Disasters: A Survey of their Roles, Experiences, and Challenges," (2014) *Biosecurity and Bioterrorism.* 12 (no. 2), 85-93.

Selck, Frederic, Y. He, and S.T. Normand: "On the accuracy of classifying hospitals on their performance measures," (2013) *Statistics in Medicine.* 33 (no. 7), 1081-\-1103.

Selck, Frederic, J.F. Bridges, S.C. Searle, and N.A. Martinson: "Designing Family-Centered Male Circumcision Services: A Conjoint Analysis Approach," (2012) *The Patient.* 5 (no. 2), 101-11.

Selck, Frederic and S.L. Decker: "Was the Increase in U.S. Welfare Participation in the 1960s Really Unexplained?" (2012) *Review of Economics of the Household.* 10 (no. 4), 541-56.

Selck, Frederic, K.J. Rhambia, R.E. Waldhorn, A.K. Mehta, C. Franco, and E.S. Toner: "A Survey of Hospitals to Determine the Prevalence and Characteristics of Health Coalitions for Emergency Preparedness and Response," (2012) *Biosecurity and Bioterrorism.* 10 (no. 3), 304-13.

Selck, Frederic, E. Sheehy, K. O'Connor, R. Luskin, R. Howard, D. Cornell, J. Finn, T. Mone, and F. Delmonico: "Investigating Geographic Variation in Mortality in the Context of Organ Donation," (2012) *American Journal of Transplantation.* 12 (no. 6), 1598-1602.

Selck, Frederic, J.F.P. Bridges, G. Gray, J. McIntyre, and N.A. Martinson: "Condom Avoidance and the Determinants of Demand for Male Circumcision–A Conjoint Analysis," (2011) *Health Policy and Planning.* 26 (no. 4), 298-306.

Selck, Frederic, S.P. Wall, B.J. Kaufamn, A.J. Gilbert, Y. Yshkov, M. Goldstein, J.E. Rivera, D. O'Hara, H. Lerner, M. Saveta, M. Torres, C.L. Smith, Z. Hedrington, K.G. Munjal, M. Machado, S. Montella, M. Pressman, L.W. Teperman, N.N. Dubler, and L. R. Goldfrank: "Derivation of the Uncontrolled Donation after Circulatory Determination of Death for New York City," (2011) *American Journal of Transplantation.* 11 (no. 7), 1417-26.

Selck, Frederic, J.F.P. Bridges, S.C. Searle, and N.A. Martinson: "Engaging Families in the Design of Social Marketing Strategies for Male Circumcision Services in Johannesburg, South Africa," (2010) *Social Marketing Quarterly*. 16 (no. 3), 60-76.

Selck, Frederic, E.B. Grossman, L.E. Ratner, and J.F. Renz: "Utilization, Outcomes, and Retransplantation of Liver Allografts from Donation after Cardiac Death: Implications for Further Expansion of the Deceased-Donor Pool," (2008) *Annals of Surgery*. 248 (no. 4), 599-607.

Selck, Frederic, P. Deb, and E.B. Grossman: "Deceased Organ Donor Characteristics and Clinical Interventions Associated with Organ Yield," (2008) *American Journal of Transplantation.* 8 (no. 5), 965-74.

Selck, Frederic and Y. Yushkov: "An Approach to Needle Biopsy Technique to Increase Glomerulus Yield," (2008) *Transplantation Proceedings.* 40 (no. 4), 1051-53.

Working Papers

"Penalizing Generic Drugs with the CPI Rebate Will Reduce Competition and Increase the Likelihood of Drug Shortages." With Richard Manning. 2017. *Available at* www.accessiblemeds.org/sites/default/files/2017-09/Bates-White-White-Paper-Report-CPI-Penalty-09-12-2017.pdf.

"Can Care Provided at Community Health Centers Substitute for Emergency Room Care for the Uninsured?" With S.L. Decker. 2015. Revision requested from *Health Services Research.*

"Community Health Centers and Access to Care for the Uninsured." With S.L. Decker. 2015. Revision requested from *Health Economics*.

"Physician Agency and the Cost of Diligence: Evidence from Prescribing Behavior in Medicaid." With S.L. Decker and B. Herring. 2015.

"Transplant Market Concentration and the Underutilization of Viable Organ Donors: Theory and Evidence from Liver Transplants." With B. Herring. 2015.

"Who among the Working-Age Disabled on Medicaid Transitions into Dual Eligibility?" With S.L. Decker. 2015.

Presentations and Panels

"The Pitfalls of Using Sampling for False Claims Act Liability." Southern Economics Association Annual Meeting, Washington, D.C., 2016.

"Case Study: Irreparable Harm and Public Interest." Bates White Life Sciences Symposium, Washington, D.C., 2016.

"The Role of an Economist in Life Sciences Litigation." Eastern Economics Association Annual Meeting, Washington, D.C., 2016.

"Our Best Shot: Expanding Prevention through Vaccination in Older Adults." Alliance for Aging Research Briefing, Washington, D.C., 2015.

"Transplant Market Competition and the Utilization of Suboptimal Organ Donors: Theory and Evidence from Liver Transplants."

American Society of Health Economists Bi-annual Meeting, 2014.

Southeastern Health Economics Study Group, 2012.

AcademyHealth Health Economics Interest Group, 2012.

AcademyHealth Annual Research Meeting (Selected as Best Abstract), 2012.

Johns Hopkins Health Economics Seminar, 2011.

"Who among the Working-age Disabled on Medicaid Transitions into Dual Eligibility?"

American Society of Health Economists Bi-annual Meeting, 2014.

George Mason University Health Administration and Policy Seminar, 2014.

"Health Information Technology Adoption in the Emergency Department."

AcademyHealth Annual Research Meeting, 2013.

Workshop on Health Information Technology and Economics, 2012.

"NCHS Linked Data Files: Resources for Research and Policy." Agency for Healthcare Research and Quality, Rockville, Maryland, 2013.

"Differences in the Use of Ambulatory Health Care by Insurance Status and the Role of Community Health Centers."

Federal Committee on Statistical Methodology, 2012.

Eastern Economics Association, 2011.

Association for Public Policy Analysis and Management Fall Research Meeting, 2011.

Johns Hopkins Health Economics Seminar, 2011.

"Do Physicians Account for Out-of-Pocket Costs when Prescribing? Theory and Evidence from Medicaid."

Association for Public Policy Analysis and Management Fall Research Meeting, 2012.

AcademyHealth Annual Research Meeting, 2012.

American Society of Health Economists Bi-annual Meeting, 2012.

"Using Drug Data from the National Ambulatory Medical Care Survey and National Hospital Ambulatory Medical Care Survey." National Conference on Health Statistics, Washington, D.C., 2012.

"Evaluating Cost and Effectiveness for Prepositioning Strategies for Medical Countermeasures." Institute of Medicine Board on Health Sciences Policy, Washington, D.C., 2011.

"Measuring the Global Costs of Infectious Disease." Center for Biosecurity—UPMC, Washington, D.C., 2009.

"Deceased Organ Donor Characteristics and Clinical Interventions Associated with Organ Yield."

