

THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

AZURITY PHARMACEUTICALS, INC.,
et al.,

Plaintiffs,

v.

ALKEM LABORATORIES LTD., et al.,

Defendants.

Civil No. 25-12118 (CPO/EAP)
(Consolidated)

OPINION

The matter comes before the Court on the Motion of Plaintiffs Braintree Laboratories, Inc. (“Braintree”), Sebela US Inc. (“Sebela”), and Azurity Pharmaceuticals, Inc. (“Azurity”) (collectively, “Plaintiffs”) to substitute Azurity in place of Braintree and Sebela under Federal Rule of Civil Procedure 25(c), terminate Braintree and Sebela as Plaintiffs, and amend all related case captions to reflect Azurity as the sole Plaintiff. ECF No. 55 (Pls.’ Mot.). Defendants Alkem Laboratories Ltd. (“Alkem”) and Hetero USA Inc. (“Hetero”) (collectively, “Defendants”) have opposed the Motion, ECF No. 58 (Defs.’ Opp.), and Plaintiffs have filed a reply brief, ECF No. 60 (Pls.’ Reply). The Court has considered the parties’ submissions and decides the matter without oral argument pursuant to Federal Rule of Civil Procedure 78(b) and Local Civil Rule 78.1. For the following reasons, the Court **DENIES WITHOUT PREJUDICE** Plaintiffs’ requested relief.

RELEVANT FACTUAL AND PROCEDURAL BACKGROUND

On June 25, 2025, Plaintiffs Braintree and Sebela filed this lawsuit alleging that Defendant Alkem infringed their patents for New Drug Application (“NDA”) No. 213135 for SUTAB®, a sodium sulfate, magnesium sulfate, and potassium chloride osmotic laxative used for cleansing the

colon in preparation for colonoscopies. ECF No. 1 (Alkem Compl.) ¶¶ 12, 30.¹ On July 22, 2025, Plaintiffs filed a similar lawsuit against Defendant Hetero. Civ. A. No. 25-13632, ECF No. 1 ¶¶ 19, 33 (Hetero Compl.). By way of Stipulation and Order entered on November 3, 2025, the Court consolidated both cases for purposes of all pretrial matters.

The cases proceeded without significant issue until December 19, 2025, when Plaintiffs indicated that Azurity had acquired the entirety of the U.S. rights to the SUTAB® product and the asserted patents from Braintree and Sebela under an Asset Purchase Agreement. ECF No. 39 at 1 (Joint Ltr.). Thereafter, Braintree and Sebela sought to substitute Azurity in their place as Plaintiff and to have Braintree and Sebela dismissed from the case. *Id.* Defendants did not object to Azurity being added as a party to the litigation but would not agree to the dismissal of Braintree and Sebela as Plaintiffs without assurances that they would fully participate in discovery. *Id.* at 2. Following a conference, the Court ordered, with the consent of all parties, that Azurity be added as a Plaintiff/Counterclaim Defendant, leaving Braintree and Sebela as additional Plaintiffs/Counterclaim Defendants. ECF No. 43 (Dec. 29, 2025 Order). The Court further directed Plaintiffs to submit a copy of the Asset Purchase Agreement between Braintree and Azurity for *in camera* review. ECF No. 41 ¶ 1.

Upon receipt and review of the Asset Purchase Agreement, the Court directed Azurity to file a motion for substitution, ECF No. 50 (Order), which Azurity filed on January 21, 2026, Pl.'s Mot. Defendants opposed the Motion on February 3, 2026, Defs.' Opp., and Azurity filed its reply on February 10, 2026, Pls.' Reply. This matter is now ripe for resolution.

¹ Unless otherwise specified, all ECF numbers refer to the lead case at Civil Action No. 25-12118.

