

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**IN RE VILOXAZINE**

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

**OPINION & ORDER**

This matter comes before the Court by way of two disputes contained within the parties' February 18, 2026 discovery dispute letters. Letters, D.E.s 57, 58. First, Defendant Apotex Inc. ("Apotex") seeks to prevent Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus") from designating its Senior Vice President Intellectual Property & Chief Scientific Officer, Dr. Padmanabh P. Bhatt ("Bhatt"), as an in-house designee under the Discovery Confidentiality Order ("DCO"), D.E. 57, at 4-5; D.E. 58, at 1-4. Second, Supernus seeks to cross share Defendants' confidential information with other Defendants without the producing defendant's consent, D.E. 57, at 2-4; D.E. 58, at 4-5.

The Court considers the disputes without oral argument pursuant to Federal Rule of Civil Procedure 78 and Local Civil Rule 78.1. For the reasons set forth below, Bhatt may serve as Supernus's in-house designee under the DCO, but confidential information produced by one Defendant may not be disclosed to other Defendants without the producing Defendant's consent.

**I. BACKGROUND**

Supernus brought the instant patent infringement actions under the Hatch-Waxman Act against Defendants Appco Pharma LLC and Somerset Therapeutics LLC (collectively, "Appco");

Apotex; Aurobindo Pharma Limited and Aurobindo Pharma U.S.A., Inc. (collectively “Aurobindo”); Zydus Lifesciences Global FZE, Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited (collectively, “Zydus”); Creekwood Pharmaceuticals, LLC (“Creekwood”); MSN Pharmaceuticals Inc. (“MSN”); Zenara Pharma Private Limited and Biophore Pharma Inc. (collectively, “Zenara”); and Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. (collectively, “Macleods”) (together, “Defendants”). The Court consolidated these actions on December 23, 2025. Consolidation Order, D.E. 40. These consolidated actions stem 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”).

Supernus markets Qelbree® (viloxazine extended-release capsules in 100 mg, 150 mg, and 200 mg strengths), an FDA-approved treatment for ADHD in adults and children aged 6 and older. Six patents covering Qelbree® are listed in the FDA’s Orange Book. The drug received FDA approval on April 2, 2021, and was granted five-year new chemical entity exclusivity expiring April 2, 2026. Because viloxazine qualifies as a new chemical entity and patent litigation was filed during the one-year window beginning 48 months after approval, the standard 30-month stay is extended to allow seven and a half years from the approval date to elapse.

Thus, each stay runs through October 2, 2028.<sup>1</sup>

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<sup>1</sup> In Civil Action No. 25-12183, *Supernus v. Appco Pharma LLC and Somerset Therapeutics LLC*, Appco filed ANDA No. 220326 seeking FDA approval to manufacture and market generic viloxazine extended-release capsules (100 mg, 150 mg, and 200 mg) prior to expiration of the Orange Book patents. Appco and Somerset notified Supernus by letter on May 21, 2025 of their Paragraph IV certification against the patents-in-suit. Supernus responded by filing suit on June

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26, 2025, asserting infringement of six patents and seeking injunctive relief. On September 22, 2025, the defendants answered with defenses of noninfringement and invalidity and filed counterclaims seeking declarations to the same effect. Supernus answered those counterclaims on October 28, 2025.

In Civil Action No. 25-12184, *Supernus v. Apotex, Inc.*, Apotex filed ANDA No. 220456 seeking approval for the same three strengths of generic viloxazine and sent Supernus a Paragraph IV notice letter on May 22, 2025. Supernus filed suit on June 26, 2025, asserting infringement of the same six patents and seeking injunctive relief. Apotex answered on September 19, 2025, raising multiple affirmative defenses including noninfringement, invalidity, lack of standing, no basis for injunctive relief, and no exceptional case, and also filed counterclaims for declarations of noninfringement and invalidity. Supernus answered the counterclaims on October 24, 2025.