American Society of Transplantation Annual Research Meeting, 2008.

North American Transplant Coordinators Organization Annual Meeting, 2007.

"Utilization, Outcomes, and Retransplantation of Liver Allografts from Donation after Cardiac Death: Implications for Further Expansion of the Deceased-Donor Pool." International Liver Transplantation Society Meeting, 2008.

Honors and Distinctions

Inaugural Johns Hopkins Alison Snow Jones Memorial Prize, 2012.

AcademyHealth/NCHS Health Policy Fellowship, 2011 to 2012.

Johns Hopkins Sommer Scholar Graduate Fellowship, 2008 to 2013.

Co-Investigator, Health Resource and Services Administration, 2007 to 2008.

Professional Activities

Project Lead, Housing and Urban Development/NCHS Data Linkage, Centers for Disease Control and Prevention, 2013 to 2014.

Steering Committee Member, Health Economics Research Group, Center for Disease Control and Prevention, 2013 to 2014.

Chair, Honors and Awards Subcommittee, Student Coordinating Committee, Johns Hopkins University, 2009 to 2010.

President, AcademyHealth Chapter of Johns Hopkins University, 2008 to 2009.

President, Hunter College Society for Economics, 2007 to 2008.

Referee

Biosecurity and Bioterrorism

BMC Family Practice

BMC Medical Research Methodology

European Journal of Public Health

Health Affairs

Health Care: The Journal of Delivery Science and Innovation

Journal of Healthcare Engineering

Journal of the International Association for Official Statistics

Statistics in Medicine

Attachment A-2
Materials Considered

Addendums

3/28/2024 Notice of Appeal (Add1)

3/28/2024 Memorandum Order Granting Rule 60(b) Motion for Relief (Add5–9)

3/28/2024 Amended Final Judgment (Add10–13)

4/17/2024 Memorandum Order Denying Motion to Stay (Add14-17)

Interviews

Dr. Steven Nathan, Inova Fairfax Hospital, Director of the Advanced Lung Disease and Transplant Programs, interviewed on February 9, 2024.

Mr. David Barton, United, Associated Vice President of Managed Markets and Reimbursement, interviewed on February 14, 2024.

Mr. Greg Bottorff, United, Senior Vice President of Sales & Marketing, interviewed on February 14, 2024.

Mr. Brian Patterson, United, Manager of Corporate Accounting, interviewed on February 16, 2024.

Patents

Treprostinil Administration by Inhalation, U.S. Patent No. 10,716,793 (filed 1/31/2020, issued 7/21/2020).

Research materials

Abbott Laboratories v. Sandoz, Inc., 544 F.3d 1341, (Fed. Cir. 2008).

AbbVie Press Release, "AbbVie Receives U.S. FDA Approval of VIEKIRA PAK (Ombitasvir/Paritaprevir/Ritonavir Tablets; Dasabuvir Tablets) for the Treatment of Chronic Genotype 1 Hepatitis C," 12/19/2014, https://news.abbvie.com/2014-12-19-AbbVie-Receives-U-S-FDA-Approval-of-VIEKIRA-PAK-TM-Ombitasvir-Paritaprevir-Ritonavir-Tablets-Dasabuvir-Tablets-for-the-Treatment-of-Chronic-Genotype-1-Hepatitis-C.

Aerami Therapeutics Press Release, "Aerami Therapeutics Announces Expansion of the AER-901 (inhaled imatinib) Development Program in Pulmonary Hypertension Supported by Phase 1 Clinical Trial Data and Continued Progress," 2/23/2023, https://www.aerami.com/news-media/press-releases/detail/20/aerami-therapeutics-announces-expansion-of-the-aer-901.

Aerami Therapeutics Website, Pipeline, https://www.aerami.com/pipeline (accessed 1/22/2024).

AMA, "How Are Prescription Drug Prices Determined?," 4/9/2019, available at: https://www.ama-assn.org/print/pdf/node/20881.

Amazon.com Inc. v. Barnesandnoble.com Inc., 73 F. Supp. 2d 1228, (W.D. Wash. 1999).

American Lung Association, "Treating and Managing Pulmonary Arterial Hypertension," 10/26/2023, https://www.lung.org/lung-health-diseases/lung-disease-lookup/pulmonary-arterial-hypertension/treating-and-managing.

Amgen Press Release, "FDA Approves Amgen's New Cholesterol-Lowering Medication Repatha (evolocumab)," 8/27/2015, https://www.amgen.com/newsroom/press-releases/2015/08/fda-approves-amgens-new-cholesterollowering-medication-repatha-evolocumab.

Apple, Inc. v. Samsung Elecs. Co., 695 F.3d 1370, (Fed. Cir. 2012).

Apple, Inc. v. Samsung Elecs. Co., 809 F.3d 633, (Fed. Cir. 2015).

Assist Website, Financial Support, https://www.utassist.com/tyvaso-pah/financial-support (accessed 1/16/2024).

Assist Website, Product Distribution, https://www.utassist.com/tyvaso-pah/product-distribution (accessed 1/16/2024).

Banbury, Catherine and Will Mitchell (1995), "The Effect of Introducing Important Incremental Innovations on Market Share and Business Survival," *Strategic Management Journal* 16(S1): 161-182.

Barlas, Stephen (2016), "Health Plans and Drug Companies Dip Their Toes Into Value-Based Pricing: The Pressure Is on P&T Committees to Monitor Utilization," *P&T* 41(1): 39–53.

Baughman, Robert P., et. al. (2022), "Riociguat for Sarcoidosis-Associated Pulmonary Hypertension: Results of a 1-Year Double-Blind, Placebo-Controlled Trial," *Chest* 161(2): 448–457.

Behr, Jürgen (2022), "Inhaled Treprostinil in Pulmonary Hypertension in the Context of Interstitial Lung Disease: A Success, Finally," *American Journal of Respiratory and Critical Care Medicine* 205(2): 144–145.

Berndt, Ernst R. and Joseph P. Newhouse (2012), "Pricing and Reimbursement in US Pharmaceutical Markets," in Patricia M. Danzon and Sean Nicholson eds., *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, Oxford, UK: Oxford University Press.

Berry, Steven, James Levinsohn, and Ariel Pakes (1995), "Automobile Prices in Market Equilibrium," *Econometrica* 63(4): 841–890.

BioPharma Dive, "Amgen Cuts US Repatha Price 60% Amid Market Pressure," 10/24/2018, https://www.biopharmadive.com/news/amgen-cuts-us-repatha-price-60-amid-market-pressure/540517/.

BioPharma Dive, "Gilead Forecasts Steep Slide in 2018 Hepatitis C Revenues," 2/6/2018, https://www.biopharmadive.com/news/gilead-hepatitis-c-revenues-slide-fourth-quarter-earnings/516494/.

Blue Cross Blue Shield Blue Care Network of Michigan Website, How Does Step Therapy Work, https://www.bcbsm.com/individuals/help/pharmacy/what-is-step-therapy/ (accessed 1/30/2024).

