

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., *et al.*

Plaintiffs,

v.

SANDOZ INC., *et al.*

Defendants.

1:20CV1589

MEMORANDUM AND ORDER

This matter arises on Plaintiffs' ("Astellas") motion to supplement the complaint and demand for a jury trial. [D.I. 620](#), [622](#). Defendants (collectively, "the Generics Manufacturers") oppose supplementation and assert the Court should decide infringement and validity based on the record developed at the bench trial. [D.I. 628](#).

The Court agrees with the Generics Manufacturers. This litigation is in advanced stages and the Federal Circuit contemplated a narrow role for the Court on remand. Therefore, adding additional allegations on this issue would prejudice the Generics Manufacturers and the Court, who have completed a bench trial based on Astellas's ANDA claims, and delay resolution of this matter even further. Moreover, this matter has been litigated as an ANDA case and it would be prejudicial to change the focus to a traditional infringement case at this stage. To the extent Astellas seeks a jury trial on the issue submitted to the bench in 2023, they waived the right by trying the issues in equity and the Court declines to retry with an advisory jury under Rule 39(c) as a matter of discretion. Nothing in this order precludes Astellas from litigating the Generics Manufacturers' entry to the market and seeking a jury trial on infringement by filing a related case. The Court only concludes, in its discretion based on the unique

circumstances in this case, that the issues arising from the Generics Manufacturers' launch of their competing product are best addressed in a separate action.

BACKGROUND

This case is one of several in a long running patent dispute regarding a sustained release mirabegron formulation sold by Astellas under the brand name Myrbetriq®. The drug is covered by several patents held by Astellas, including the patent in suit, United States Patent No. 10,842,780 (“780 Patent”).

This case initially arose when the Generics Manufacturers filed Abbreviated New Drug Applications (“ANDAs”) for their generic sustained release formulations of mirabegron. [D.I. at 1](#). ANDAs are a procedure that allows a manufacturer of a generic drug to receive FDA approval based on the existing brand-name drug's safety and efficacy studies. [21 U.S.C. § 355\(j\)](#). This procedure allows the generics manufacturers to enter the market on an abbreviated time frame compared to the traditional application process. Laura J. Grebe, Comment, *Generic Entry in a Rough Economy- Proposed Legislation May Ease Health Care Costs*, 14 Marq. Intell. Prop. L. Rev. 167, 172 (2010). Under the Hatch-Waxman Act, an innovative manufacturer is permitted to file a patent infringement action based on the ANDA and seek an injunction preventing the drug from entering the market. [35 U.S.C. § 271\(e\)\(2\)](#). However, because ANDA proceedings usually occur before the generic drug has gone to market and caused damage to the innovative manufacturer, only equitable remedies (i.e., injunctive and declaratory relief) are generally available. See Robert A. Matthews, [6 Annotated Patent Digest § 39:154](#) (collecting cases). As a result, issues in ANDA cases, including infringement and validity, are usually

resolved by a bench trial rather than a jury trial. *Id.* This legal context shaped the way this case has been litigated.

In its initial complaint, Astellas sought equitable relief including: (1) a declaration that the products described in the Generics Manufacturers' ANDAs infringed the '780 Patent, and (2) a permanent injunction barring the Generics Manufacturers from bringing their products to market. [D.I. 1 at 40–41](#). The original complaint did not seek damages, but reserved the right to assert damages claim, should the Generics Manufacturers market their products. *Id.* at 41. After filing the complaint, the Parties litigated this case as an ANDA case, focused on the propriety of injunctive relief. See e.g., [D.I. 495 ¶ 124](#) (listing relief sought at trial). This culminated in a bench trial, where the Court considered infringement, the Generics Manufacturers' enablement invalidity theory, and Astellas's entitlement to injunctive relief. See [D.I. 526–530](#), transcripts. After trial, the Court entered judgement after concluding the '780 Patent was an invalid attempt to patent a natural law applied via routine, conventional, and well-known methods. See [D.I. 571](#).

