UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VILOXAZINE

Civil Action No. 25-12183 (MEF) (MAH)

OPINION

The non-Zydus Defendants,[1] through Defendants Zenara Pharma Private Limited and Biophore Pharma Inc., seek leave to amend their invalidity contentions and join the Zydus Defendants' contentions for the method-of-treatment patents. June 10, 2026 Letter from Non-Zydus Defendants, D.E. 111. Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus" or "Plaintiff") opposes the request on two grounds: (1) the non-Zydus Defendants have not demonstrated good cause or adequate diligence; and (2) the amendment would significantly prejudice Supernus. June 10, 2026 Letter from Supernus, D.E. 112, at 4-5. The Court considers the request to amend invalidity contentions without oral argument pursuant to Federal Rule of Civil Procedure 78 and Local Civil Rule 78.1. For the reasons set forth below, the non-Zydus Defendants' request to amend is denied.

[1] The Zydus Defendants are Zydus Lifesciences Global FZE, Zydus Lifesciences Limited, and Zydus Pharmaceuticals (USA) Inc. D.E. 111 at 1 n.1.

The non-Zydus Defendants are as follows: (1) Appco Pharma LLC and Somerset Therapies LLC; (2) Apotex Inc.; (3) Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc.; (4) MacLeods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc.; (5) MSN Pharmaceuticals Inc.; and (6) Zenara Pharma Private Limited and Biophore Pharma Inc. *Id.*

I. BACKGROUND

Defendants in the present actions are Appco Pharma LLC and Somerset Therapeutics LLC; Apotex; Aurobindo Pharma Limited and Aurobindo Pharma U.S.A., Inc.; Creekwood Pharmaceuticals, LLC; MSN Pharmaceuticals Inc.; Zenara Pharma Private Limited and Biophore Pharma Inc.; Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. (collectively, the "non-Zydus Defendants"); and Zydus Lifesciences Global FZE, Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited (collectively, "Zydus" or the "Zydus Defendants") (together, "Defendants"). Joint Discovery Plan, D.E. 36, at 4. Supernus brought the current patent infringement actions against Defendants under the Hatch-Waxman Act based on Paragraph IV notices sent by each of the Defendants. *Id.*

These consolidated actions originate from Abbreviated New Drug Applications ("ANDAs") submitted to the Food and Drug Administration ("FDA") by Defendants seeking to sell generic versions of Qelbree® before the expiration of U.S. Patent Nos. 9,358,204 ("the '204 patent"); 9,603,853 ("the '853 patent"); 9,662,338 ("the '338 patent"); 11,324,753 ("the '753 patent"); 11,458,143 ("the '143 patent"); and 12,121,523 ("the '523 patent") (collectively, "the patents-in-suit"). Compl., D.E. 1, at 1-2.

Supernus markets Qelbree® (extended-release capsules of viloxazine in strengths of 100 mg, 150 mg, and 200 mg). Qelbree® is an FDA-approved treatment for ADHD in adults and children aged 6 and older. *Id.* at 9-10. There are six patents listed in the FDA's Orange Book that cover Qelbree®. *Id.* at 10. The patents fall into two groups: (i) the formulation patents (*i.e.*, the '204, '853, and '338 patents) and (ii) the method-of-treatment patents (*i.e.,* the '753, '143, and '523 patents). *Id.* at 10-11. The drug received FDA approval on April 2, 2021, and was granted a five-year new chemical entity exclusivity set to expire on April 2, 2026. Joint

Discovery Plan, D.E. 36, at 5-6. However, the standard 30-month stay is extended in the present case to allow seven-and-one-half years to elapse from the approval date. The extended stay is because viloxazine qualifies as a new chemical entity, and patent litigation was filed during the one-year window beginning forty-eight months after approval. *Id.* Therefore, each stay runs through October 2, 2028. *Id.*

Supernus filed suit against the non-Zydus Defendants on dates ranging from June 26, 2025, to December 16, 2025, for infringements of all six of the patents-in-suit, *i.e.*, both the formulation and method-of-treatment patents. *See generally* Civil Action Nos. 25-12183, 25-12184, 25-12186, 25-13201, 25-13204, 25-13207, 25-15399, 25-18683. Plaintiff first filed suit against Zydus on June 26, 2025, but alleged infringements as to only the formulation patents. *See generally* Civil Action No. 25-12188.