Borrell, Joan-Ramon (2003), "Drug Price Differentials Caused by Formularies and Price Caps," *International Journal of the Economics of Business* 10(1): 35–48.

Broadcom Corp. v. Emulex Corp., 732 F.3d 1325, (Fed. Cir. 2013).

BTIG, "'793 IPR Decisions Affirmed on Appeal, Leaving YUTREPIA Launch On Track for Mid-2024 or Earlier. Increasing PT to $29 from $18," 12/20/2023.

Cao, Ying, et al. (2015), "Company reputation and the cost of equity capital," *Review of Accounting Studies* 20: 42–81.

Celsis In Vitro, Inc. v. CellzDirect, Inc., 664 F.3d 922, (Fed. Cir. 2012).

Centers for Medicare and Medicaid Services Website, Medicare Part B Drug Average Sales Price, https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price (accessed 1/11/2024).

Centers for Medicare and Medicaid Services, October 2011 ASP Pricing File, https://www.cms.gov/license/ama?file=/Medicare/Medicare-Fee-for-Service-Part-B Drugs/McrPartBDrugAvgSalesPrice/downloads/April_2011_NOC_Pricing_File.zip.

Centers for Medicare and Medicaid Services, October 2023 ASP Pricing File, https://www.cms.gov/files/zip/october-2023-asp-pricing-file.zip.

Cigna Healthcare Website, Step Therapy, https://static.cigna.com/assets/chcp/resourceLibrary/pharmacyResources/pharmSteptherapy.html (accessed 1/30/2024).

Cigna Website, What is Prior Authorization, https://www.cigna.com/knowledge-center/what-is-prior-authorization (accessed 1/30/2024).

Cigna, "Cigna National Formulary Coverage Policy," 12/13/2023, available at: https://static.cigna.com/assets/chcp/pdf/coveragePolicies/cnf/cnf_070_coveragepositioncriteria_proton_pump_inhibitors_st.pdf.

Cleveland Clinic Website, "PCSK9 Inhibitors," https://my.clevelandclinic.org/health/drugs/22550-pcsk9-inhibitors (accessed 2/2/2024).

ClinicalTrials.gov Website, An Open-Label ProSpective MultiCENTer Study to Evaluate Safety and Tolerability of Dry Powder Inhaled Treprostinil in PH (ASCENT), https://clinicaltrials.gov/study/NCT06129240 (accessed 2/19/2024).

CNBC, "A $14,000 Cholesterol Drug Gets a Price Cut as Regeneron, Sanofi Strike Deal With Express Scripts," 5/1/2018, https://www.cnbc.com/2018/05/01/regeneron-sanofi-chop-cholesterol-drug-price-in-express-scripts-pact.html.

CNBC, "Pricing Wars Heating Up Over Hepatitis C Drugs," 2/4/2015, https://www.cnbc.com/2015/02/04/pricing-wars-heat-up-over-hepatitis-c-drugs.html.

Code of Federal Regulations, 21 C.F.R. § 314.105 (2016).

Cohen, Wesley, et al. (2002), "R&D Spillovers, Patents and the Incentives to Innovate in Japan and the United States," *Research Policy* 31(8-9): 1349-1367.

Danneels, Erwin (2002), "The Dynamics of Product Innovation and Firm Competences," *Strategic Management Journal* 23(12): 1095-1121.

Dhont, Sebastiaan, et al. (2022), "Pulmonary Hypertension in Interstitial Lung Disease: An Area of Unmet Clinical Need," *ERJ Open Research* 8: 1–9.

DiMasi, Joseph A., Henry G. Grabowski, and Ronald W. Hansen (2016), "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," *Journal of Health Economics* 47: 20–33.

Douglas Dynamics, LLC v. Buyers Prod. Co., 717 F.3d 1336, (Fed. Cir. 2013).

E.I. du Pont de Nemours & Co. v. Polaroid Graphics Imaging, Inc., 706 F. Supp. 1135, (D. Del.1989).

eBay Inc. v. MercExchange, LLC, 547 U.S. 388, (2006).

Elliot, Graham and Allan Timmermann (2016), Economic Forecasting, Princeton, *New Jersey: Princeton University Press*.

Epstein, Andrew and Jonathan Ketcham (2014), "Information Technology and Agency in Physicians' Prescribing Decisions," *The Rand Journal of Economics* 45(2): 422–448.

FDA Website, Abbreviated New Drug Application (ANDA), https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda (accessed 8/31/2023).

FDA Website, Drugs@FDA Glossary of Terms, https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms# (accessed 1/12/2024).

FDA Website, Orphan Drug Designations and Approvals, Tyvaso, https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=189104 (accessed 1/5/2024).

FDA Website, Rare Diseases at FDA, https://www.fda.gov/patients/rare-diseases-fda (accessed 1/5/2024).

FDA, "Abbreviated Approval Pathways for Drug Products: 505(b)(2) or ANDA?," 9/19/2019, available at: https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/abbreviated-approval-pathways-drug-product-505b2-or-anda.

FDA, "Determining Whether to Submit an ANDA or a 505(b)(2) Application: Guidance for Industry," 5/2019, available at: https://www.fda.gov/media/124848/download.

FDA, "Overview of the 505(B)(2) Regulatory Pathway for New Drug Applications," undated, available at: https://www.fda.gov/media/156350/download.

FDA, Tyvaso (treprostinil) Approval Letter, 7/30/2009, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2009/022387s000ltr.pdf.

FDA, Tyvaso DPI (treprostinil) Approval Letter, 5/23/2022, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/214324Orig1s000ltr.pdf.

Federal Trade Commission (2003), "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy," *Federal Trade Commission*.

Feldman, Maryann (1999), "The New Economics of Innovation, Spillovers and Agglomeration: A Review of Empirical Studies," *Economics of Innovation and New Technology* 8(1-2): 5-25.

Fierce Pharma, "Amgen Faces Tough One-Two Blow as Competition Mounts for Repatha and Sensipar," 3/13/2018, https://www.fiercepharma.com/corporate/amgen-faces-tough-one-two-blow-as-competition-mounts-for-repatha-and-sensipar.

Fierce Pharma, "Sorry, Gilead. AbbVie Cuts Exclusive Hep C Deal with Express Scripts," 12/22/2014, https://www.fiercepharma.com/sales-and-marketing/sorry-gilead-abbvie-cuts-exclusive-hep-c-deal-express-scripts.

Fudenberg, Drew et al. (1983), "Preemption, Leapfrogging and Competition in Patent Races," *European Economic Review* 22: 3–31.

Gallini, Nancy (1992), "Patent Policy and Costly Imitation," *The RAND Journal of Economics* 23(1): 52-63.

Gilbert, Richard (2006), "Looking for Mr. Schumpeter: Where Are We in the Competition-Innovation Debate?," in Adam B. Jaffe, Josh Lerner, and Scott Stern, eds., *Innovation Policy and the Economy*, Volume 6, Cambridge, MA: The MIT Press.

Gilbert, Richard J. and David M. G. Newbery (1982), "Preemptive Patenting and the Persistence of Monopoly," *The American Economic Review* 72(3): 514–526.