The Federal Circuit reversed. [Astellas Pharma, Inc. v. Sandoz Inc., No. 2023-2032, 2024 WL 4219374, at *7 \(Fed. Cir. Sept. 18, 2024\)](#). The panel determined the Court overstepped its bounds and abused its discretion by finding the '780 Patent invalid on a theory not argued or developed by the parties. *Id.* at *6. The panel instructed the Court to “adjudic[ate] the issues properly raised and supported by the record. Those issues are limited to infringement and validity under [35 U.S.C. § 112](#).” *Id.* The panel did not reverse based on trial error or order a new trial. Instead, the panel remanded “for adjudication of the case as it was shaped by the parties.” *Id.* at *7.

While the case was before the Federal Circuit, the Generics Manufacturers launched their sustained release mirabegron formulations. See [D.I. 623](#). After the Federal Circuit issued its mandate, Astellas filed the present motion to supplement and sought to add allegations regarding the product launch, willfulness, and infringement damages. [D.I. 620, 622](#).

LEGAL STANDARDS

[Fed. R. Civ. P. 15\(d\)](#) provides “[o]n motion and reasonable notice, the court may, on just terms, permit a party to serve a supplemental pleading setting out any transaction, occurrence, or event that happened after the date of the pleading to be supplemented.” Supplementation under Rule 15(d) is within the discretion of the trial court but “[l]eave to supplement should be granted if it will promote the just disposition of the case, will not cause undue prejudice or delay and will not prejudice the rights of any parties.” [Medeva Pharma Ltd. v. Am. Home Prod. Corp.](#), 201 F.R.D. 103, 104 (D. Del. 2001). A court “should apply the Rule in a manner securing the just, speedy, and inexpensive determination of every action.” *Id.* “Substantial or undue prejudice to the non-moving party” in the form of “additional discovery, cost, and preparation to defend against new facts or new theories” “is a sufficient ground for denial of leave” [Cureton v. Nat’l Collegiate Athletic Ass’n](#), 252 F.3d 267, 273 (3d Cir. 2001).¹

[Fed. R. Civ. P. 38](#) governs the right to a jury trial in a civil case. It preserves “the right of trial by jury as declared by the Seventh Amendment of the Constitution—or as provided by federal statute.” *Id.* The Seventh Amendment provides for a jury trial for “suits at common law” and does not extend to cases seeking equitable relief. U.S. Const.

¹ In patent cases, the district court applies regional circuit law for general procedural issues. [Wordtech Sys., Inc v. Integrated Networks Sols., Inc.](#), 609 F.3d 1308, 1318 (Fed. Cir. 2010).

amend. VII; *Lytle v. Household Mfg., Inc.*, 494 U.S. 545, 550 (1990). Like other constitutional rights, the Seventh Amendment is not absolute and the right to a jury trial can be waived by litigation conduct, including failure to submit a timely jury demand, and participating in a bench trial without objection. See *Fed. R. Civ. P. 39(b)* (“Issues on which a jury trial is not properly demanded are to be tried by the court.”); *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 331 (1979) (“At common law a litigant was not entitled to have a jury determine issues that had previously been adjudicated by a chancellor in equity.”); Wright R. Miller, 9 *Fed. Prac. & Proc. Civ. § 2321* (4th Ed. 2024) (collecting authority indicating, “[t]he jury trial right also may be waived even when it had been properly demanded, as it has in many, many cases, by a wide range of conduct, such as failing to object to or actually participating in a bench trial . . .”). Even if a jury trial right has been waived, a district court can grant a jury trial as a matter of discretion under *Fed. R. Civ. P. 39(b)*, on “any issue for which a jury might have been demanded” or order a trial with an advisory jury under *Fed. R. Civ. P. 9(c)*.