The Court held a scheduling conference on December 17, 2025, and entered a Pretrial Scheduling Order on December 18, 2025, Pretrial Scheduling Order, D.E. 38. The Court consolidated these actions for pretrial purposes[2] on December 23, 2025. Consolidation Order, Dec. 23, 2025, D.E. 40.

On March 5, 2026, the Court entered an Amended Scheduling Order that, *inter alia*, directed Defendants to serve any invalidity contentions by March 10, 2026. Amended Scheduling Order, Mar. 5, 2026, D.E. 68, at 3-4. Defendants worked together to submit joint invalidity contentions on March 10, 2026. D.E. 111, at 1-2; D.E. 112, at 2. At that time, however, Supernus had not brought suit against Zydus for the method-of-treatment patents.

[2] Supernus sought consolidation for both pretrial purposes and trial. Joint Discovery Plan, Dec. 15, 2025, D.E. 36, at 3. The Defendants agreed only to consolidation for pretrial purposes. *Id.* The Amended Scheduling Order allows the parties "the right to seek consolidation of these cases for the purposes of trial at a later date." Consolidation Order, Dec. 23, 2025, D.E. 40, at 4 n.1.

Therefore, the non-Zydus Defendants worked on and jointly served the contentions for the method-of-treatment patents without Zydus's input. *Id.*

On April 2, 2026, Supernus sued Zydus for infringement of the three method-of-treatment patents. *See generally* Civil Action No. 26-3543. On May 5, 2026, that suit and the above-mentioned actions were consolidated into the current action. Consolidation Order, D.E. 96. After Zydus was sued on the method-of-treatment patents, it served invalidity contentions regarding those patents on May 6, 2026. D.E. 111, at 2; D.E. 112, at 2. Although these contentions overlap considerably with the joint invalidity contentions, they assert additional invalidity theories, namely for patents that included the Martin, Pataki, and Spencer references. D.E. 112, at 2.

On May 8, 2026, the non-Zydus Defendants sought Supernus's consent to adopt the Zydus contentions. D.E. 111, at 2; D.E. 112, at 2. The additional contentions consist of three prior-art references and associated obviousness theories. Letter, June 2, 2026, D.E. 107, at 1. But Supernus would not consent, and so on June 10th, the parties filed the instant dispute letters concerning the non-Zydus Defendants' request to amend their contentions.

The non-Zydus Defendants argue there is good cause to permit them to amend their invalidity contentions. They contend that the joint invalidity contentions would have included the additional invalidity contentions the Zydus Defendants assert as to the method-of-treatment patents, had Supernus already alleged that the Zydus Defendants infringed the method-of-treatment patents. The non-Zydus Defendants also contend that permitting them to adopt the Zydus Defendants' amendments will not protract these proceedings because Supernus must address them as to the Zydus Defendants in any event. D.E. 111, at 3. In fact, the non-Zydus Defendants assert that denying their proposed amendment would fragment this action because

the differing invalidity contentions might require different experts and corresponding reports and depositions. *Id*. By contrast, the non-Zydus Defendants assert that allowing them to adopt the Zydus contentions will return the action to the position that consolidation purported to achieve. *Id*. at 3-4. In that regard, the non-Zydus Defendants observe that Supernus had already agreed to one set of contentions from all Defendants in order to streamline the case. *Id.* Further, they point to the early stage of the litigation and argue that the application for the amendment is timely. *Id.* at 2-3.