In Civil Action No. 25-12186, *Supernus v. Aurobindo Pharma Ltd. and Aurobindo Pharma U.S.A., Inc.*, Aurobindo filed ANDA No. 220487 for the same generic viloxazine formulations and provided Paragraph IV notice on May 29, 2025. Supernus sued on June 26, 2025 for infringement of the six patents-in-suit, seeking injunctive relief. Aurobindo answered on August 29, 2025, asserting defenses of noninfringement, invalidity, and failure to state a claim for exceptional case.

In Civil Action No. 25-12188, *Supernus v. Zydus Lifesciences Global FZE, Zydus Pharms. (USA) Inc., and Zydus Lifesciences Ltd.*, Zydus filed ANDA No. 220545 for generic viloxazine capsules, challenging only three of the six patents, the '204, '853, and '338 patents. A Paragraph IV notice letter was sent to Supernus on May 27, 2025, though the parties dispute which Zydus entity filed the ANDA and sent the notice. Supernus filed suit on June 26, 2025 for infringement of those three patents. Zydus answered on September 22, 2025 with defenses of noninfringement and invalidity and counterclaimed for declarations of the same. Supernus answered the counterclaims on October 28, 2025.

In Civil Action No. 25-13201, *Supernus v. Creekwood Pharm., LLC*, Creekwood filed ANDA No. 220277 for the 100 mg and 200 mg strengths of generic viloxazine and notified Supernus by Paragraph IV letter on June 4, 2025. Supernus filed suit on July 11, 2025, asserting infringement of the six patents-in-suit and seeking injunctive relief. On September 19, 2025, Creekwood answered with several affirmative defenses including noninfringement, invalidity, and lack of subject matter jurisdiction, and filed counterclaims seeking a declaration of noninfringement across all patents and invalidity of three of the six. Supernus answered on October 24, 2025.

In Civil Action No. 25-13204, *Supernus v. MSN Pharm. Inc.*, MSN filed ANDA No. 220551 for all three strengths of generic viloxazine and sent a Paragraph IV notice on June 5, 2025. Supernus sued on July 11, 2025 for infringement of all six patents, seeking injunctive relief. MSN answered on September 22, 2025 with defenses including noninfringement, invalidity, no exceptional case, and safe harbor under 35 U.S.C. § 271(e)(1), along with counterclaims for declarations of noninfringement and invalidity. Supernus answered the counterclaims on October 28, 2025.

On February 18, 2026, the parties filed discovery dispute letters concerning two issues that had arisen in drafting the Discovery Confidentiality Order. First, Apotex seeks to prevent Supernus from designating Bhatt, as an in-house designee. Letters, D.E. 57, at 4-5; D.E. 58, at 1-4. Supernus designated Bhatt its Senior Vice President of Intellectual Property and Chief Scientific Officer as its in-house designee under the DCO. Bhatt has overseen and managed all of Supernus's patent litigation for more than a decade. All Defendants, with the exception of

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In Civil Action No. 25-13207, *Supernus v. Zenara Pharma Priv. Ltd. and Biophore Pharma Inc.*, Zenara filed ANDA No. 220376 for all three strengths and sent Paragraph IV notice on June 9, 2025. Supernus filed suit on July 11, 2025, asserting infringement of all six patents and seeking injunctive relief. Zenara answered on September 16, 2025, raising defenses of noninfringement, invalidity and/or unenforceability, prosecution history estoppel, failure to state a claim, no exceptional case, and no injunctive relief.

In Civil Action No. 25-15399, *Supernus v. Macleods Pharm. Ltd. and Macleods Pharma USA, Inc.*, Macleods filed ANDA No. 220570 for the 150 mg and 200 mg strengths of generic viloxazine and sent Paragraph IV notice on August 1, 2025. Supernus filed suit on September 9, 2025, for infringement of all six patents, seeking injunctive relief. Macleods answered on September 29, 2025, with defenses of noninfringement, invalidity and/or unenforceability, lack of subject matter jurisdiction, failure to state a claim, and prosecution history estoppel, along with counterclaims for declarations of noninfringement and invalidity. Supernus answered the counterclaims on November 3, 2025.