DISCUSSION

The Court concludes in its discretion, that the ANDA action should proceed in a separate case from the traditional infringement action and the present case should be decided on the existing record by the Court. The Court proceeds in two parts. First, it addresses why supplementation is inappropriate, given the current posture of the case. Second, it explains why this course of action does not deprive Astellas of its jury trial right under the Seventh Amendment.

A. Astellas's Motion to Supplement

The Court concludes allowing Astellas to supplement its complaint to add a traditional infringement theory “at this advanced stage in the proceeding, would be counterproductive to a just, speedy, and inexpensive determination of this matter.” [MOSAID Techs. Inc. v. LSI Corp.](#), No. CV 10-192-RGA, 2014 WL 3361924, at *2 (D. Del. July 2, 2014); *c.f.* [Masimo Corp. v. Philips Elec. N. Am. Corp.](#), No. Masimo Corp. v. Philips Elecs. N. Am. Corp., No. CIVA 09-80-JJF-MPT, 2010 WL 1609899, at *3 (D. Del. Apr. 20, 2010) (no undue delay or prejudice when there was no scheduling order and discovery was “nascent.”); [Micron Tech., Inc. v. Rambus Inc.](#), 409 F. Supp. 2d 552, 559 (D. Del. 2006) (no undue delay or prejudice when there was no trial date and discovery schedule could be modified); *see also* Wright R. Miller, 9 [Fed. Prac. & Proc. Civ. § 1510](#) (collecting authority indicating “[u]ndue or further delay of the action when other parties are prepared to proceed to a determination of the original action also has been put forward to justify denying leave to file a supplemental pleading”). For example, in [MOSAID Techs.](#), the court denied a motion to supplement when the case was on the eve of trial and the plaintiff sought to add a new theory of liability based on later events and the defendants sought to add new defenses and counterclaims. [2014 WL 3361924](#) at *1.

Here, this matter proceeded to trial on an ANDA track and the parties expended substantial resources engaging in discovery, presenting evidence, prosecuting an appeal, and creating a record for the Court to determine Astellas's entitlement to injunctive relief related to the Generics Manufacturers' ANDAs. At this stage, switching gears to a traditional infringement theory would require the parties to address evidence of infringement based on the actual product rather than the ANDA, engage in expert

discovery, assess damages, develop a factual record regarding the Generics Manufacturers' launch of their competing mirabegron formulation, and hold a jury trial on the newly raised issues. *Id.* (recognizing that supplementation will involve a response from the opposing party, discovery, and motion practice, delaying resolution of the case). Overall, this case is analogous to *MOSAID Techs.* because it is close to the finish line and Astellas's proposed amended complaint and the Generics Manufacturers' defenses would bring the parties back to the pleadings stage on key issues, delaying resolution of this case for months or years. This case proceeded to trial as an ANDA case, the Court has the record to rule on ANDA relief, and the Court is prepared to resolve it as an ANDA case. Overall, Astellas's proposed supplement will fundamentally change the case that was shaped by the parties at a late stage in the litigation, cutting against supplementation and cutting in favor of resolving claims related to the Generics Manufacturers' product launch in a separate action.

This determination is consistent with the mandate from the Federal Circuit, who envisioned a limited role for the Court on remand. Specifically, the panel spent a large portion of the order explaining the litigation choices made, the issues that went to trial, and instructed the Court to "adjudicate[e] the case as it was shaped by the parties." See [Astellas Pharma, Inc., 2024 WL 4219374](#) at *3, *7 (emphasis added). The panel further limited the Court's inquiry on remand to "infringement and validity under 35 U.S.C. § 112" the grounds that the parties' disputes narrowed to before trial. *Id.* at *6. In denying Astellas's motion to reassign the panel instructed the Court to "resolve the outstanding issues" by taking "an objective measured, and thorough look into the legal issues and *evidence of record.*" *Id.* at *7 (emphasis added). Taken together, these sections indicate

that the panel envisioned a limited remand to address the specific contentions shaped by the parties' prior litigation choices and did not envision a fundamental shift in the issues or evidence in this matter. The parties shaped this dispute in a particular way, as an ANDA dispute, and the Federal Circuit wants the Court to resolve it on those terms.