Gilead Sciences, Inc. Press Release, "U.S. Food and Drug Administration Approves Gilead's Harvoni (Ledipasvir/Sofosbuvir) he First Once-Daily Single Tablet Regimen for the Treatment of Genotype 1 Chronic Hepatitis C," 10/10/2014, https://www.gilead.com/news-and-press/press-room/press-releases/2014/10/us-food-and-drug-administration-approves-gileads-harvoni-ledipasvirsofosbuvir-the-first-oncedaily-single-tablet-regimen-for-the-treatment-of.

Gilead Sciences, Inc. Press Release, "U.S. Food and Drug Administration Approves Gilead's Sovaldi (Sofosbuvir) for the Treatment of Chronic Hepatitis C," 12/6/2013, https://www.gilead.com/news-and-press/press-room/press-releases/2013/12/us-food-and-drug-administration-approves-gileads-sovaldi-sofosbuvir-for-the-treatment-of-chronic-hepatitis-c.

Gilead Sciences, Inc., Form 10-K, 2013.

Gilead Sciences, Inc., Form 10-K, 2014.

Gilead Sciences, Inc., Form 10-K, 2016.

Gilead Sciences, Inc., Form 10-K, 2019.

Greenhalgh, Christine and Mark Rogers (2010), *Innovation, Intellectual Property, and Economic Growth*, Princeton, NJ: Princeton University Press.

Hajar, Rachel (2019), "PCSK 9 Inhibitors: A Short History and a New Era of Lipid-lowering Therapy," *Heart Views* 20(2): 74–75.

Haynes, Zachary, Abhimanyu Chandel, and Christopher King (2023), "Pulmonary Hypertension in Interstitial Lung Disease: Updates in Disease, Diagnosis, and Therapeutics," *Cells* 12(19): 2394.

Health Affairs Health Policy Brief, "Formularies," 9/2017, available at: https://www.healthaffairs.org/do/10.1377/hpb20171409.000177/full/hpb_2017_09_14_formularies-1687871374910.pdf.

Hepatitis C: State of Medicaid Access, "The Actual Cost of HCV Treatment," c. 2023, available at https://stateofhepc.org/wp-content/uploads/2023/02/State-of-Hep-C-Treatment-Costs-Fact-Sheet.pdf.

Hill, Nicholas, et al (2022), "INSPIRE: Safety and Tolerability of Inhaled Yutrepia (treprostinil) in Pulmonary Arterial Hypertension (PAH)," *Pulmonary Circulation* 12(3): 1–11.

Hilton v. Braunskill, 481 U.S. 770, (1987).

Hsieh, Ping-Hung, Chandra S. Mishra and David H. Gobeli (2003), "The Return on R&D Versus Capital Expenditures in Pharmaceutical and Chemical Industries," *IEEE Transactions on Engineering Management* 50(2): 141–150.

Hypbritech, Inc. v. Abbott Laboratories, 849 F.2d 1446, (Fed. Cir. 1988).

Investopedia, "Market Capitalization: How Is It Calculated and What Does It Tell Investors?," 12/14/2023, https://www.investopedia.com/terms/m/marketcapitalization.asp.

Joshi, Amol M., and Atul Nerkar (2011), "When Do Strategic Alliances Inhibit Innovation by Firms? Evidence From Patent Pools in the Global Optical Disc Industry," *Strategic Management Journal* 32(11): 1139-1160.

Katz, Michael L., and Carl Shapiro (1987), "R&D Rivalry with Licensing or Imitation," *The American Economic Review* 77(3): 402–420.

L.E.K. Consulting, "Financial Ecosystem of Pharmaceutical R&D: Annex A," 9/2021, available at: https://www.rand.org/content/dam/rand/pubs/external_publications/EP60000/EP68954/RAND_EP68954.annexa.pdf.

Ladenburg Thalmann, "Liquidia Prevails in '793 PTAB CAFC Appeal; PH-ILD PDUFA 1/24/24; Buy & $30 PT," 12/21/2023.

Lee, Yong - Gil, et al. (2008), "Technological Convergence and Open Innovation in the Mobile Telecommunication Industry," *Asian Journal of Technology Innovation* 16(1): 45-62.

Lemley, Mark A. and Carl Shapiro (2005), "Probabilistic Patents," *Journal of Economic Perspectives* 19(2): 75–98.

Levin, Richard, et al. (1987), "Appropriating the Returns from Industrial Research and Development," *Brookings Papers on Economic Activity* 1987(3): 783-831.

Lieberman, Marvin B. and David B. Montgomery (1988), "First-Mover Advantages," *Strategic Management Journal* 9: 41–58.

Liquidia Corporation, Form 10-K, 2020.

Liquidia Corporation, Form 10-K, 2021.

Liquidia Corporation, Form 10-K, 2022.

Liquidia Corporation, Form 10-Q, 2023-Q3.

Liquidia Corporation, Form 8-K, 11/7/2023.

Liquidia Press Release, "FDA Accepts Submission to Add PH-ILD to Yutrepia Label," 9/25/2023, https://www.liquidia.com/news-releases/news-release-details/fda-accepts-submission-add-ph-ild-yutrepiatm-label.

Liquidia Press Release, "FDA Grants Tentative Approval for Liquidia's YUTREPIA (Treprostinil) Inhalation Powder," 11/8/2021, https://www.liquidia.com/news-releases/news-release-details/fda-grants-tentative-approval-liquidias-yutrepiatm-treprostinil.

Liquidia Press Release, "Liquidia Corporation and Pharmosa Biopharm Announce Collaboration for Sustained-Release Inhaled Treprostinil Product in North America," 6/28/2023, https://www.liquidia.com/news-releases/news-release-details/liquidia-corporation-and-pharmosa-biopharm-announce.

Liquidia Press Release, "Liquidia Corporation Reports Full Year 2022 Financial Results and Provides Corporate Update," 3/16/2023, available at: https://www.liquidia.com/node/10286/pdf.

Liquidia Press Release, "Liquidia Provides Update on Clinical Pipeline Targeting PAH and PH-ILD," 1/5/2024, https://www.liquidia.com/news-releases/news-release-details/liquidia-provides-update-clinical-pipeline-targeting-pah-and-ph.

Liquidia Press Release, "Liquidia Submits Amendment to Add PH-ILD Indication to Tentatively Approved NDA for YUTREPIA (treprostinil) Inhalation Powder," 7/27/2023, https://www.liquidia.com/news-releases/news-release-details/liquidia-submits-amendment-add-ph-ild-indication-tentatively.

Liquidia Press Release, "U.S. Federal Circuit Affirms Earlier PTAB Decision to Invalidate All Claims of United Therapeutics Patent No. 10,716,793 ('793 Patent)," 12/20/2023, https://liquidia.com/news-releases/news-release-details/us-federal-circuit-affirms-earlier-ptab-decision-invalidate-all.

Liquidia Website, Commercial Products, https://www.liquidia.com/products-and-pipeline/Commercial-Products (accessed 1/2/2024).

Liquidia Website, Home Page, https://www.liquidia.com/ (accessed 1/8/2024).

