

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MYLAN IRELAND LTD.,

Plaintiff,

- against -

NOSTRUM LABORATORIES, INC.,

Defendant.

NOSTRUM LABORATORIES, INC.,

Counterclaimant,

- against -

MYLAN IRELAND LTD. and MYLAN
PHARMACEUTICALS, INC.,

Counterclaim-Defendants.

OPINION AND ORDER

17 Civ. 2782 (ER)

Ramos, D.J.:

In 2015, Mylan Ireland Ltd. (“Mylan”) and Nostrum Laboratories, Inc. (“Nostrum”) entered into agreements whereby Nostrum would produce several drugs for Mylan. Mylan brings this breach-of-contract action alleging that Nostrum failed to meet production standards for [REDACTED] and to pay certain rebates. Nostrum asserts counterclaims for Mylan’s rejection of the drugs and other alleged breaches. Pending before the Court is Mylan’s motion for leave to file its Third Amended Complaint (“TAC”), which asserts additional claims for deficiencies in the production of [REDACTED] and more unpaid rebates. For the reasons set forth below, Mylan’s motion is GRANTED.

I. Factual and Procedural Background¹

A. The Parties' Agreements

In May 2015, Mylan and Nostrum entered into an Asset Purchase Agreement (“APA”) and Supply Agreement under which Mylan purchased Nostrum’s licensing rights and regulatory approvals for four drugs, and Nostrum agreed to manufacture and supply those products for Mylan. TAC ¶¶ 8, 11, 13. The products included [REDACTED]

[REDACTED]. TAC ¶ 12.

Under the Supply Agreement, prior to each calendar quarter, Mylan had to provide Nostrum with its forecast of the quantities of each product that it would require for the next four quarters. Supply Agreement § 2.2. In order to actually receive the products, Mylan then had to submit a purchase order for its desired quantity. *Id.* § 2.3.1. Nostrum was required to accept such purchase orders, so long as the requested quantity did not exceed [REDACTED] of the most recent forecast for the nearest quarter. *Id.*

Nostrum was required to “Manufacture the Product(s) in accordance with the Required Standards,” which included applicable law and the “Specifications” defined in the Supply Agreement as procedures and standards set forth in regulatory approvals “and as otherwise provided by Mylan.” *Id.* §§ 1.21–.22, 2.7. Nostrum was not permitted to change the Specifications without Mylan’s prior approval. *Id.* § 6.6.

The APA and Supply Agreement also required Nostrum to pay Mylan a “true up” or rebate depending on Mylan’s profit margin or sales each year. For example, in 2015, if Mylan’s

¹ The following facts are drawn from the allegations in Mylan’s proposed TAC, which the Court accepts as true for purposes of the instant motion to amend, as well as exhibits included or incorporated by reference in the TAC. *Arnold v. Research Found. for State Univ. of N.Y.*, 216 F. Supp. 3d 275, 284 (E.D.N.Y. 2016).

margin was less than [REDACTED], Nostrum had to pay Mylan the difference between its margin and [REDACTED]. APA § 3.2. Each year after that, Nostrum had to pay Mylan up to [REDACTED] depending on Mylan's sales. Supply Agreement §§ 3.2.2–3.

In the event of disputes, the parties were each required to have an executive meet and attempt to resolve the issue before filing any lawsuit. APA §§ 12.1–2; Supply Agreement §§ 12.1–2. The APA and Supply Agreement are governed by New York law. APA § 13.6; Supply Agreement § 13.7.

B. Product Issues

Mylan alleges that Nostrum failed to manufacture products in accordance with the Specifications. With respect to [REDACTED], the products allegedly did not maintain the required [REDACTED]. TAC ¶¶ 34–35. Consequently, Mylan rejected or has been unable to sell [REDACTED], and Nostrum has not replaced them. TAC ¶¶ 39–40.

