IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., *et al.* Plaintiffs, v. ZYDUS, INC., *et. al.* Defendants.	**1:20CV1589** **MEMORANDUM AND ORDER**

This matter is before the Court on the Generics Manufacturers[1] Motion for Relief from Stipulation.[2] D.I. 732. This is a consolidated patent infringement case involving several patents covering the overactive bladder drug Myrbetriq® set for trial in early 2026. The parties' current dispute involves one of these patents—United States Patent No. 10,842,780 ("'780 Patent"). The validity of the '780 Patent was previously tried to the bench in 2023. Before trial, the parties entered a case-narrowing stipulation in which the Generics Manufacturers limited their validity arguments to enablement, written description, and indefiniteness. Now they want out. The Court—in the interest of avoiding conflicting outcomes in the consolidated litigation—will let them.

BACKGROUND

The parties are intimately familiar with the background of this litigation, discussed at length in the Court's prior orders. D.I. 631; D.I. 652.

The '780 Patent action against Lupin and Zydus is the oldest case in the consolidated Myrbetriq® litigation. Astellas sued based on the Generics Manufacturers' ANDA filing and sought to enjoin them from entering the market. D.I. 1. In the leadup to

[1] Defendants Lupin and Zydus.
[2] Astellas's Motion to File a Sur-Reply (D.I. 793) is granted. The Court considered the arguments raised in Astellas's sur-reply.

the 2023 bench trial, the parties exchanged validity discovery on enablement, written description, indefiniteness, and obviousness. The month before trial, and on the clock, the parties agreed to a case-narrowing stipulation. Relevant here, Defendants stipulated that they would "not present any evidence on or assert as a defense at trial that the Asserted Claims are invalid for failing to comply with 35 U.S.C. § 103."[3] D.I. 505.

At trial, the Generics Manufacturers presented evidence and argument regarding enablement, written description, and indefiniteness. *See* D.I. 793. After trial the Court granted judgment as a matter of law to the Generics Manufacturers on other grounds. D.I. 571. While the case was on appeal, Lupin and Zydus launched their allegedly infringing product. D.I. 652 at 2. The Federal Circuit reversed. *Astellas Pharma, Inc. v. Sandoz Inc.*, 117 F.4th 1371, 1379 (Fed. Cir. 2024).

On remand, the parties disagreed on how to proceed. Astellas argued for a new trial before a jury based on the changed factual circumstances triggered by the Generics Manufacturers' product launch. D.I. 631. The Generics Manufacturers argued the Court should decide all issues litigated at the bench trial. *Id.* Ultimately, the Court took a middle path—deciding the validity issues litigated at the bench trial and leaving infringement and damages for a jury trial. D.I. 652. In its post-trial Findings of Fact and Conclusions of Law, the Court rejected the Generics Manufacturers' enablement, written description, and indefiniteness arguments. D.I. 793.

[3] 35 U.S.C. § 103 provides "[a] patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains."

At the same time, the Court consolidated the '780 action with suits related to other Myrbetriq® patents. D.I. 652 at 9–11. The goal of consolidation was to ensure an orderly and consistent adjudication of the issues related to Myrbetriq® across patents and parties. *Id.* Relevant here, one of the patents in suit in the consolidated case—U.S. Patent 12,059, 409 (the '409 Patent)—shares the same specification with the '780 Patent but recites narrowed claims. Likewise, other Defendants in the consolidated case, Ascent and MSN, plan to assert an obviousness defense at a bench trial in November 2025. The parties are currently conducting expert discovery in the consolidated litigation.

Against this backdrop, Lupin and Zydus wish to discard their prior stipulation and argue obviousness under 35 U.S.C. § 103 at the jury trial in February, 2026. D.I. 732.

LEGAL STANDARD

A stipulation is a valuable tool "to promote judicial economy by narrowing the issues in dispute during litigation." *Waldorf v. Shuta*, 142 F.3d 601, 616 (3d Cir. 1998).[4] As such "it is a well-recognized rule of law that valid stipulations entered into freely and fairly, and approved by the court, should not be lightly set aside." *Id.* (internal quotations omitted). But "in spite of the severe limitations placed on withdrawing stipulations, they are not absolute, and courts can grant parties relief from them." *Id.*

To decide whether to relieve the Generics Manufacturers of their stipulation the Court may consider: "(1) the effect of the stipulation on the party seeking to withdraw the stipulation . . .; (2) the effect on the other parties to the litigation . . . [and]; (3) the

[4] This issue turns on general procedural law that is not unique to patent law, so the law of the regional circuit applies. *Wordtech Sys., Inc v. Integrated Networks Sols., Inc.*, 609 F.3d 1308, 1318 (Fed. Cir. 2010).

occurrence of intervening events since the parties agreed to the stipulation." *Id.* at 617–18.[5] At bottom, this is a discretionary determination. *Id.* at 616.

DISCUSSION

Lupin and Zydus are allowed to withdraw their case-narrowing stipulation.