Liquidia Website, Pipeline, https://www.liquidia.com/products-and-pipeline/overview (accessed 1/2/2024).

Liquidia Website, Pipeline, https://www.liquidia.com/products-and-pipeline/overview (accessed 1/2/2024).

Liquidia, "J.P. Morgan Healthcare Conference," 1/10/2024.com/static-files/83cf40bb-70ba-4345-90ed-307e89e0bafb.

Liquidia, Form 10-K, 2018.

Liquidia, Form 10-K, 2019.

Liquidia, Form 15, 11/30/2020.

Mankiw, N. Gregory (2018), Principles of Economics, 8th ed., Boston, MA: Cengage Learning.

Mattingly, T. Joseph, David A. Hyman, and Ge Bai (2023), "Pharmacy Benefit Managers: History, Business Practices, Economics, and Policy," *JAMA Health Forum* 4(11): 1–14.

Mayo Clinic Website, Pulmonary Hypertension, https://www.mayoclinic.org/diseases-conditions/pulmonary-hypertension/symptoms-causes/syc-20350697 (accessed 12/29/2023).

Mazzucato, Mariana and Carlotta Perez (2015), "Innovation as Growth Policy: The Challenge for Europe," in Jan Fagerberg, Staffan Laestadius, and Ben R. Martin, eds., *The Triple Challenge for Europe: Economic Development, Climate Change, and Governance*, Oxford, UK: Oxford University Press.

Medicaid and CHIP Payment and Access Commission, "High-Cost HCV Drugs in Medicaid: Final Report," 1/2017.macpac.gov/wp-content/uploads/2017/03/High-Cost-HCV-Drugs-in-Medicaid-Final-Report.pdf.

National Heart, Lung, and Blood Institute Website, Pulmonary Hypertension – Diagnosis, https://www.nhlbi.nih.gov/health/pulmonary-hypertension/diagnosis# (accessed 1/11/2024).

National Institutes of Health Website, What are Interstitial Lung Diseases?, https://www.nhlbi.nih.gov/health/interstitial-lung-diseases (accessed 1/11/2024).

National Organization for Rare Disorders Website, Pulmonary Arterial Hypertension, https://rarediseases.org/rare-diseases/pulmonary-arterial-hypertension/ (accessed 1/11/2024).

Needham, "Top Pick for 2024; Yutrepia Opportunity in PAH/PH-ILD Markets Comes Into Focus," 1/5/2024.

Nicholson, Sean (2012), "Financing Research and Development," in Patricia M. Danzon and Sean Nicholson, eds., *The Oxford Handbook of the Economics of the Biopharmaceutical Industry*, New York, NY: Oxford University Press, Inc.

Oklahoma Health Care Authority, "Drug Utilization Review Board Meeting," 3/8/2023.gov/content/dam/ok/en/okhca/docs/about/boards-and-committees/dur/2023/march/DUR%20Packet%2003082023.pdf.

Oppenheimer, "Inhaled Treprostinil Battle Heats Up; Tyvaso Still in Driver Seat," 12/20/2023.

Parikh, Raj, et al. (2022), "Pulmonary Hypertension in Patients With Interstitial Lung Disease: A Tool For Early Detection," *Pulmonary Circulation* 12(4): 1–11.

PCMA, "PBMs Use Competition to Negotiate Lower Net Costs for Hepatitis C Treatments," c. 2021, available at: https://www.pcmanet.org/wp-content/uploads/2021/06/hcvdrugs_Infographic.pdf.

Pharmosa Website, Pipeline, https://www.pharmosa.com.tw/phases (accessed 1/22/2024).

Point32Health, "Medical Necessity Guidelines: Tyvaso (treprostinil inhalation solution)," 12/12/2023.carepartnersct.com/cpct-pdoc-tyvaso.

PR Newswire, "United Therapeutics Announces FDA Approval and Launch of Tyvaso for the Treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease," 4/1/2021, https://www.prnewswire.com/news-releases/united-therapeutics-announces-fda-approval-and-launch-of-tyvaso-for-the-treatment-of-pulmonary-hypertension-associated-with-interstitial-lung-disease-301260212.html.

Presidio Components v. American Technical Ceramics, 702 F.3d 1351, (Fed. Cir. 2012).

Pulmonary Hypertension Association Website, About Pulmonary Hypertension, https://phassociation.org/types-pulmonary-hypertension-groups/ (accessed 12/29/2023).

Qaiser, Kanza, and Adriano Tonelli (2021), "Novel Treatment Pathways in Pulmonary Arterial Hypertension," *Methodist Debakey Cardiovascular Journal* 17(2): 106–114.

Rahaghi, Farbod and Franck Rahaghi (2021), "PH-ILD: Identification, Evaluation, and Monitoring: A Diagnostic View From Both Sides," *Advances in Pulmonary Hypertension* 20(4): 103–108.

RAND Corporation Research Report, "Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships," 2021.hhs.gov/sites/default/files/documents/0a464f25f0f2e987170f0a1d7ec21448/RRA328-1-Rxsupplychain.pdf.

Refinitiv Eikon, "Q1 2023 Liquidia Corp Earnings Call," 5/4/2023.

Refinitiv Eikon, "Q3 2017 Gilead Sciences Inc Earnings Call," 10/26/2017.

Refinitiv Eikon, "Q4 2014 Gilead Sciences Inc Earnings Call," 2/3/2015.

Refinitiv StreetEvents, "Liquidia Corp at JPMorgan Healthcare Conference," 1/10/2024.

Refinitiv StreetEvents, "United Therapeutics Corp at JPMorgan Healthcare Conference," 1/8/2024.

Refinitiv StreetEvents, "United Therapeutics Corp at UBS BioPharma Conference," 11/8/2023.

Regeneron Press Release, "Regeneron and Sanofi Announce FDA Approval of Praluent (alirocumab) Injection, the First PCSK9 Inhibitor in the U.S., for the Treatment of High LDL Cholesterol in Adult Patients," 7/24/2015, https://investor.regeneron.com/news-releases/news-release-details/regeneron-and-sanofi-announce-fda-approval-praluentr-alirocumab.

Regeneron Press Release, "Regeneron and Sanofi Offer Praluent (alirocumab) at a New Reduced U.S. List Price," 2/11/2019, https://investor.regeneron.com/node/21811/pdf.

Roberts, Peter W. and Grahame R. Dowling (2002), "Corporate Reputation and Sustained Superior Financial Performance," *Strategic Management Journal* 23: 1077–1093.

Robinson, William T., Gurumurthy Kalyanaram, and Glen L. Urban (1994), "First-Mover Advantages from Pioneering New Markets: A Survey of Empirical Evidence," *Review of Industrial Organization* 9: 1–23.

Scientific American, "Inventor of Hepatitis C Cure Wins a Major Prize—and Turns to the Next Battle," 9/13/2016, https://www.scientificamerican.com/article/inventor-of-hepatitis-c-cure-wins-a-major-prize-and-turns-to-the-next-battle/.

Scotchmer, Suzanne (1991), "Standing on the Shoulders of Giants: Cumulative Research and the Patent Law," *Journal of Economic Perspectives* 5(1): 29-41.