In Civil Action No. 25-18683, *Supernus v. Macleods Pharm. Ltd. and Macleods Pharma USA, Inc.*, Macleods filed ANDA No. 220570 for the 100 mg of viloxazine and sent Paragraph IV notice on November 20, 2025. Supernus filed suit on December 16, 2025, for infringement of all six patents-in-suit. Macleods filed an answer on January 23, 2026, asserting defenses of noninfringement, invalidity and/or unenforceability, lack of subject matter jurisdiction, failure to state a claim, and prosecution history estoppel, along with counterclaims for declarations of noninfringement and invalidity. Supernus filed an answer to the counterclaims on February 27, 2026.

On May 5, 2026, a tenth action was consolidated, Civil Action No. 26-3543, *Supernus v. Zydus Lifesciences Global FZE, Zydus Pharms. (USA) Inc., and Zydus Lifesciences Ltd.*, Zydus filed ANDA No. 220545 for generic viloxazine capsules, challenging only three of the six patents-in-suit, the '753, '143, and '523 patents. Supernus filed suit on April 2, 2026. Zydus filed an answer on April 14, 2026, asserting defenses of noninfringement and invalidity, along with counterclaims for declarations of noninfringement and invalidity. Supernus filed an answer to the counterclaims on April 23, 2026.

Apotex, have consented to the designation. Supernus argues Apotex lacks a basis to block the designation because: (1) Bhatt has received confidential information in prior patent cases without any problems; (2) Supernus represents Bhatt will not participate in competitive decision-making that could potentially harm Apotex; and (3) Although Bhatt is a co-inventor on some patents, he will not participate in patent prosecution related to this case. To address Apotex's concerns, Supernus agreed to a broad prosecution bar such that Bhatt's access would be limited to Defendants' ANDAs and related technical materials. Supernus also contends that preventing Bhatt from serving as the designee would interfere with its ability to manage the litigation, because he is responsible for overseeing the company's patent disputes and coordinating with outside counsel. Supernus further notes that Apotex previously allowed Bhatt to review its confidential ANDA information in another case, which it argues undercuts Apotex's objection.

Apotex objects to allowing Bhatt to receive highly confidential information. Apotex argues the designation creates a significant risk because Bhatt is an inventor on several asserted patents and therefore a fact witness in this litigation, and exposure to confidential materials could compromise his testimony. Apotex also asserts that Bhatt has recently participated in the prosecution of related patent applications. Apotex avers that it would be exceptionally difficult to separate confidential information from independent ideas. Apotex further argues that Bhatt is not an attorney and therefore is not subject to disciplinary rules governing misuse of confidential information.

Second, Supernus seeks to share each Defendant Group's confidential information with the other Defendant Groups without first obtaining the producing Defendant's consent. Letters, D.E. 57, at 2-4; D.E. 58, at 4-5. Supernus proposes that the DCO allows limited disclosure of a Defendant Group's confidential information to the non-in-house DCO designees for the other

Defendant Groups. Supernus argues that the Defendants bear the burden of demonstrating good cause for the restriction they propose. Supernus contends that because these consolidated actions involve multiple parties and overlapping issues, permitting cross-disclosure would promote efficient case management and avoid unnecessary burdens on both Plaintiff and the Court. Supernus predicts that Defendants' proposed restriction would complicate discovery exchanges, meet-and-confer discussions, depositions, court conferences, hearings, and filings. In addition, Supernus argues that Defendants have not identified any harm that would result from cross-disclosure, particularly because the DCO would bind outside counsel and the experts. Finally, Supernus contends that if the DCO adequately protects confidential information exchanged between Supernus and the Defendant Groups, those same protections should apply to information shared between and among the Defendant Groups.