LEGAL STANDARD

Federal Rule of Civil Procedure 25(c) provides that “[i]f an interest is transferred, the action may be continued by or against the original party unless the court, on motion, orders the transferee to be substituted in the action or joined with the original party.” Fed. R. Civ. P. 25(c). The United States Court of Appeals for the Third Circuit has explained that a “‘transfer of interest’ in a corporate context occurs when one corporation becomes the successor to another by merger or other acquisition of the interest the original corporate party had in the lawsuit.” *Luxliner P.L. Export, Co. v. RDI/Luxliner, Inc.*, 13 F.3d 69, 71 (3d Cir. 1993). Rule 25(c) does not require a party or a court to take any action after an interest has been transferred. *Id.*; *see also* 7C Wright, Miller & Kane, *Federal Prac. & Proc.* § 1958, at 555 (3d ed.). The Rule provides, however, that if a party wishes to do so, it may move for substitution or joinder of a transferee in interest. Fed. R. Civ. P. 25(c). “Because joinder or substitution under Rule 25(c) does not ordinarily alter the substantive rights of parties,” the decision as to whether to grant a Rule 25(c) motion is generally within the court’s discretion. *Luxliner*, 13 F.3d at 71.

The Third Circuit has reasoned that a court’s analysis of a Rule 25(c) motion should focus on whether substitution or joinder would best “facilitate the conduct of the litigation.” *Id.* at 72; *see also Abraxis BioScience, Inc. v. Navinta LLC*, No. 07-1251, 2009 WL 904043, at *5 (D.N.J. Mar. 30, 2009) (“A joinder or substitution under Rule 25 is appropriate when a district court, in the exercise of its discretion, finds that such joinder or substitution would facilitate the conduct of a case.”); *see also* 6 Moore’s Federal Practice – Civil § 25.34 (2021) (“[T]he court must make a determination, based on the respective rights and liabilities among the parties and the transferee under the substantive law governing the case, whether it would best facilitate the conduct of the case to have the transferor remain in the case, substitute the transferee, or join the transferee and continue with both as parties.”). Where a question of fact remains as to the extent of an entity’s

ownership rights in the patents-in-suit, substitution remains inappropriate and the court may exercise its discretion to join an entity to ensure that all proper parties are named. *See Purdue Pharma L.P. v. Amneal Pharms., LLC*, Nos. 15-1152, *et al.*, 2018 WL 3725772, at *2 (D. Del. July 25, 2018); *Mars, Inc. v. JCM Am. Corp.*, No. 05-3165, 2007 WL 776786, at *2 (D.N.J. Mar. 9, 2007).

DISCUSSION

As set forth above, Braintree, Sebela, and Azurity are all named Plaintiffs in this action. Plaintiffs now seek to substitute Azurity in place of Braintree and Sebela. *See generally* Pls.’ Mot. Defendants oppose such relief on two grounds. First, they argue that without access to the Braintree/Azurity Asset Purchase Agreement, they cannot sufficiently determine whether Braintree and Sebela transferred all substantial rights in the asserted patents and the related SUTAB® NDA Product to Azurity. Defs.’ Opp. at 8-9. Second, they contend that substitution at this juncture of the litigation would significantly prejudice Defendants, and that Plaintiffs have otherwise failed to show that substitution would “facilitate the conduct of the case.”² *Id.* at 2-8. The Court addresses each argument individually.

A. Whether Braintree and Sebela Transferred All Substantial Rights in the Asserted Patents and the Related SUTAB® NDA Product to Azurity

Defendants first argue that Plaintiffs have not established that Braintree and Sebela transferred all substantial rights in the asserted patents and the related SUTAB® NDA Product. Defs.’ Opp. at 8. Specifically, they maintain that despite their repeated requests to review the governing agreement among Braintree, Sebela, and Azurity, Azurity has refused, claiming that the agreement is confidential. *Id.* (citing ECF No. 58-1, Decl. of Jakob B. Halpern (“Halpern Decl.”)),

² Defendants actually raise this argument as two separate arguments. Because the questions of prejudice and facilitation of the litigation substantially overlap, the Court addresses them as a singular argument.