Mylan also encountered problems with [REDACTED]. In April 2016, Nostrum shut down production of [REDACTED]. TAC ¶ 44. In July 2016, after resolving the [REDACTED], Nostrum informed Mylan that it needed to [REDACTED]. TAC ¶ 45. Mylan responded that [REDACTED]. TAC ¶ 46. Mylan proposed that Nostrum make [REDACTED] under the existing Specifications to cover Mylan's requirements while Nostrum conducted testing on the new [REDACTED]. *Id.* Alternatively, Nostrum could immediately [REDACTED]. TAC ¶ 47. Nostrum insisted on [REDACTED],

asserting that additional testing was unnecessary because Nostrum would use [REDACTED] [REDACTED] that had already received regulatory approval for the [REDACTED]. TAC ¶¶ 48–49.

In November 2016, Mylan approved changes to the Specifications to permit Nostrum to make three test batches of [REDACTED]. TAC ¶ 50. At that time, Mylan also submitted three purchase orders for the batches with requested delivery in January 2017. TAC ¶ 43. In light of the needed changes, these purchase orders replaced the prior orders that Mylan had placed.² Katz Decl. Ex. F.

The changes did not go smoothly, however, and Nostrum discovered that two of the three batches failed to conform to the revised Specifications. TAC ¶ 50. Nostrum could not supply the [REDACTED] until it determined the cause of the problem. *Id.* Nostrum initiated an investigation into the failed batches in January 2017 and did not complete its investigation until a year-and-a-half later in June 2018. TAC ¶ 51. In the meantime, Mylan was forced to discontinue sales of [REDACTED]. *Id.*³

C. Nonpayment of Rebates

Mylan alleges that Nostrum has failed to pay each of the yearly rebates that it is owed. In March 2016, Mylan invoiced Nostrum for approximately [REDACTED] [REDACTED]. TAC ¶¶ 17–18. In April 2017, January 2018, and February 2019, Mylan invoiced Nostrum for [REDACTED], based on

² Although Mylan provided Nostrum with several forecasts throughout 2016 and 2017, Mylan has alleged only five instances of purchase orders for [REDACTED]: two orders placed in May 2016, and three orders in November 2016 that superseded the prior two orders. TAC ¶ 43.

³ While not at issue in the instant motion to amend, Mylan also alleges the Nostrum failed to cooperate in transferring technology to Mylan so that it could produce all four products on its own. TAC ¶¶ 65–67.

Mylan's sales from the prior year. TAC ¶¶ 59–60, 101–102, 106–107. Nostrum refused to pay each invoice. *Id.*

In an effort to resolve the rebate and product disputes, executives from both parties held meetings in July 2016, May 2017, June 2018, and most recently on February 18, 2019—three days before Mylan issued the latest rebate invoice on February 21, 2019. TAC ¶¶ 54–55, 68, 106, 108. These negotiations were unsuccessful. *Id.*

D. Procedural History

On April 17, 2017, Mylan filed its Complaint against Nostrum, alleging that Nostrum had breached the APA, Supply Agreement, and implied covenant of good faith and fair dealing. Compl. ¶¶ 30–48. On May 26, 2017, Mylan filed an Amended Complaint, asserting claims for Nostrum's failure to pay the 2015 and 2016 rebates, failure to supply [REDACTED], refusal to [REDACTED], and breach of the implied covenant. Am. Compl. ¶¶ 44–69. On July 21, 2017, Mylan filed a Second Amended Complaint ("SAC"), asserting the same claims. SAC ¶¶ 57–86.

On September 7, 2017, Nostrum answered and asserted counterclaims against Mylan and an affiliated entity. Nostrum alleged that Mylan had breached the APA, Supply Agreement, and implied covenant of good faith and fair dealing; was equitably estopped from challenging the [REDACTED]; had negligently and fraudulently misrepresented its position on the [REDACTED]; and was required to indemnify Nostrum. Countercl. ¶¶ 72–135. Nostrum also alleged that Mylan had wrongfully rejected deliveries of [REDACTED] [REDACTED]. *Id.* ¶¶ 57–61.