Defendants argue that the Court should not permit Supernus unfettered discretion to produce a Defendant Group's confidential information to other Defendant Groups without obtaining the producing Defendant Group's consent. Defendants emphasize that the Defendant Groups are all direct competitors, making it important for each Defendant Group to control whether and to what extent its confidential information is shared with other the other Defendant Groups. They reason that allowing Plaintiff to disclose such information without consent, and therefore without advance notice to the producing Defendant Group, would undermine the producing Defendant Group's ability to control the dissemination of its confidential information, contrary to the purpose of the DCO. Defendants also argue that one Defendant Group's confidential information is irrelevant to the other Defendant Groups' claims and defenses.

Defendants dispute Plaintiff's claim that the consent requirement would create an undue burden, Defendants maintain that the DCO is intended to require careful handling of

confidential information and limit its use to purposes of the litigation. Defendants maintain that the DCO is designed to balance confidentiality interests with the need to use the information in the case, and that sharing the producing Defendant Group's confidential information with other Defendant Groups, which have no need for it, would not serve that purpose. Accordingly, Defendants argue that each Defendant Group, not Supernus, should determine whether its confidential information may be disclosed to the other Defendant Groups.

## II. LEGAL STANDARD

The party seeking a protective order bears the burden of demonstrating good cause for its issuance. Fed. R. Civ. Pro. 26(c). When a party seeks to include a patent prosecution bar in a protective order, Federal Circuit law governs and the request is evaluated under Federal Rule of Civil Procedure 26's good cause standard. *In re Deutsche Bank Tr. Co. Ams.*, 605 F.3d 1373, 1378 (Fed. Cir. 2010). To establish good cause, the party seeking to limit disclosure must show that disclosure would result in a specific and serious injury. *Saldi v. Paul Revere Life Ins. Co.*, 224 F.R.D. 169, 175 (E.D. Pa. 2004); *Deutsche Bank*, 605 F.3d at 1378.

A court evaluates good cause for a protective order by balancing the private and public interests at stake, including privacy concerns, the purpose for seeking the information, potential embarrassment, the public importance of the information, whether sharing among litigants would promote fairness and efficiency, whether the party seeking confidentiality is a public entity, and whether the case involves issues of public significance. *Glenmede Tr. Co. v. Thompson*, 56 F.3d 476, 483 (3d Cir. 1995). These factors are neither mandatory nor exhaustive. *Id.* Although confidentiality orders generally protect sensitive information, courts recognize that even rigorous efforts to preserve confidentiality may not fully prevent inadvertent disclosure. *Deutsche Bank*, 605 F.3d at 1378. Courts must therefore determine "whether an unacceptable opportunity for

inadvertent disclosure exists” on a counsel-by-counsel basis according to the particular facts presented. *Id.* (quoting *U.S. Steel Corp. v. United States*, 730 F.2d 1465, 1467-68 (Fed. Cir. 1984)). Courts retain broad discretion in determining the appropriate level of protection that is required. *Id.* at 1380.

When deciding whether to restrict discovery, courts balance the requesting party’s need for the information against the potential harm that disclosure may cause to the producing party. *Saldi*, 224 F.R.D. at 175. Courts must evaluate whether access should be permitted based on the specific circumstances surrounding the individual’s activities, association, and relationship with the party. *Boehringer Ingelheim Pharms., Inc. v. Hercon Lab'ys Corp.*, No. 89-484, 1990 WL 160666, at \*1 (D. Del. Oct. 12, 1990). In making this determination, courts consider whether the individual may later face difficulty separating confidential information obtained during litigation from their own independent work. *Id.* at \*1. Courts consider whether the individual seeking access participates in competitive decision-making, meaning participation in a client’s business or strategic decisions, such as pricing, product design, or similar decisions, made in light of confidential information about a competitor. *Brit. Telecomms. PLC v. IAC/InterActiveCorp*, 330 F.R.D. 387, 390 (D. Del. 2019) (allowing an in-house attorney access to highly confidential information where his role was limited to supervising litigation, he was not involved in patent prosecution or competitive decision-making, and restrictions on future patent-selection activities reduced the risk of misuse). Courts have recognized that in-house counsel are not automatically barred from accessing confidential information under a protective order. *Boehringer*, 1990 WL 160666, at \*1 (holding in-house counsel were permitted access to confidential information under a protective order where safeguards and professional obligations minimized the risk of inadvertent disclosure, but denying access to in-house technical personnel because their roles