Standard Havens Prods., Inc. v. Gencor Indus., 897 F.2d 511, (Fed. Cir. 1990).

State Industries, Inc. v. Mor-Flo Industries, 883 F.2d 1573, (Fed. Cir. 1989).

SVB, "IQVIA Script Trends for the Week Ended April 15, 2022," 4/22/2022.

TD Cowen, "Tyvaso '793 Patent PTAB Decision Affirmed in Appeals Court as Expected," 12/20/2023.

Tettey, Abraham, et al. (2021), "Therapy for Pulmonary Arterial Hypertension: Glance on Nitric Oxide Pathway," *Frontiers in Pharmacology* 12: article 767002.

The New York Times, "F.D.A. Approves Pill to Treat Hepatitis C," 12/6/2013, https://www.nytimes.com/2013/12/07/business/fda-approves-pill-to-treat-hepatitis-c.html.

The New York Times, "Sales of Sovaldi, New Gilead Hepatitis C Drug, Soar to $10.3 Billion," 2/3/2015, https://www.nytimes.com/2015/02/04/business/sales-of-sovaldi-new-gilead-hepatitis-c-drug-soar-to-10-3-billion.html.

The New Yorker, "A Better Treatment for Hepatitis C," 12/9/2013, https://www.newyorker.com/tech/annals-of-technology/a-better-treatment-for-hepatitis-c.

The Wall Street Journal, "States Work to Strike Deals for Hep C Drug Discounts," 1/29/2015, https://www.wsj.com/articles/states-work-to-strike-deals-for-hep-c-drug-discounts-1422492687.

The Wall Street Journal, "What the 'Shocking' Gilead Discounts on its Hepatitis C Drugs Will Mean," 2/4/2015, https://www.wsj.com/articles/BL-270B-1426.

Treprostinil Injection Website, Home Page, https://trepinjection.com/ (accessed 12/29/2023).

Turban, Daniel B. and Daniel M. Cable (2003) "Firm Reputation and Applicant Pool Characteristics," *Journal of Organizational Behavior* 24: 733–751.

Tyvaso DPI Website, Home Page, https://www.tyvaso.com/dpi/ (accessed 2/20/2024).

Tyvaso Website, Frequently Asked Questions (PH-ILD), https://www.tyvasohcp.com/ph-ild/what-is-tyvaso/faqs/ (accessed 2/23/2024).

Tyvaso Website, Frequently Asked Questions, https://www.tyvasohcp.com/pah/inhaled-prostacyclin/faqs/ (accessed 1/5/2024).

Tyvaso Website, Tyvaso DPI, https://www.tyvaso.com/pah/about-tyvaso/tyvaso-dpi/ (accessed 1/5/2024).

U.S. Department of Justice and the Federal Trade Commission, "Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition," April 2007. (Quoting U.S. Department of Justice and the Federal Trade Commission, "Antitrust Guidelines for the Licensing of Intellectual Property, 1995.)

U.S. Food & Drug Administration Website, Orphan Products: Hope for People With Rare Diseases, https://www.fda.gov/drugs/information-consumers-and-patients-drugs/orphan-products-hope-people-rare-diseases (accessed 2/2/2024).

U.S. Food & Drug Administration, "Small Business Assistance: Frequently Asked Questions for New Drug Product Exclusivity," 2/11/2016, https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-new-drug-product-exclusivity.

UBS, "3Q Wrap: Headline Risk of Competitive Threat Overrated," 11/1/2023.

UCSF Health Website, Pulmonary Hypertension and Interstitial Lung Disease, https://www.ucsfhealth.org/education/pulmonary-hypertension-and-interstitial-lung-disease (accessed 1/11/2024).

Ulku, Hulya (2004), "R&D, Innovation, and Economic Growth: An Empirical Analysis," *International Monetary Fund Working Paper*.

United Healthcare, "Prior Authorization / Medical Necessity – PAH Agents," 6/1/2023, available at: https://www.uhcprovider.com/content/dam/provider/docs/public/prior-auth/drugs-pharmacy/commercial/h-p/PA-Med-Nec-PAH.pdf.

United Press Release, "United Therapeutics Announces FDA Acceptance of Tyvaso DPI New Drug Application for Priority Review," 6/16/2021, https://ir.unither.com/press-releases/2021/06-16-2021-145947051.

United Press Release, "United Therapeutics Announces FDA Approval of Tyvaso DPI," 5/24/2022, https://ir.unither.com/press-releases/2022/05-24-2022.

United Press Release, "United Therapeutics Provides an Update on the Progress of the Tyvaso DPI New Drug Application," 10/18/2021, https://ir.unither.com/press-releases/2021/10-18-2021-151607305.

United Website, Complete Pipeline, https://pipeline.unither.com/ (accessed 1/26/2024).

United Website, United Therapeutics Corporation History, https://www.unither.com/about-us/history (Accessed 1/5/2024).

United, 2022 Corporate Responsibility and Public Benefit Report.

United, Adcirca Label, 9/2020, available at: https://pi.lilly.com/us/adcirca-pi.pdf.

United, Form 10-K, 2011.

United, Form 10-K, 2012.

United, Form 10-K, 2013.

United, Form 10-K, 2014.

United, Form 10-K, 2015.

United, Form 10-K, 2016.

United, Form 10-K, 2017.

United, Form 10-K, 2018.

United, Form 10-K, 2019.

United, Form 10-K, 2020.

United, Form 10-K, 2021.

United, Form 10-K, 2022.

United, Form 10-K, 2023.

United, Form 10-Q, 2023-Q2.

United, Orenitram Label, 8/2023, available at: https://www.orenitramhcp.com/media/content/files/Orenitram-Prescribing-Information.pdf.

United, Remodulin Label, 7/2021, available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/021272Orig1s032lbl.pdf.

United, Tyvaso DPI Label, 11/2023, https://www.tyvaso.com/pdf/TYVASO-DPI-PI.pdf.

United, Tyvaso Label, 5/2022, https://www.tyvaso.com/pdf/TYVASO-PI.pdf.

UnitedHealthcare, "Clinical Pharmacy Programs," 6/1/2023 https://www.uhcprovider.com/content/dam/provider/docs/public/resources/pharmacy/step-therapy/Step-Therapy-Nexium.pdf.

Varian, Hal (2014), *Intermediate Microeconomics: A Modern Approach*, 9th ed., New York, NY: W.W. Norton & Company, Inc.

Veeco Instruments Inc. v. SGL Carbon, LLC, No. 17-CV-2217 (PKC), (E.D.N.Y. 2017).

Wall Street Journal, "For Prescription Drug Makers, Price Increases Drive Revenue," 10/5/2015, https://www.wsj.com/articles/for-prescription-drug-makers-price-increases-drive-revenue-1444096750.

WebMD, "Pulmonary Arterial Hypertension," 8/10/2023, https://www.webmd.com/lung/pulmonary-arterial-hypertension.

Wedbush, "Don't Call It a Comeback...Initiating at OP and $10 PT," 10/9/2023.