Ex. C). Defendants assert that Azurity has relied on a heavily redacted excerpt from the Asset Purchase Agreement stating that ““Braintree’s entire interest in and to the patents-in-suit and for which all claims of patent infringement have been brought have been transferred from Braintree to Azurity.”” Defs.’ Opp. at 5 (quoting ECF No. 55-3 at 5 (citing Decl. of Keith J. Miller (“Miller Decl.”), Ex. B)). Defendants contend, however, that the operative assignment documents governing the patents provided that the inventors “covenanted—and Braintree retained—continuing obligations to procure, maintain, enforce, and defend the patents, including obligations to participate in any proceedings relating to those patents[.]” *Id.* at 5-6 (citing Halpern Decl., Ex. B at 1-2). Thus, according to Defendants, it is not clear that the Asset Purchase Agreement conveyed the “full bundle of substantive rights and responsibilities associated with the patents.” *Id.* at 6.

Plaintiffs counter that “Braintree has completely divested itself of its entire interest in the patents-in-suit,” and thus “no longer has standing to continue as a party.” Pls.’ Reply at 1. They claim that “[t]he relevant portion of the Agreement, to which Defendants have access, is clear: Azurity acquired all of the right, title, and interest in the patents-in-suit,” as well as in the SUTAB® NDA. *Id.* at 2. Given that Azurity is the owner by assignment of the patents-in-suit and Braintree is neither patent owner nor exclusive licensee, Plaintiffs claim that only Azurity has standing. *Id.* at 2-3. And to the extent Defendants cite the original agreement between the inventors and Braintree, Plaintiffs assert that the Asset Purchase Agreement assigned that agreement to Braintree’s successor or assignee. *Id.* at 2-3.

Here, deciding the issue of substitution in the face of the present record runs contrary to the weight of jurisprudence. Courts have repeatedly recognized that, “[w]here questions remain as to the extent of the transfer of an ownership interest in the patents-in-suit, the court in its discretion may choose to join a party pursuant to Rule 25(c), rather than substitute one party for

another.” *Purdue Pharma L.P.*, 2018 WL 3725772, at *3; *see also Eastman Chem. Co. v. Alphapet Inc.*, No. 09-971, 2011 WL 13054223, at *4 (D. Del. Dec. 9, 2011) (“When there is uncertainty regarding the nature and extent of the alleged transfers of interest from a named party to a third party, it is more appropriate to join the alleged transferees, rather than to substitute them.” (footnote omitted)); *Mars, Inc. v. JCM Am. Corp.*, 2007 WL 776786, at *2 (noting that because “the record [was] insufficient to determine exactly what rights and obligations were transferred,” the court would exercise its discretion to join an alleged patent assignee, rather than substitute the assignee for the plaintiff); *ISI Int’l, Inc. v. Borden Ladner Gervais, LLP*, No. 98-7614, 2002 WL 230904, at *3-4 (N.D. Ill. Feb. 15, 2002) (rejecting a motion for substitution in favor of joinder where legal sufficiency of transfer agreement at issue was unclear); *Centillion Data Sys., Inc. v. Am. Mgmt. Sys., Inc.*, 200 F.R.D. 618, 619-20 (S.D. Ind. 2001) (denying a motion for substitution in patent infringement lawsuit because although it was clear that the patents-in-suit had been transferred, it was unclear whether other interests in the case had been transferred and finding that this uncertainty weighed definitively against substitution).

Defendants here have only had the opportunity to review an isolated portion of an otherwise heavily redacted Asset Purchase Agreement, leaving them solely reliant on Plaintiffs’ representations and otherwise stymied in their efforts to ascertain whether all substantive rights to the patents-in-suit and SUTAB® NDA have been transferred to Azurity. While the Court has received an unredacted version of the Asset Purchase Agreement suggesting that a substantial portion of Braintree’s and Sebela’s rights to the patents-in-suit have been transferred to Azurity, deciphering the intricacies of the seventy-five-page contract would require a unilateral analysis by the Court unaided by the parties’ adversarial arguments and evidentiary proofs. Given this uncertainty, it is more appropriate that Braintree and Sebela remain named as Plaintiffs alongside

the already-joined Azurity rather than substituting Azurity in their place, so that this case may proceed until the record can be more fully developed.