created a heightened risk that confidential information could influence future work). Courts are more cautious about allowing in-house technical personnel access to confidential information when adequate safeguards cannot prevent the risk that confidential information will influence their future work. *Id.* at \*7.

### III. ANALYSIS

#### A. Apotex Has Not Shown Good Cause to Exclude Bhatt as Supernus's In-House Designee.

Apotex has not shown good cause to prevent Bhatt from serving as Supernus's in-house designee under the DCO. The central question is whether Bhatt's access to Apotex's confidential materials would create an unacceptable opportunity for inadvertent disclosure. That risk is minimal in light of the restrictions placed on Bhatt's access and the safeguards incorporated into the proposed DCO.

First, Bhatt's responsibilities in this matter are limited to overseeing and managing Supernus's patent litigation and coordinating with outside counsel. In addition, Bhatt will not be involved in any competitive decision-making for the products or patents in suit. Bhatt's role is therefore limited to litigation management rather than competitive decision-making.

Second, the proposed safeguards significantly reduce the possibility that confidential information could influence future patent activities. Bhatt will not prosecute any patents relating to this action. In addition, Supernus agreed to a broad patent prosecution bar for this matter, to mitigate any risk that confidential information obtained during discovery could influence future patent prosecution.

Third, Bhatt's access to confidential materials is limited to Apotex's ANDA and related technical materials, including technical documents, notebooks, and communications concerning the ANDAs. Bhatt will not have access to Apotex's confidential business or commercial

information. Limiting Bhatt's access to technical ANDA materials substantially reduces the competitive risk associated with disclosure of sensitive information.

Fourth, Bhatt has previously served as Supernus's DCO designee in numerous patent litigations without incident. That history suggests that allowing Bhatt to review confidential materials does not present a demonstrated risk of misuse. Moreover, seven of the eight Defendants in this consolidated action consented to Bhatt's designation. Although the consent of other Defendants is not determinative, it further suggests that Bhatt's access does not pose an obvious competitive threat. In fact, Apotex itself previously consented to Bhatt receiving Apotex's confidential ANDA information in another case under substantially similar circumstances. That prior consent undermines the assertion that Bhatt's access in this matter presents a specific and serious injury.

Finally, excluding Bhatt from serving as Supernus's designee would impose a meaningful burden on Supernus's ability to manage this litigation. Bhatt is responsible for overseeing and managing Supernus's patent litigation and has performed that role for over a decade. Effective management of the case requires open and candid discussions between Bhatt and outside counsel regarding technical details of Apotex's ANDA. Preventing Bhatt from reviewing those materials would significantly impair Supernus's ability to supervise its litigation strategy. When the minimal risk of inadvertent disclosure is balanced against the substantial burden that exclusion would impose on Supernus, the balance weighs in favor of permitting Bhatt to serve as the in-house designee. The restrictions here are comparable to the type of tailored safeguards that other courts have found sufficient to mitigate disclosure risks. For example, in *British Telecommunications*, the court permitted an in-house attorney to access confidential information where that attorney's role was limited to litigation supervision, he was not involved in patent-