On July 5, 2018, Mylan filed a pre-motion letter requesting permission to file the TAC, and following a pre-motion conference, Mylan formally moved to amend on August 20, 2018. The TAC adds claims for Nostrum's failure to pay the 2017 rebate and to supply [REDACTED]

██████████. On March 25, 2019, Mylan filed a letter requesting permission to revise the TAC to include a claim for Nostrum’s failure to pay the 2018 rebate as well.

Discovery is underway and is currently scheduled to be completed by October 7, 2019.
Doc. 72.

II. Discussion

Federal Rule of Civil Procedure 15(a)(2) allows a party to amend its pleading with the other party’s written consent or the Court’s leave. Fed. R. Civ. P. 15(a)(2). “The court should freely give leave [to amend] when justice so requires.” *Id.* The “liberal spirit” of Rule 15 embodies a “strong preference for resolving disputes on the merits.” *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 190–91 (2d Cir. 2015) (quoting *Williams v. Citigroup Inc.*, 659 F.3d 208, 212–14 (2d Cir. 2011)). Motions to amend are ultimately within the discretion of the district court judge, who may deny leave to amend for “good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party.” *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007). The party opposing the motion to amend bears the burden of establishing that amendment would be futile, unduly prejudicial, or in bad faith. *Usov v. Lazar*, No. 13 Civ. 818 (RWS), 2014 WL 4354691, at *8 (S.D.N.Y. Sept. 2, 2014).

Nostrum opposes Mylan’s proposed amendment on the grounds of futility and undue prejudice. The Court will address each argument in turn.

A. Futility

An amendment to a pleading is futile if the proposed claim would not withstand a motion to dismiss pursuant to Rule 12(b)(6). *Dougherty v. N. Hempstead Bd. of Zoning Appeals*, 282 F.3d 83, 88 (2d Cir. 2002). To withstand a motion to dismiss, the plaintiff must allege sufficient facts that, when accepted as true, “state a claim to relief that is plausible on its face.” *Ashcroft v.*

Iqbal, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* (citing *Twombly*, 550 U.S. at 556). Because the Court evaluates the amendment “through the prism of a Rule 12(b)(6) analysis,” the Court accepts the plaintiff’s factual allegations as true and draws all reasonable inferences in favor of the plaintiff. *Henneberry v. Sumitomo Corp. of Am.*, 415 F. Supp. 2d 423, 433 (S.D.N.Y. 2006). However, the Court is not required to credit legal conclusions, bare assertions, or conclusory allegations. *Iqbal*, 556 U.S. at 678, 681, 686 (citing *Twombly*, 550 U.S. at 555).

Under New York law, to state a claim for breach of contract, the plaintiff need only allege “(1) the existence of an agreement, (2) adequate performance of the contract by the plaintiff, (3) breach of contract by the defendant, and (4) damages.” *Eternity Glob. Master Fund Ltd. v. Morgan Guar. Tr. Co. of N.Y.*, 375 F.3d 168, 177 (2d Cir. 2004) (quoting *Harsco Corp. v. Segui*, 91 F.3d 337, 348 (2d Cir. 1996)). Although Nostrum suggests the absence of an agreement because Mylan did not submit, and Nostrum could not accept, certain purchase orders, Def.’s Mem. 7–8, there is no dispute that the APA and Supply Agreement constitute enforceable agreements. However, the parties dispute whether Mylan satisfied certain conditions precedent before Nostrum could be held liable for breach of its obligations under the Supply Agreement [REDACTED] and the rebates.

1. Purchase Orders for [REDACTED]

Nostrum argues that Mylan’s claims [REDACTED] are futile, because Mylan’s forecasts for its requirements did not impose an obligation on Nostrum to supply products in the absence of a purchase order, and some of Mylan’s purchase orders [REDACTED] were canceled. Def.’s Mem. 5–10. Mylan responds that under the doctrine of anticipatory

repudiation, once Nostrum informed Mylan in July 2016 that it needed to [REDACTED] and would not [REDACTED] pursuant to the original required Specifications, Mylan could at that point sue for breach and need not perform futile acts such as placing a purchase order. Pl.’s Reply 4–5 (citing N.Y. U.C.C. Law § 2-610).