B. Whether Substitution Will Facilitate the Conduct of the Litigation or Will Result in Prejudice

Beyond the lingering question regarding the extent of the interests transferred, the Third Circuit has emphasized that a court’s focus when assessing a Rule 25(c) motion must be on whether substitution or joinder would best “facilitate the conduct of the litigation.” *Luxliner*, 13 F.3d at 72. Given the procedural posture of the current litigation, the Court finds that the prejudice attendant to the requested substitution—particularly without a showing of any meaningful facilitation of the litigation—warrants denial of Plaintiffs’ Motion at this juncture. A review of the statutory scheme governing this case provides some context.

Plaintiffs brought this action for infringement against Defendants based on Defendants’ filing of an Abbreviated New Drug Application (“ANDA”) under the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”), Pub. L. No. 98-417, 98 Stat. 1585 (1984). The Hatch-Waxman Act establishes a regulatory scheme governing the approval of generic versions of previously approved brand-name drugs and provides a mechanism for resolving patent disputes between brand-name and generic manufacturers prior to generic market entry. *See FTC v. Actavis, Inc.*, 570 U.S. 136, 142-43 (2013). As part of this statutory scheme, an ANDA applicant must (1) give notice to a patent holder that the ANDA has been filed and (2) set forth a detailed statement for the applicant’s opinion that the patent is invalid, unenforceable, or will not be infringed by the generic drug (the “Paragraph IV certification”). *See* 21 U.S.C. § 355(j)(2)(B). A patent owner can then bring a patent infringement suit against a generic applicant immediately upon receiving notice that the generic applicant is challenging a patent by filing an ANDA. *See generally Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1342

(Fed. Cir. 2007). “A patent owner who brings an infringement claim against an ANDA filer within [45 days of the Paragraph IV certification] invokes an automatic 30-month stay preventing the otherwise immediate approval of the ANDA.” *Id.* at 1343 n.8 (citing 21 U.S.C. § 355(j)(5)(B)(iii)). The stay begins on the date the Paragraph IV certification was provided. 21 U.S.C. § 355(j)(5)(B)(iii).

Here, by letter dated May 15, 2025, Defendant Alkem notified Plaintiffs Braintree and Sebela that it had submitted its ANDA to the FDA prior to the expiration of the patents-in-suit. Alkem Compl. ¶ 30. By letter dated June 11, 2025, Hetero notified Plaintiffs Braintree and Sebela that it had submitted its ANDA to the FDA prior to the expiration of the patents-in-suit. Hetero Compl. ¶ 36. Braintree and Sebela then filed the current suits for patent infringement within forty-five days of those letters, thereby triggering the thirty-month stays beginning on May 15, 2025, for the Alkem suit and June 11, 2025, for the Hetero suit. At the time Plaintiffs filed their substitution motion on January 21, 2026, more than seven months of each of those periods had elapsed, leaving less than two years in which to complete this litigation.

As Defendants note, in that time period, “[d]iscovery has proceeded based on Braintree’s and Sebela’s roles as patent owners and product developers—roles that carry unique first-hand knowledge central to this litigation, including inventorship, conception, reduction to practice, and prosecution history of the asserted patents, and development and commercialization of the SUTAB® NDA and the patented product.” Defs.’ Opp. at 3. Defendants observe that Plaintiffs’ Federal Rule of Civil Procedure 26(a)(1) Initial Disclosures identified at least six employees, including senior executives at Sebela and inventors with relevant knowledge concerning the SUTAB® NDA, and related information regarding the patents. *Id.* at 4 (citing Halpern Decl., Ex. A at 2-3). In addition, Defendants argue that Plaintiffs Braintree and Sebela also represented that after entry of a protective order, they would produce “[d]ocuments related to the ownership of, and