prosecution or patent-selection decisions, he was barred from reviewing source code, and any access to highly confidential materials barred him from later participating in the identification, selection, or infringement analysis of additional patents to assert against the defendants. 330 F.R.D. at 394-95. Although *British Telecommunications* involved an in-house attorney rather than a non-attorney inventor, the case supports the broader principle that carefully tailored restrictions may sufficiently mitigate disclosure risks. In light of the multiple safeguards imposed, including the prohibition on competitive decision-making, the prosecution bar preventing Bhatt from prosecuting patents related to this action, and the limitation of his access to Apotex's ANDA and related documents rather than business or commercial information, the risk of inadvertent disclosure is sufficiently mitigated. Under these circumstances, the restrictions in the DCO adequately protect Apotex's confidential information while allowing Supernus to use its chosen litigation manager to oversee the case. Accordingly, Apotex has not shown that Bhatt's designation presents a specific and serious injury. Therefore, Bhatt may serve as Supernus's in-house designee subject to the restrictions and safeguards contained in the DCO.

**B. The DCO Should Require the Producing Defendant's Consent Before Cross-Disclosure of Confidential Information**

The question is whether the DCO should permit Supernus to disclose one Defendant Group's confidential information to other Defendant Groups without the producing Defendant Group's consent. Defendants have demonstrated that cross-disclosure of confidential information among the Defendant Groups presents a meaningful risk of competitive harm. Defendants in this consolidated action are direct competitors, and the confidential materials at issue include sensitive information relating to their ANDA products, product formulation, development processes, and the status of FDA review and approval. Allowing one Defendant

Group's confidential information to be shared with competing Defendant Groups without the producing Defendant Group's consent would undermine that Defendant Group's ability to control dissemination of competitively sensitive information. Defendants' proposed restriction preserves each Defendant Group's control over its own confidential information while still allowing discovery to proceed. Under the proposed approach, Supernus may either redact the confidential information of a particular Defendant Group before sharing materials with other Defendant Groups, or seek the producing Defendant Group's consent before disclosure. This procedure does not prohibit the use of confidential information in the litigation but instead ensures that disclosure occurs only where necessary and appropriate.

By contrast, Supernus's proposed provision would permit unrestricted sharing of a Defendant Group's confidential information with the other Defendant Groups, including their outside counsel, experts, consultants, and litigation vendors, without prior notice to the producing Defendant Group. Such a rule would effectively eliminate the producing Defendant Group's ability to control the dissemination of its own confidential information and could expose sensitive competitive information to direct market competitors. Supernus's efficiency arguments do not outweigh these confidentiality concerns. Although cross-sharing may simplify certain discovery exchanges, the burden of redacting documents or seeking consent does not significantly impede litigation and is consistent with the purpose of a confidentiality order, which is to ensure careful handling of sensitive information. Moreover, Supernus has not demonstrated that the confidential information of one Defendant Group is necessary for the other Defendant Groups to litigate their claims or defenses. The Court cannot discount the possibility that certain of a Defendant Group's confidential information is relevant to another Defendant Group. But any such production is far better handled on an individual basis, as opposed to a wholesale

distribution of confidential information across all Defendant Groups. In balancing the parties' interests, the potential competitive harm from unrestricted cross-disclosure outweighs the administrative burdens that Supernus identifies. Requiring consent before disclosure strikes an appropriate balance between protecting Defendants' confidentiality interests and allowing the litigation to proceed efficiently. Accordingly, the DCO should require Supernus to obtain the producing Defendant's consent before disclosing that Defendant's confidential information to other Defendants.

#### **IV. CONCLUSION & ORDER**

For the foregoing reasons,

IT IS HEREBY ORDERED as follows:

1. Dr. Padmanabh P. Bhatt may serve as Supernus's in-house designee under the DCO.
2. Supernus may not disclose confidential information produced by one Defendant Group to the other Defendant Groups without the producing Defendant Group's consent.
3. Within **fourteen days** of this Opinion, the parties shall jointly submit a revised Discovery Confidentiality Order consistent with the Court's rulings.

*s/ Michael A. Hammer*  
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**United States Magistrate Judge**

Dated: May 20, 2026