The Court need not resolve this debate, because Mylan alleges that it *did* place three purchase orders in November 2016, with delivery scheduled for January 2017. TAC ¶ 43. Those purchase orders were never canceled, and Nostrum was required to accept and honor them under the Supply Agreement. Supply Agreement § 2.3.1. However, two of the three batches failed to conform to the Specifications (even as revised), and Nostrum did not deliver any of them by January 2017. TAC ¶¶ 50–51. Accordingly, Mylan has plausibly alleged Nostrum’s breach for failure to supply [REDACTED].

Nostrum further argues that, even though two of those three batches allegedly failed to conform to the Specifications, it nonetheless complied with the revised manufacturing instructions as approved by Mylan. Def.’s Mem. 12–13. Nostrum’s argument fails in two ways. First, accepting Mylan’s allegations as true, Mylan has alleged that Nostrum manufactured two batches that did not conform with the revised Specifications, which is a plausible breach in and of itself. Second, Mylan alleges that Nostrum did not deliver any of the three batches by the delivery date of January 2017, which plausibly constitutes a separate breach.

Because Mylan has plausibly alleged that Nostrum breached its obligation to [REDACTED] [REDACTED] and to do so in compliance with the Specifications, this claim is not futile.⁴

⁴ Nostrum also contends that it cannot be liable for lost profits or consequential damages for this breach under the limitation of liability provision in the Supply Agreement. Def.’s Mem. 16–18. However, that limitation does not apply to liability for “fraud or willful misconduct.” Supply Agreement § 10.3. Here, Mylan alleges that Nostrum unilaterally decided that the Specifications had to be changed, refused Mylan’s alternative proposals, and refused to provide information needed to evaluate the changes. TAC

2. Implied Covenant of Good Faith and Fair Dealing

In addition, Nostrum argues that Mylan's claim for breach of the implied covenant of good faith and fair dealing [REDACTED] is futile because it is duplicative of the contract claim. Def.'s Mem. 18–19. “The covenant of good faith and fair dealing ‘embraces a pledge that neither party shall do anything which will have the effect of destroying or injuring the right of the other party to receive the fruits of the contract.’” *Obex Sec., LLC v. Healthzone Ltd.*, No. 10 Civ. 6876 (SAS), 2011 WL 710608, at *2 (S.D.N.Y. Feb. 28, 2011) (quoting *511 W. 232nd Owners Corp. v. Jennifer Realty Co.*, 773 N.E.2d 496, 500 (N.Y. 2002)). However, “a claim for breach of the implied covenant [of good faith and fair dealing] will be dismissed as redundant where the conduct allegedly violating the implied covenant is also the predicate for breach . . . of an express provision of the underlying contract.” *Id.* (alteration in original) (quoting *ICD Holdings S.A. v. Frankel*, 976 F. Supp. 234, 243–44 (S.D.N.Y. 1997)).

Here, as part of its implied covenant claim, Mylan alleges that Nostrum “failed to act in good faith by remedying the manufacturing and quality issues relating to the Nostrum Products in a timely manner to avoid or minimize any interruption in supply.” TAC ¶ 97. Mylan further alleges that Nostrum refused options that Mylan presented to maintain or limit interruption to its sales while Nostrum [REDACTED], and withheld from Mylan [REDACTED]. TAC ¶¶ 46–49. These allegations do not appear to transgress any express contract provisions at issue and thus are not duplicative of the contract claims.

Accordingly, Mylan's claim for breach of the implied covenant of good faith and fair dealing is not futile.

¶¶ 45, 48–49. These allegations are sufficient to plausibly allege willful misconduct and remove the limitation of liability.