the conception and reduction to practice of, the inventions claimed in the patents-in-suit” and “[d]ocuments concerning the development of the oral dosage formulation comprising sodium sulfate, magnesium sulfate, and potassium chloride for inducing purgation of the colon of a subject claimed in the patents-in-suit.” *Id.* at 4-5 (quoting Halpern Decl., Ex. A at 4-5). Notwithstanding their representations that their employees have first-hand knowledge of the issues pertinent to this litigation, Plaintiffs Braintree and Sebela have not provided any relevant information listed in their initial disclosures and have not responded to any previously served discovery—all under the guise that Plaintiff Azurity will be substituted in their stead. *Id.*

Plaintiffs argue that substitution would not materially prejudice Defendants or disrupt ongoing discovery because fact discovery does not close until December 2026. Pls.’ Reply at 1. Further, they claim that, as early as November 2025, Defendants were on notice that Plaintiffs would be seeking to substitute Azurity as Plaintiff and that Azurity was the proper target of all discovery requests. *Id.* at 2 n.1. Plaintiffs posit that granting substitution will allow Defendants to obtain discovery from a single party—Azurity—rather than duplicative discovery from multiple Plaintiffs.³ *Id.* at 5. To the extent Defendants still need discovery from Braintree and Sebela, Plaintiffs claim that they can seek it through third-party discovery pursuant to Federal Rule of Civil Procedure 45, and that “Braintree is a sophisticated and experienced litigant that will comply with any and all third-party discovery obligations.” *Id.* at 7.

³ Plaintiffs cite two other cases pending in this Court where Azurity was “promptly substituted as plaintiff” and “discovery is proceeding without issue or delay.” Pls.’ Reply at 5 (citing *Azurity Pharms., Inc. v. Lupin Ltd. et al.*, No. 25-13133 (D.N.J.); *Azurity Pharms., Inc. v. Strides Pharma Inc. et al.*, No. 25-16717 (D.N.J.)). Pls.’ Reply at 5. In both of those cases, however, the substitution was accomplished by consent order. *See Azurity Pharms., Inc. v. Lupin Ltd. et al.*, No. 25-13133 (D.N.J.), at ECF No. 49; *Azurity Pharms., Inc. v. Strides Pharma Inc. et al.*, No. 25-16717 (D.N.J.), at ECF No. 9. And Plaintiffs cannot provide any proof that discovery will be without issue in those matters.

Plaintiffs' argument, however, disregards several key points. Primarily, regardless of the December 2026 fact discovery deadline, the parties remain confined by the thirty-month stay in which this case must be completed. Because Braintree and Sebela have failed to comply with discovery obligations⁴ on the unilateral belief that Azurity is the proper respondent,⁵ they have squandered several months of that time.⁶ Moreover, Braintree and Sebela have not disputed that the Federal Rules of Civil Procedure require only that a party produce documents and items in its "possession, custody, or control." Fed. R. Civ. P. 34. While Plaintiffs represent that Azurity "took possession of all discoverable information following the acquisition," Pls.' Reply at 2 n.1, Defendants aptly note that the determination of what is discoverable cannot unilaterally rest in Plaintiffs' discretion and that it is likely that Azurity does not maintain possession, custody, or

⁴ Plaintiffs contend that this argument is a "red herring." Pls.' Reply at 2 n.1. They contend that Defendant Alkem served discovery requests on October 6, 2025, and the parties mutually agreed to extend the deadline for response until December 5, 2025. *Id.* In early November 2025, after the Asset Purchase Agreement was finalized, Plaintiffs "promptly" informed Defendants that Azurity would seek substitution and all discovery should be sought from Azurity, which had taken possession of "all discoverable information following the acquisition." *Id.* Nonetheless, on December 12, 2025, Defendant Hetero served Braintree and Sebela with requests for production. *Id.* The parties then agreed to further extend the deadline to respond to Defendants' written discovery.