Supernus argues that the non-Zydus Defendants have not established good cause for the proposed amendment under Local Patent Rule 3.7. D.E. 112, at 3-4. Supernus emphasizes that the new prior-art references and associated obviousness theories are based entirely on public information and were readily available to the non-Zydus Defendants, as they were to Zydus. *Id.* at 1, 4. In response to the non-Zydus Defendants' argument that allowing the amendment now facilitates coordination of the consolidated actions, Supernus observes that it previously consented to a one-week extension to serve invalidity contentions to allow the Defendants to coordinate and streamline their contentions. *Id.* at 4. Supernus also argues that allowing the non-Zydus Defendants to adopt the additional Zydus contentions would prejudice it because it would add new invalidity theories into six separate trials. *Id.*

II. LEGAL STANDARD

The Local Patent Rules for the District of New Jersey require early disclosure of the patentee's infringement contentions and the alleged infringer's invalidity contentions. *Sanofi-Aventis v. Barr Lab'ys, Inc.*, 598 F. Supp. 2d 632, 637 (D.N.J. 2009) (describing the disclosure requirements as something that must be disclosed "*ultra* early" (emphasis in original)). One salient purpose of such early disclosure is "to further the goal of full, timely discovery and

provide all parties with adequate notice and information with which to litigate their cases." *King Pharms., Inc. v. Sandoz Inc.*, No. 08-5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010) (quoting *Comp. Accelerations Corp. v. Microsoft Corp.*, 503 F. Supp. 2d 819, 822 (E.D. Tex 2007)) (internal quotations omitted). The rules "are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *King Pharms.*, 2010 WL 2015258, at *4 (citing *Atmel Corp. v. Info. Storage Devices, Inc.*, No. 95-1987, 1998 WL 775115, at *2 (N.D. Cal. Nov. 5, 1998)) (internal quotations omitted); *see also Shire LLC v. Amneal Pharma. LLC,* Civ. No. 11-3781, 2013 WL 6858953, at *2 (D.N.J. Dec. 26, 2013) ("Amendments to infringement and invalidity contentions are not granted as liberally as requests for amendments to pleadings, in part, because 'the philosophy behind amending claim charts is decidedly conservative and designed to prevent the "shifting sands' approach,' to a party's contentions . . . . Particularly, in the District of New Jersey, the Local Patent Rules emphasize *"ultra* early disclosure of infringement and invalidity contentions for patent cases arising under the Hatch–Waxman Act.") (internal quotations and citations omitted).

Local Patent Rule 3.7 allows for amendment of contentions "*only* by order of the Court upon a timely application and showing of good cause." The Federal Circuit has established that with respect to "good cause," parties must "proceed with diligence in amending those contentions when new information comes to light in the course of discovery." *O2 Micro Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1366-68 (Fed. Cir. 2006). Thus, "[g]ood cause 'considers first whether the moving party was diligent in amending its contentions.'" *Dr. Reddy's Lab'ys*, 2013 WL 1145359, at *3 (quoting *Acer, Inc. v. Tech. Prob. Ltd.*, 2010 WL 3618687, at *3 (N.D. Cal. Sept. 10, 2020)). The moving party bears the burden of establishing

diligence and must prove that it was diligent not only in moving to amend, but also in discovering the grounds for the amendment. *O2 Micro*, 467 F.3d at 1366. The standard of diligence is not satisfied "merely because new evidence was revealed during discovery." *Id.* The moving party must also prove "that it was diligent in its search for relevant prior art." *Jazz Pharms., Inc. v. Roxane Lab'ys, Inc.*, No. 10-6108, 2013 WL 785067, at *3 (D.N.J. Feb. 28, 2013). If the court finds diligence, then it must consider whether the non-moving party would suffer prejudice if the court allows the amendment. *Id.* at *5.

III. ANALYSIS

a. Good Cause

The core issue is whether the non-Zydus Defendants have established good cause for their amendment. The Court finds that the non-Zydus Defendants have failed to do so, and therefore that Local Patent Rule 3.7 compels the Court to deny the request.

Establishing good cause requires a showing of diligence. *O2 Micro*, 467 F.3d at 1366. The "burden is on the movant to establish diligence rather than on the opposing party to establish a lack of diligence." *Id.* The "onus . . . to produce" is not on the Plaintiff, but rather on the Defendants, to "conduct a diligent search for prior art." *Jazz Pharmaceuticals, Inc. v. Roxane Lab'ys*, No. 6108, 2013 WL 785067, at *7 (D.N.J. July 30, 2012). *See also Shire LLC,* 2013 WL 6858953, at *4 (D.N.J. Dec. 26, 2013) (denying amendment where movant provided "no explanation as to why . . . [their] public search failed to uncover the public document").