Wedbush, "Federal Circuit Affirms '793 PTAB Decision; Tyvaso DPI's Dominance to Persist," 12/21/2023.

Wedbush, "Tyvaso DPI Royalty Deal Pads Balance Sheet, Underscores Blockbuster Potential," 1/3/2024.

Wells Fargo, "UTHR: LQDA Wins Federal Circuit Case as Expected; Limited Fundamental Impact to UTHR," 12/20/2023.

Wooldridge, Jeffrey M. (2006), *Introductory Econometrics: A Modern Approach*, 3rd ed., Mason, OH: Thomson South-Western.

Yahoo Finance, Liquidia Corporation (LQDA), https://finance.yahoo.com/quote/LQDA/ (accessed 4/17/2024).

Yahoo Finance, Liquidia Corporation Historical Data, https://finance.yahoo.com/quote/LQDA/history?period1=1701388800&period2=1703980800&interval=1d&filter=history&frequency=1d&includeAdjustedClose=true (accessed 2/14/2024).

Yahoo Finance, United Therapeutics Corporation Historical Data, https://finance.yahoo.com/quote/UTHR/history?period1=1701388800&period2=1703980800&interval=1d&filter=history&frequency=1d&includeAdjustedClose=true (accessed 2/14/2024).

Yahoo News, "Gilead Falls on AbbVie and Express Scripts Deal: 3 Biotech ETFs to Watch - ETF News And Commentary," 12/23/2014, https://news.yahoo.com/gilead-falls-abbvie-express-scripts-170205245.html.

Yanadori, Yoshio and Victor Cui (2013), "Creating Incentives for Innovation? The Relationship Between Pay Dispersion in R&D Groups and Firm Innovation Performance," *Strategic Management Journal* 34(12): 1502-1511.

Zacks, "United Therapeutics (UTHR)," 12/8/2023.

Ziemnowicz, Christopher (2013), "Joseph A. Schumpeter and Innovation," *Encyclopedia of Creativity, Invention, Innovation and Entrepreneurship*, 1171-1176.

Documents provided by United

Liquidia, "J.P. Morgan Healthcare Conference," 1/10/2024 (Final - JPM Deck 2024.01.09 1515 (sent).pdf).

Liquidia, "42nd Annual J.P. Morgan Healthcare Conference," 1/10/2024 (Liquidia Corp Conf Presentation Call 2024110 RT000000003029674077.pdf).

United, "Treprostinil Marketing 2022 Business Plan," c. 2022 (2022 Business Plan_for distributon_FINAL (002).pptx).

United, United Therapeutics Tyvaso Forecast (2023–2035), 9/6/2023 (UTHR Forecast 2023–2035 09-06-2023.xlsx).

United, 2023 Business Planning UT Marketing, c. 2023 (2023 Marketing Business Plan FINAL.docx).

United, Marketing Brand Plans, c. 2021 (Consolidated Marketing Plan 2021_11302020.pptx).

United, Tyvaso DPI and Nebulized Tyvaso Gross Margins, c. 2024 (Tyvaso DPI and Nebulized Tyvaso Gross Margins.xlsx).

Attachment B-1

Tyvaso and Tyvaso DPI Net Revenues and Gross Profits

Year	Source	Net Revenues	Gross Profit
2009	[A]	$ 20.3	$ 15.0
2010	[B]	$ 151.8	$ 121.7
2011	[C]	$ 240.4	$ 208.4
2012	[D]	$ 325.6	$ 271.8
2013	[E]	$ 438.8	$ 378.0
2014	[F]	$ 463.1	$ 405.6
2015	[G]	$ 470.1	$ 446.2
2016	[H]	$ 404.6	$ 385.0
2017	[I]	$ 372.9	$ 354.4
2018	[J]	$ 415.2	$ 397.9
2019	[K]	$ 415.6	$ 396.0
2020	[L]	$ 483.3	$ 458.8
2021	[M]	$ 607.5	$ 580.7
2022	[N]	$ 873.0	$ 819.5
2023	[O]	$ 1,233.7	$ 1,085.7
Total	[P]	$ 6,915.9	$ 6,324.6

Notes and sources:

Monetary values are in millions.

Values include revenues for Tyvaso and Tyvaso DPI.

Net Revenues and Gross Profit:

[A] United, Form 10-K, 2011, at F-46.

[B] United, Form 10-K, 2012, at F-48.

[C] United, Form 10-K, 2013, at F-47.

[D] United, Form 10-K, 2014, at F-44.

[E] United, Form 10-K, 2015, at F-44.

[F] United, Form 10-K, 2016, at F-43.

[G] United, Form 10-K, 2017, at F-44.

[H] United, Form 10-K, 2018, at F-48.

[I] United, Form 10-K, 2019, at F-48.

[J] United, Form 10-K, 2020, at F-35.

[K] United, Form 10-K, 2021, at F-32.

[L] United, Form 10-K, 2022, at F-32.

[M]–[O] United, Form 10-K, 2023, at F-32.

[P] equals the sum of [A] through [O].

Attachment B-2

Tyvaso and Tyvaso DPI Net Revenues as a Percentage of United Revenues

Year	Source	Tyvaso and Tyvaso DPI Net Revenues	United Total Revenues	Net Revenues as a Percentage of Total Revenues
2010	[A]	$ 151.8	$ 592.9	25.6%
2011	[B]	$ 240.4	$ 743.2	32.3%
2012	[C]	$ 325.6	$ 916.1	35.5%
2013	[D]	$ 438.8	$ 1,117.0	39.3%
2014	[E]	$ 463.1	$ 1,288.5	35.9%
2015	[F]	$ 470.1	$ 1,465.8	32.1%
2016	[G]	$ 404.6	$ 1,598.8	25.3%
2017	[H]	$ 372.9	$ 1,725.3	21.6%
2018	[I]	$ 415.2	$ 1,627.8	25.5%
2019	[J]	$ 415.6	$ 1,448.8	28.7%
2020	[K]	$ 483.3	$ 1,483.3	32.6%
2021	[L]	$ 607.5	$ 1,685.5	36.0%
2022	[M]	$ 873.0	$ 1,936.3	45.1%
2023	[N]	$ 1,233.7	$ 2,327.5	53.0%
Total	[O]	$ 6,895.6	$ 19,956.7	34.6%

Notes and sources:

Monetary values are in millions.

Tyvaso and Tyvaso DPI Net Revenues from Attachment B-1 at Net Revenues.

United Total Revenues:

[A] United, Form 10-K, 2012, at F-5.

[B] United, Form 10-K, 2013, at F-5.

[C] United, Form 10-K, 2014, at F-5.

[D] United, Form 10-K, 2015, at F-5.

[E] United, Form 10-K, 2016, at F-5.

[F] United, Form 10-K, 2017, at F-6.

[G] United, Form 10-K, 2018, at F-6.

[H] United, Form 10-K, 2019, at F-9.

[I] United, Form 10-K, 2020, at F-7.

[J] United, Form 10-K, 2021, at F-6.

[K] United, Form 10-K, 2022, at F-6.

[L]–[N] United, Form 10-K, 2023, at F-6.

[O] Tyvaso and Tyvaso DPI Net Revenues and United Total Revenues: equals the sum of [A] through [N].

Net Revenues as a Percentage of Total Revenues = Tyvaso and Tyvaso DPI Net Revenues / United Total Revenues.

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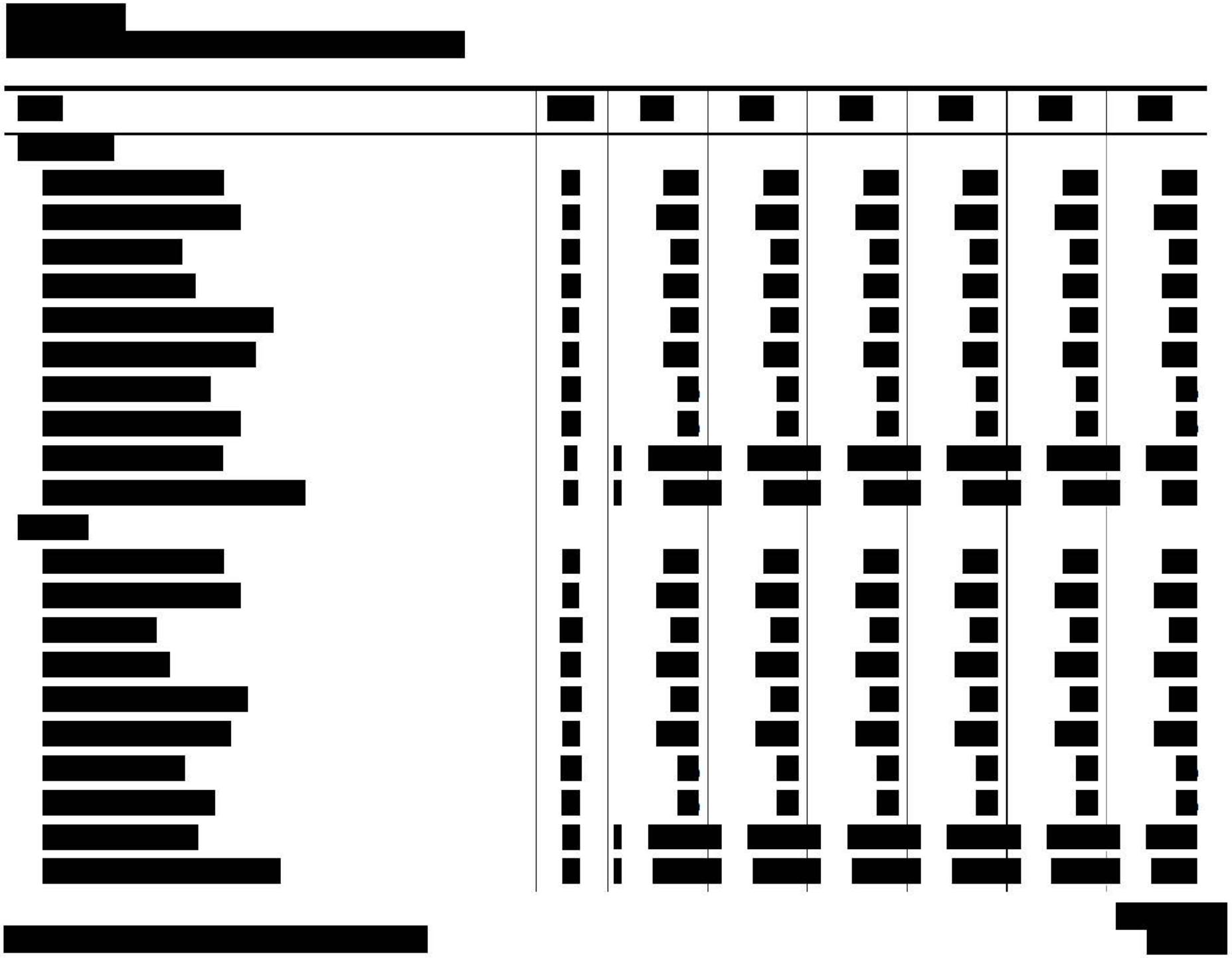

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Notes and sources:

[A] United, United Therapeutics Tyvaso Forecast (2023–2035), 9/6/2023 (UTHR Forecast 2023–2035 09-06-2023.xlsx, at tab "forecast" at row 37).

[B] United, United Therapeutics Tyvaso Forecast (2023–2035), 9/6/2023 (UTHR Forecast 2023–2035 09-06-2023.xlsx, at tab "forecast" at row 38).

[C] United, United Therapeutics Tyvaso Forecast (2023–2035), 9/6/2023 (UTHR Forecast 2023–2035 09-06-2023.xlsx, at tab "forecast" at row 44).

[D] = ([A] + [B]) × [C].

[redacted]

[F] = [D] × (1 - [E]).

[G] United, United Therapeutics Tyvaso Forecast (2023–2035), 9/6/2023 [redacted]

[I] = [G] × (1 - [H]). [redacted]

[J] = ([F] × [I]) / 1,000,000.

[K] = [A].

[L] = [B].

[M] United, United Therapeutics Tyvaso Forecast (2023–2035), 9/6/2023 [redacted]

[N] = ([K] + [L]) × [M].

[redacted]

[P] = [N] × (1 - [O]).

[Q] United, United Therapeutics Tyvaso Forecast (2023–2035), 9/6/2023 [redacted]

[S] = [Q] × (1 - [R]). [redacted]

[T] = ([P] × [S]) / 1,000,000.

[U] = [J] + [T].

[V] United, United Therapeutics Tyvaso Forecast (2023–2035), 9/6/2023 [redacted]

[W] United, United Therapeutics Tyvaso Forecast (2023–2035), 9/6/2023 [redacted]

[X] = [V] + [W].

[Y] = [X] - [U].

[Z] equals [Y] from the current year plus [Z] from the previous year.

[AA] For purposes of this analysis, I estimate a discount rate of 8%. See:

Oppenheimer, "Inhaled Treprostinil Battle Heats Up; Tyvaso Still in Driver Seat," 12/20/2023, at 2.

Wells Fargo, "UTHR: LQDA Wins Federal Circuit Case as Expected; Limited Fundamental Impact to UTHR," 12/20/2023, at 2.

[AB] = [Y] / (1 + [AA])^(Year - 2023).

I estimate that revenues are earned at the end of each year. Present value is calculated as of the beginning of 2024.

[AC] equals [AB] from the current year plus [AC] from the previous year.

CERTIFICATE OF SERVICE

I hereby certify that on April 18, 2024, the foregoing document was filed using the Court's CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

/s/ Douglas H. Carsten
Douglas H. Carsten

CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limitation of Federal Circuit Rule 27(d)(2)(A). This brief contains 4,541 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

This motion complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6). This motion has been prepared in a proportionally spaced typeface, 14-point Century Schoolbook font, using Microsoft Word for Office 365. As permitted by Fed. R. App. P. 32(g), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ Douglas H. Carsten
Douglas H. Carsten