As a preliminary matter, the Federal Circuit's mandate does not prevent the Court from reliving Lupin and Zydus of their stipulation. "[T]he mandate rule 'forecloses reconsideration of issues implicitly or explicitly decided on appeal.'" *TecSec, Inc. v. Int'l Bus. Machines Corp.*, 731 F.3d 1336, 1341–42 (Fed. Cir. 2013). Astellas primarily relies on a statement in the background section where the panel wrote "[t]hen, on February 1, 2023, the parties filed a joint stipulation in which Astellas agreed to assert only claims 5, 20, and 25 of the '780 patent, while Sandoz agreed to limit its invalidity defenses to only those arising under § 112. J.A. 6591–93. Accordingly, in the days leading up to trial, Sandoz waived any challenge to the asserted claims arising under §§ 102 and 103." *Astellas Pharma, Inc.*, 117 F.4th at 1376. In context, the panel was describing the way the parties shaped the litigation to explain why the Court messed up in straying from their presentation. *See id.* at 1379 ("[T]he district court abused its discretion in holding the asserted claims invalid under 35 U.S.C. § 101, a ground not invoked by Sandoz . . ..") And the panel was (correctly) explaining that the stipulation limited the validity theories before the Court at trial. The panel was not asked to address and did not address whether the Generics Manufactures could seek relief from the stipulation before the Court. *See generally Astellas Pharma, Inc.*, 117 F.4th 1371 (addressing only the party presentation principle as grounds for reversal). In other words, the Federal Circuit did not "implicitly or

[5] Other factors apply only to factual stipulations and need not be discussed here.

explicitly" decide that Lupin and Zydus had always and forever waived an obviousness challenge. *TecSec, Inc.*, 731 F.3d at 1341–42. Assured that this issue was not decided by the Federal Circuit, the Court turns to the *Waldorf* factors.

Prejudice to the Generics Manufacturers. Maintaining the stipulation in the consolidated case creates two specific risks to the Generics Manufacturers (and Astellas for that matter). One, following the stipulation risks inconsistent results between defendants and patents. Specifically, two defendants, MSN and Ascent, are already raising an obviousness challenge '780 Patent. If the Court were to find the '780 Patent invalid, it would create an odd situation in which a patent is invalid for one defendant and valid for another. Not only that but Lupin and Zydus are raising an obviousness challenge to the '409 Patent, meaning the jury could come to diverging verdicts on what is, for obviousness purposes, the same patent. A divergence between parties and patents would be unfair to the Generics Manufacturers. Two, following the stipulation encourages unproductive satellite litigation. Lupin and Zydus have suggested that if they are not able to proceed here, they will file a new case for declaratory relief—unbounded by the stipulation. And, if Ascent and MSN succeeds at their bench trial or the jury buys Lupin and Zydus's obviousness arguments, the parties will litigate this issue over again. Finally, if the Court prevents Lupin and Zydus from arguing obviousness and the Federal Circuit reverses, there is a real possibility of a fourth trial on the '780 Patent. Overall, following the stipulation engenders a messier procedural environment and wasted resources for all parties, including Astellas. This unfairness supports reliving Lupin and Zydus of their stipulation.

Prejudice to Astellas. On the other side of the ledger, Astellas faces minimal prejudice. Obviousness is not new. The parties created a record on it in 2022 and 2023, including expert discovery, and Astellas was prepared to go to trial against that theory. Indeed, Astellas is defending against an obviousness challenge to a member of the same patent family and an obviousness challenge to the *same* patent in the consolidated litigation. And obviousness is determined based on the prior art at the time of the Patent's effective date, meaning there cannot have been prejudicial changes to the state of the art in the interim. This is not a situation in which a party seeks to inject a novel or underdeveloped issue that requires the other party to fundamentally change its trial strategy or engage in burdensome and unexpected discovery. *Contrast Waldorf*, 142 F.3d at 616 (affirming denial of a motion to withdraw a stipulation to liability shortly before trial); *Allergan, Inc. v. Mankind Pharma Ltd.*, No. CV 23-272, 2024 WL 4213722, at *1–2 (D. Del. July 22, 2024) (denying reintroduction of validity when no discovery had taken place on validity and fact discovery closed). This litigation looks the same after reliving Lupin and Zydus of the stipulation—just with one more patent number on the expert reports and jury instructions.[6] Under these atypical circumstances, Astellas does not face significant prejudice from the reintroduction of obviousness—favoring relief from the stipulation.

Changes in Circumstances.[7] Finally, the Myrbetriq® litigation looks different than it did when the Parties entered their pretrial stipulation. At the time of the stipulation, the Generics Manufacturers were litigating a single patent in an ANDA posture. Now, they

[6] The Court is cognizant of Astellas's concern that Lupin and Zydus are using this motion to lay groundwork for a later request to delay trial. To be clear: the Court will not entertain changes to the trial schedule based on this issue. Obviousness discovery for the '780 and '409 Patents is largely coextensive and if Lupin and Zydus want to pursue this theory, they should be ready to litigate it on the existing schedule.

[7] The briefing on this point was not especially helpful because both sides spent most of their pages relitigating who was at fault for the change in circumstances for infringement – an issue that was settled back in December. D.I. 652.

are facing a consolidated case involving four patents. Thus, the litigation today implicates new uniformity concerns that were not present when Lupin and Zydus entered the stipulation. So, the litigation has expanded in such a way that merits revisiting the stipulation.

CONCLUSION

This issue is a close call. Ultimately, the unfairness associated with potential inconsistent outcomes between patents and defendants outweighs the prejudice of litigating an issue that is already a part of the consolidated litigation. In the interest of a uniform and clean resolution of the Myrbetriq® litigation, IT IS ORDERED:

1. Defendants' Motion to Clarify or Provide Relief from Stipulation, D.I. 732, is granted.
2. Plaintiff's Motion to File a Sur-Reply, D.I. 793, is granted.

Dated this 30th day of May, 2025.

BY THE COURT:

s/ Joseph F. Bataillon
Senior United States District Judge