3. 2018 Rebate

Although Nostrum does not oppose Mylan’s adding a claim for the 2017 rebate payment, it opposes Mylan’s recent revision to the TAC to add a claim for the 2018 rebate. Because Mylan did not invoice Nostrum for the 2018 rebate until February 21, 2019—three days *after* the parties allegedly met and conferred—Nostrum argues that Mylan failed to hold a proper meet-and-confer, which was required before Mylan could enforce Nostrum’s obligation to pay the 2018 rebate. Def.’s Mar. 27, 2019 Letter 2.

At this stage in the proceedings, accepting Mylan’s allegations as true and drawing all reasonable inferences in its favor, the Court must reject Nostrum’s argument. Before any litigation, the Supply Agreement required that disputes be “submitted to an executive officer of each of the Parties having authority to resolve such Dispute” and that each party “cause its designated executive officer to meet and be available to attempt to resolve such issue.” Supply Agreement § 12.1. Mylan alleges that on February 18, 2019, the parties held a mediation with business executives but were unable to resolve the dispute concerning the 2018 rebate. TAC ¶ 108. This is sufficient to plausibly allege that Mylan satisfied the meet-and-confer requirement during the mediation. The fact that Mylan only later sent Nostrum an invoice is not dispositive, as Mylan may plausibly raise a dispute before it makes a formal written demand.⁵ Accordingly, Mylan’s claim for payment of the 2018 rebate is not futile.

B. Undue Prejudice

In determining whether a proposed amendment would unduly prejudice the opposing party, courts consider whether the amendment would “(i) require the opponent to expend

⁵ Nostrum also contests whether the mediation actually dealt with the 2018 rebate or whether the designated executives attended. However, these are purely factual challenges to Mylan’s allegations, which the Court must accept as true at this stage.

significant additional resources to conduct discovery and prepare for trial; (ii) significantly delay the resolution of the dispute; or (iii) prevent the plaintiff from bringing a timely action in another jurisdiction.” *Block v. First Blood Assocs.*, 988 F.2d 344, 350 (2d Cir. 1993). “[T]he longer the period of an unexplained delay, the less will be required of the nonmoving party in terms of a showing of prejudice.” *Id.* (quoting *Evans v. Syracuse City Sch. Dist.*, 704 F.2d 44, 47 (2d Cir. 1983)).

Nostrum contends that the TAC will unduly prejudice it because Mylan should have brought its new claims earlier. Def.’s Mem. 20–21. Nostrum is wrong. Mylan requested leave to bring [REDACTED] one week after Nostrum completed its year-and-a-half-long investigation into the noncompliant batches in June 2018 (and during that entire time Nostrum was allegedly in breach for not supplying [REDACTED]). See TAC ¶¶ 50–51. Mylan requested permission to add the 2018 rebate claim less than three weeks after its invoice became due in March 2019. See TAC ¶ 107. Mylan’s claims are timely, and it would have been impossible or imprudent to bring them earlier in the SAC in July 2017.

Nostrum also argues that adding these claims would needlessly complicate the case and, in the alternative to denying leave to plead the new claims, suggests severing and staying them. Def.’s Mem. 22–24. Nostrum is wrong again. This case already involves issues [REDACTED] [REDACTED] because Nostrum has asserted counterclaims for Mylan’s rejection of [REDACTED]. See Countercl. ¶¶ 57–61. The 2018 rebate involves identical issues as the 2016 and 2017 rebates. Discovery is ongoing and can be adjusted to include these additional issues. Severing and staying these claims would only produce inefficiencies, while “[i]t clearly serves the purpose of judicial economy, and is less burdensome to the parties, to allow Plaintiff to bring all of its claims at once rather than to try the issues piecemeal.”


Doylestown Elec. Supply Co. v. Maryland Cas. Ins. Co., 942 F. Supp. 1018, 1020 (E.D. Pa. 1996).

III. Conclusion

Mylan's motion for leave to file the TAC, including its revisions proposed on March 25, 2019, is GRANTED. Mylan is permitted to file the TAC under seal, with a redacted copy filed on the public docket.

It is SO ORDERED.

Dated: March 30, 2019
New York, New York



Edgardo Ramos, U.S.D.J.