In this case, the non-Zydus Defendants do little to establish diligence. They neither explain their failure or inability to discovery the prior-art references, nor produce evidence of reasonable measures taken to find the prior art references that Zydus subsequently found and included in its contentions. *See Shire LLC,* 2013 WL 6858953, at *4 (denying request where

defendants failed to conduct a "diligent search for prior art" that "includes taking reasonable measures to review documents relating to the patents-in-suit and tailoring its public search appropriately"). The non-Zydus Defendants' emphasis on coordination falls short for two reasons. First, although coordination among the cases is useful, it does not excuse a defendant's fundamental obligation to conduct a diligent search for prior art and to formulate its invalidity contentions in a timely manner. Second, the non-Zydus Defendants' coordination argument actually highlights Zydus's ability to discover the prior-art references and formulate its invalidity theories within the deadline to do so.[3]

This is not a case where the failure to include the specified prior art was due to the discovery of new information revealed after the non-Zydus Defendants' invalidity contentions were filed. *See*, *e.g.*, *Auxilium Pharms., Inc. v. Watson Lab'ys, Inc.*, No. 12-3084, 2013 WL 12149760, at *4 (D.N.J. Nov. 11, 2013) (defendant showed requisite diligence in prior art search where basis for amendments to contentions for publicly available prior art is knowledge obtained through discovery of plaintiff's "internal, confidential documents"); *Intri-Plex Techs., Inc. v. NHK Int'l Corp.*, No. 17-1097, 2019 WL 920206, at *4 (N.D. Cal. Jan. 15, 2019) (diligence requirement satisfied for proposed amendments where defendants discovered additional prior art references through later document production by plaintiff). Rather, the prior art references at

[3] As set forth above, the non-Zydus Defendants' coordination-versus-fragmentation argument fails in the absence of a demonstration of diligence. But the Court also questions the non-Zydus Defendants' fragmentation argument for logistical reasons. The non-Zydus Defendants contend that if the Court denies the amendment, the parties will present different invalidity theories involving different experts and additional depositions. D.E. 111 at 3. But those additional experts are the result of Zydus's non-overlapping contentions, not denying the amendments, and must still appear in the Zydus matter. Denying the amendment does not expand discovery or the scope of expert testimony. Further, because the cases are not consolidated for trial, those additional experts would appear only in the Zydus trial, if the matters remain separate for trial purposes.

issue had been publicly available and accessible to the non-Zydus Defendants during the period of coordination used to finalize their single set of invalidity contentions.

Although "mistake or inadvertence do not necessarily negate or preclude a finding of good cause," *Fennec Pharms. Inc. v. Cipla Ltd.*, No. 23-123, 2024 WL 4432773, at *5-6 (D.N.J. Oct. 7, 2024), this issue is not a case of mistake and can be distinguished from instances where there is a risk of proceeding with error in the submitted contentions. *See Amgen Inc. v. Kashiv Biosciences, LLC*, No. 18-3347, 2019 WL 5445974, at *3 (D.N.J. Oct. 24, 2019) (finding "it would be a waste of judicial resources to push forward with claim construction as it has been submitted . . . knowing well that it contains what one side claims is an error"). Nor can this be a case of inadvertence, considering the realities of all six Defendants working together with sophisticated and experienced counsel.[4]

IV. CONCLUSION

For the foregoing reasons, the Court denies the non-Zydus Defendants' request to amend their invalidity contentions to adopt the Zydus Defendants' contentions. An Order consistent with this Opinion will issue.

s/ Michael A. Hammer
United States Magistrate Judge

Dated: July 6, 2026

[4] Because the Court finds that the non-Zydus Defendants have not established good cause, the Court need not consider whether allowing the amendments would prejudice Supernus.