This argument, however, disregards that although Azurity was added to the case on December 29, 2025, Braintree and Sebela had *pre-existing* discovery obligations. Azurity has not yet been substituted as the sole plaintiff in place of Braintree and Sebela, and so long as the latter two Plaintiffs remain in the case, they retain an obligation to respond to discovery. And while the parties can agree to certain extensions of certain internal discovery response deadlines, the thirty-month stay continues to run.

⁵ Plaintiffs attempt to lay blame on Defendants for "resist[ing] substitution for *three months* based on unfounded allegations about Azurity's ownership of the patents-in-suit and unsubstantiated concerns about discovery." Pls.' Reply at 5 (emphasis in original). As discussed above, however, Defendants' concerns about the extent of Azurity's ownership remain well founded, particularly when they have not been privy to a substantial portion of the Asset Purchase Agreement.

⁶ *Cf. Abraxis Bioscience, Inc. v. Navinta LLC*, 07-1251, 2009 WL 904043, at *6 (D.N.J. Mar. 30, 2009) (permitting joinder of patent transferee where transferee had already been providing documents and discovery as if it were a party; thus, no concern of potential delay existed).

control of all relevant records or witnesses. Defs.’ Opp. at 6-7. Finally, although Plaintiffs contend that Defendants have the option of using non-party discovery mechanisms under Federal Rule of Civil Procedure 45, Plaintiffs fail to acknowledge that non-party discovery requires a stronger showing of relevance than routine party discovery. *Hall v. Johnson & Johnson*, No. 18-1833, 2023 WL 8830784, at *4 (D.N.J. Dec. 20, 2023). And non-parties are generally afforded greater protection from discovery than a party. *Id.*; *see also Fashion G5 LLC v. Anstalt*, No. 14-5719, 2016 WL 7009043, at *3 (S.D.N.Y. Nov. 29, 2016) (holding that “[b]ecause the disclosure obligations of Fed. R. Civ. P. 26 only apply to parties, dismissing [a defendant under Rule 25] from this case would hamper Plaintiff’s ability to take discovery from [that defendant], an entity whose alleged conduct forms the basis for two of Plaintiff’s causes of action”); *Eastman Chem. Co.*, 2011 WL 13054223, at *5 (noting that “a court must consider how joinder or substitution would impact the efficient procedure of the litigation” when making a Rule 25(c) determination and recognize that the mere availability of Rule 45 as a discovery tool is not a replacement for party discovery).

In light of the foregoing, the Court finds that granting Plaintiffs’ requested relief will not facilitate the conduct of the litigation and may result in unwarranted prejudice to Defendants. The thirty-month stay under the Hatch-Waxman Act is slowly dissipating. While the parties have until December to complete fact discovery, substitution will result in duplication of already completed efforts because Defendants will need to re-serve all existing discovery requests on Azurity and then pursue Rule 45 subpoenas directed to Braintree’s and Sebela’s previously-identified witnesses.⁷ And Braintree’s and Sebela’s ongoing failure to respond to the existing discovery

⁷ Plaintiffs argue that two of the named inventors, Mark Cleveland and Russ Pelham, are not Braintree employees, and thus, non-party discovery will be required regardless of whether substitution is granted. Pls.’ Reply at 7 n.4. The mere fact that Defendants will have to engage in

requests undermines their current attempts to assure Defendants that they will willingly comply with third-party discovery.

CONCLUSION

In light of the foregoing, the Court denies Plaintiffs' Motion for Substitution without prejudice. As it currently stands, Braintree, Sebela, and Azurity are all named Plaintiffs to this action and should conduct discovery accordingly. Once fact discovery closes and Defendants have had the opportunity to develop the rights and obligations of the parties, Plaintiffs may renew their motion for substitution.

An appropriate Order follows.

s/Elizabeth A. Pascal
ELIZABETH A. PASCAL
United States Magistrate Judge

cc: Christine P. O'Hearn, U.S.D.J.

some third-party discovery, however, does not justify converting the majority of the needed discovery into non-party discovery.