This does not mean Astellas is without remedy for the Generics Manufacturers' decision to bring their allegedly infringing products to market. Astellas is welcome to file a traditional infringement action, where it can shape discovery and scope of relief as necessary and pursue a jury trial on damages without delaying final judgment on its entitlement to injunctive relief under ANDA. No doubt the Court's decision in the instant ANDA litigation may bear on the justiciability of a subsequent infringement action, but no more than it would if the Generics Manufactures began marketing subsequent to any ANDA decisions by this Court.

B. Astellas's Jury Trial Demand

The Court next turns to the scope of Astellas's jury trial right. The Court divides its discussion into two categories: (1) issues raised in Astellas's proposed amended complaint, and (2) issues tried to the Court in the previous bench trial.

Astellas has a right to a jury trial regarding the issues raised in its proposed amended complaint. Astellas asserts a claim for infringement damages, the quintessential legal remedy. See [Tegal Corp. v. Tokyo Electron Am., Inc.](#), 257 F.3d 1331, 1340 (Fed. Cir. 2001). Moreover, should Astellas file a traditional infringement action it will be able to make a timely demand for a jury trial. Fed. R. Civ. P. 38. Therefore, this order has no impact on Astellas's right to a jury trial on these issues, it only requires Astellas to exercise that right in a separate action.

By contrast, Astellas is not entitled to a jury trial on the issues tried to the Court by bench trial, including ANDA infringement, entitlement to an injunction under [35 U.S.C. § 271\(e\)\(4\)](#), and validity under [35 U.S.C. § 112](#). Caselaw is instructive. In *In Re Andrx Pharma, Inc.*, the parties went to trial in an ANDA posture and the district court's judgment on infringement and validity was affirmed by the Federal Circuit. *In re Andrx Pharms., Inc.*, [399 F. App'x 582, 583 \(Fed. Cir. 2010\)](#). On remand, the innovative manufacturer added a claim for infringement damages and the generics manufacturer sought mandamus from the Federal Circuit. *Id.* at [584](#). It claimed the addition of legal relief violated its right to a jury trial because, had the innovative manufacturer sought damages earlier, it would have had the right to a jury trial on infringement and validity. *Id.* The Federal Circuit denied mandamus because "there is no right to jury trial that we can preserve by issuing mandamus." *Id.* Specifically, "[t]he infringement and validity trial has already occurred, and Andrx is not entitled to a jury trial on issues already tried during the bench trial on the equitable claims." *Id.* The Third Circuit has held similar. *Fenstermacher v. Philadelphia Nat. Bank*, [493 F.2d 333, 338 \(3d Cir. 1974\)](#) (holding that plaintiff waived his right to a jury trial by "solicit[ing] . . . a final adjudication" in injunctive proceedings); *Robinson v. Johnson*, [449 F. App'x 205, 207 \(3d Cir. 2011\)](#) (similar). Indeed, the Federal and Third Circuits' conclusions are consistent with Courts around the country who have determined that a party waives its Seventh Amendment right to a jury trial by submitting issues to a bench trial without objection. See e.g., *Royal Am. Managers, Inc. v. IRC Holding Corp.*, [885 F.2d 1011, 1018 \(2d Cir. 1989\)](#) (holding participation in a jury trial without objection waives right to a jury trial); *Edmo v. Corizon, Inc.*, [935 F.3d 757, 802 \(9th Cir. 2019\)](#) (holding defendant waived its right to a jury trial by "vigorously participat[ing]"

in equitable proceedings and that participation “waived the [defendant's] right to a jury trial with respect to issues common to [plaintiff's] request for an injunction”).

Here, Astellas made the decision to treat this case as an ANDA case and move forward to a trial on the merits in front of the Court, seeking a final judgment and injunctive relief. This was not a careless decision, but a matter of strategy. Choosing to proceed to a bench trial allowed Astellas an opportunity to resolve its infringement claims before the Generics Manufacturers entered the market and before it suffered economic harm resulting from their alleged infringement. At no point during the lead up to the bench trial, did Astellas object to the bench trial, wait for its legal remedies to ripen, or indicate it would prefer to have infringement and validity decided by a jury. Therefore, Astellas “actively solicited a final adjudication” of ANDA infringement and validity by the Court, waiving its right to a jury trial on those issues. [Fenstermacher, 493 F.2d at 338](#). Though Astellas may now regret its litigation strategy, the Seventh Amendment does not require “a second bite at the apple.” [Edmo, 935 F.3d at 802](#). Therefore, *Andrx Pharma, Inc.* controls because “[t]he infringement and validity trial has already occurred, and [Astellas] is not entitled to a jury trial on issues already tried during the bench trial on the equitable claims.” [399 F. App'x at 583](#).

Astellas attempts to distinguish *Andrx Pharma, Inc.* arguing the case involved findings of fact and conclusions of law that were affirmed by the Federal Circuit, while here, the Court was reversed. [D.I. 629 at 4](#). This is a distinction without a difference. The determinative fact in *Andrx Pharma, Inc.* was that the “[t]he infringement and validity trial has already occurred” not that the judgment was affirmed on appeal. [399 F. App'x at 583](#). Likewise, in determining whether a party waived their right to a jury trial, the focus

of the courts is the litigant's conduct, not the status of the judgment itself. See [Fenstermacher](#), 493 F.2d at 338 (focusing on the act of soliciting resolution by the court). Indeed, the leading federal procedure treatise recognizes “[o]nce the opportunity to demand a trial has been waived, the right is not revived by a reversal on appeal.” Wright R. Miller, 9 [Fed. Prac. & Proc. Civ. § 2321](#). Therefore, the Federal Circuit’s reversal did not affect Astellas’s waiver of its right to a jury trial on the issues submitted to the Court.

The Court retains discretion to retry the case with an advisory jury under Rule 39(c) but declines to do so because an advisory jury would not aid the timely and effect disposition of this case.² The decision to try a case with an advisory jury is discretionary. [Koninklijke Philips N.V. v. Hunt Control Sys., Inc.](#), No. CV113684SRCCLW, 2016 WL 6892079, at *4 (D.N.J. Nov. 21, 2016). Here, the Court concludes where the parties have created a record on infringement and validity, the Federal Circuit did not order a new trial on remand, and retrial would be expensive and time consuming for the Court and the parties, retrial with an advisory jury is not warranted.

CONCLUSION

For the reasons stated above, IT IS ORDERED:

1. Astellas’s Motion to Supplement ([D.I. 620](#)) is denied. This order does not preclude Astellas from raising these issues in a related case.

² Rule 39(b) does not provide authority to order a jury trial, notwithstanding Astellas’s waiver, because, given the Court’s decision on the supplementation issue, only claims for injunctive relief remain in this litigation, meaning there is no “issue for which a jury might have been demanded” had Astellas filed a timely request for a jury trial back in 2023. [Tegal Corp.](#), 257 F.3d at 1341 (finding no jury issue in a case seeking only injunctive relief).

2. Astellas's request for a jury trial on issues previously tried to the Court denied.
This order does not preclude Astellas from requesting a jury trial in a related case.
3. Within 14 days of this order the Parties will simultaneously file briefing addressing any pertinent changes in law that have occurred since the parties' post-trial briefing. The parties may file a response any time before the scheduled hearing.
4. The parties shall inform the Court of their availability for a hearing in Wilmington, between November 7, 2024, and November 15, 2024. At the hearing, the parties will present closing argument on the legal and factual issues raised in the 2023 bench trial.

Dated this 22nd day of October, 2024.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge