

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IMPAX LABORATORIES, INC.,

Plaintiff,

-against-

TURING PHARMACEUTICALS AG,

Defendant.

USDC SDNY
DOCUMENT
ELECTRONICALLY FILED
DOC#
DATE FILED: 11/16/2016

OPINION AND ORDER

16 Civ. 3241 (ER)

Ramos, D.J.:

Impax Laboratories, Inc. (“Impax” or “Plaintiff”) brought this action against Turing Pharmaceuticals AG (“Turing” or “Defendant”) on May 2, 2016, seeking to recover millions of dollars of rebate liability related to sales of the drug Daraprim. Before the Court is Defendant’s motion to dismiss with prejudice Plaintiff’s unjust enrichment claim (Count V of the Amended Complaint). For the following reasons, Defendant’s motion is GRANTED.

I. BACKGROUND¹

A. The Medicaid Drug Rebate Program

In order for pharmaceutical manufacturers to obtain Medicaid coverage for their prescription drugs, they must participate in the Medicaid Drug Rebate Program, a program designed to help lower Medicaid spending on outpatient prescription drugs. First Amended Complaint (“Am. Compl.”) (Doc. 34) ¶¶ 16–17. The program requires each manufacturer to execute a rebate agreement with the United States Department of Health and Human Services (“HHS”) and to submit certain certified pricing data to the Centers for Medicare and Medicaid

¹ The following facts are drawn from the Amended Complaint and are assumed true for the purposes of deciding Defendant’s motion.

Services (“CMS”) on a periodic basis for each of its covered outpatient drugs. *Id.* Each drug is linked to its manufacturer through its unique National Drug Code (“NDC”), part of which represents the manufacturer’s unique labeler code. *Id.* ¶ 1.

The pricing data submitted to CMS includes the best price and average manufacturer price (“AMP”) for each drug. *Id.* ¶ 17 & n.1. CMS uses the pricing data to calculate a unit rebate amount (“URA”) for each drug and transmits that information to the states. *Id.* ¶ 17. Each state then uses that data to calculate on a quarterly basis the rebate due from each manufacturer for the purchase of its drugs with Medicaid funds. *Id.* If a manufacturer fails to certify the relevant pricing data or pay the rebate liability due, it may be subject to, among other things, exclusion from the program, meaning its drugs may no longer be eligible for Medicaid coverage. *Id.* ¶ 21.

B. Impax Acquires Daraprim

In March 2015, Impax acquired Amedra Pharmaceuticals LLC (“Amedra”) and CorePharma LLC (“CorePharma”) and, in so doing, acquired the United States marketing rights for the drug Daraprim, an antiprotozoal medication mainly used to treat toxoplasmosis, a high risk and often times life-threatening disease for those affected by HIV, AIDS, cancer, and other diseases weakening the immune system. *Id.* ¶¶ 14, 16. By way of this transaction, Impax also acquired certain inventory of the drug, labeled with Amedra’s labeler codes, and assumed Amedra’s obligations under its Medicaid rebate agreement with HHS. *Id.* ¶ 16.

C. Turing Acquires Daraprim

Approximately five months after acquiring the rights to Daraprim, Impax sold those rights to Turing, along with its inventory of the drug, pursuant to an Asset Purchase Agreement

(“APA”) dated August 7, 2015 (the “Closing Date”).² *Id.* ¶ 22. Rather than require Turing to repackage all of the inventory with Turing’s own labeler codes right away, Impax authorized Turing to retain and sell to third parties any inventory containing Amedra’s labeler codes. *Id.*; *see* APA § 8.5(a).

Because Impax would remain liable for all rebate liability associated with Turing’s sales of Amedra-labeled Daraprim, Turing agreed to reimburse Impax for all rebate liability “directly arising out of or in connection with” Turing’s use, marketing, or sales of Daraprim under Amedra’s labeler codes. APA § 2.4(a); *see id.* §§ 8.3, 9.2(d) & Ex. E. In addition, because Impax would remain obligated to certify pricing data to CMS for Turing’s sales of Amedra-labeled Daraprim, Turing agreed to provide and certify its pricing data to Impax. APA § 9.2(e) & Ex. E.

Exhibit E to the APA sets forth in detail the parties’ respective roles and responsibilities related to Turing’s sale of Amedra-labeled Daraprim after the Closing Date. APA § 9.2(d), (e). On the 10th business day of each month, Impax was required to provide Turing with certain monthly and quarterly data with respect to Amedra-labeled Daraprim. APA, Ex. E at 1. Turing was then responsible for calculating certain data, including the best price and AMP for the drug. *Id.* No later than the 25th of each month, Turing was required to provide Impax with that data, as well as a communication that the calculations were reviewed, were accurate, and were approved by Turing. *Id.* No later than 30 days following the end of each month, Impax was required to submit all applicable information to CMS and to certify that information in accordance with CMS guidelines. *Id.* Impax was then required to process and pay all state Medicaid rebates for

² The APA is attached as Exhibit 1 to the Declaration of Kenneth M. Katz in Support of Defendant’s Motion to Dismiss Plaintiff’s Unjust Enrichment Claim (“Katz Decl.”) (Doc. 61). Because this agreement is incorporated by reference in the Amended Complaint, the Court may consider it in ruling on Turing’s motion to dismiss. *Roth v. Jennings*, 489 F.3d 499, 509 (2d Cir. 2007).

Amedra-labeled Daraprim and submit, on a monthly basis, documentation of those payments to Turing. *Id.* at 1–2. Finally, Turing was required to reimburse Impax for all Medicaid rebates, including interest, within 30 days from the date of each invoice. *Id.* at 2.

D. Turing Raises the Price of Daraprim

Shortly after acquiring the rights to Daraprim, Turing raised the price of the drug from \$17.63 per pill to \$750 per pill. Am. Compl. ¶ 26. In addition to dramatically increasing the cost of the drug for consumers, the price increase had two effects underlying the claims in this suit.

First, pursuant to a distribution agreement with Walgreen Company (“Walgreen”) that Turing assumed as part of the APA, *see* APA §§ 2.1, 2.2(a)(vi) & sched. 2.2(a), Walgreen was required, within 30 days of Turing raising the price of Daraprim, to pay Turing for the increased value of the inventory it held on hand, including inventory Walgreen originally purchased from Impax. *Id.* ¶ 28. Impax estimates that Walgreen was obligated to pay Turing approximately \$73,000 per 100-count bottle of Daraprim at the time of the price increase to account for this shelf stock adjustment. *Id.*³

Second, the price increase generated a significant amount of rebate liability, as a result of the increase in the drug’s AMP. On October 29, 2015, Turing provided Impax with its certification of pricing data for the third quarter of 2015 (“Q3 2015”). *Id.* ¶ 29. This data included, among other things, a quarterly AMP of \$750.000000 and a best price of \$17.628000. *Id.* After Impax reported this data to CMS, state Medicaid agencies invoiced Impax for over \$19 million in Medicaid rebate liability for that quarter. *Id.* ¶¶ 29–30.⁴ In January 2016, Impax

³ Turing has not demanded payment of this amount from Walgreen. *See* Pl.’s Opp’n Mem. (Doc. 63) at 6; Def.’s Reply Mem. (Doc. 72) at 1.

⁴ According to Impax, had those units been invoiced to Impax based on Daraprim’s pre-APA pricing, the total rebate liability for this period would have been just under \$375,000. Am. Compl. ¶ 30.

invoiced Turing for its share of the Q3 2015 rebate liability, which Impax calculated at approximately \$17.8 million. *Id.* ¶ 32.

On February 1, 2016, Turing provided Impax with its certification of pricing data for the fourth quarter of 2015 (“Q4 2015”). *Id.* ¶ 38. This data included, among other things, a quarterly AMP of \$719.392134 and a best price of \$719.392134. *Id.* Impax reported this data to CMS, and estimates that state Medicaid agencies will, in total, invoice Impax for over \$14 million in Medicaid rebate liability for that quarter. *Id.* ¶¶ 38–39. On March 1, 2016, Impax invoiced Turing for an additional \$2.4 million in rebate liability for Q3 2015 and Q4 2015. *Id.* ¶ 40.

On April 19, 2016, Impax sent a third invoice to Turing, requesting that it pay approximately \$10.2 million in rebate liability for Q4 2015. *Id.* ¶ 48 n.13. To date, the January, March, and April 2016 invoices remain outstanding. *Id.* ¶¶ 48, 92.

E. Turing Does Not Reimburse Impax and This Action Ensues

On February 16, 2016, Impax sent Turing a letter demanding that Turing pay the January 2016 invoice. *Id.* ¶ 34. Instead of responding to the letter, on March 22, 2016, Turing forwarded Impax a memorandum prepared by its attorneys at Reed Smith LLP. *Id.* ¶ 35. The memorandum suggested that the rebate liability invoiced to Turing was potentially overstated because the URA calculated by CMS, based on pricing data Turing certified to Impax, “may be incorrect.” *Id.* The memorandum further suggested that Impax and Turing might explore a “revised URA calculation.” *Id.*

On April 26, 2016, Impax’s CEO, G. Frederick Wilkinson, sent a letter to Turing’s CEO, Ron Tilles, explaining that if Turing did not pay the rebate liability due, Impax would need to take action to protect its rights. *Id.* ¶ 36. Wilkinson also demanded that Turing comply with its

other reporting obligations under the APA. *Id.* In telephone calls that followed that day, Tilles offered to make a \$1 million payment toward the rebate liability, which Impax found insufficient. *Id.* Turing also provided some pricing data for the first quarter of 2016 (“Q1 2016”), but Impax found the data insufficient. *Id.* ¶ 56. The following evening, April 27, 2016, Turing provided pricing data for *Turing*-labeled Daraprim and “recommended” that Impax report that data to CMS in place of the pricing data for *Amedra*-labeled Daraprim for Q1 2016. *Id.* ¶ 57.

On May 2, 2016, Impax brought the instant suit against Turing, seeking a declaratory judgment that Turing breached the APA, an order compelling specific performance of Turing’s reporting obligations under the APA, and damages for Turing’s breach of the APA. Complaint (“Compl.”) (Doc. 1) ¶¶ 65–76. Impax also sought a temporary restraining order and preliminary injunction ordering Turing to, among other things, stop selling *Amedra*-labeled Daraprim. The Court denied the requests, finding that although Impax had established a likelihood of success on the merits, it failed to demonstrate irreparable harm. *See* Doc. 31 (May 10, 2016 Transcript); Doc. 29 (May 18, 2016 Transcript). On May 24, 2016, Turing filed its answer to the complaint, along with a counterclaim for Impax’s alleged breach of the duty of good faith and fair dealing by refusing to engage with Turing to correct the errors in the pricing data submitted to CMS. Answer with Counterclaim (“Answer to Compl.”) (Doc. 27) ¶¶ 77–97. The parties thereafter began discovery.

On June 15, 2016, Turing provided Impax with documents purporting to certify a revised quarterly AMP of \$13.897496 for each of Q3 2015 and Q4 2015. Am. Compl. ¶ 42. According to Impax, Turing provided no plausible explanation for why a restatement was proper, and its revised certification provided insufficient data and information necessary to satisfy the regulatory requirements for restating pricing data to CMS. *Id.* ¶¶ 43–44.

Approximately one week later, on June 24, 2016, Impax amended its complaint to add allegations regarding Turing’s restatement, as well as allegations regarding the Walgreen shelf stock adjustment. Impax also asserted a new claim for unjust enrichment, alleging, in relevant part, that Turing received “a substantial windfall in the form of [Walgreen’s] payment for the increased value of the inventory *Impax* sold to Walgreen that Walgreen still held on hand at the time of the price increase,” that “[a]t the same time, Impax has been severely damaged by the price increase, through the dramatic resulting increase in [r]ebate [l]iability it has had to bear,” and that “[i]f it is determined that the [APA] does not require Turing to reimburse Impax for that [r]ebate [l]iability, it would nevertheless be inequitable and unjust to permit Turing to retain the its [*sic*] windfall benefit at Impax’s expense.” *Id.* ¶ 103 (emphasis in original). Turing thereafter added a counterclaim for Impax’s breach of the APA for failing to report the restated pricing data Turing supplied on June 15. Answer to First Amended Complaint with Counterclaims (“Answer to Am. Compl.”) (Doc. 43) ¶¶ 109–115.

Turing now moves to dismiss Impax’s claim for unjust enrichment under Rule 12(b)(6) of the Federal Rules of Civil Procedure. Impax opposes the motion.⁵

II. LEGAL STANDARD

Under Rule 12(b)(6), a complaint may be dismissed for “failure to state a claim upon which relief can be granted.” Fed. R. Civ. P. 12(b)(6). When ruling on a motion to dismiss pursuant to Rule 12(b)(6), the Court must accept all factual allegations in the complaint as true and draw all reasonable inferences in the plaintiff’s favor. *Koch v. Christie’s Int’l PLC*, 699 F.3d 141, 145 (2d Cir. 2012). However, the Court is not required to credit “mere conclusory

⁵ The parties are also in the process of filing cross-motions for summary judgment, with briefing scheduled to be complete on December 16, 2016.

statements” or “[t]hreadbare recitals of the elements of a cause of action.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). “To survive a motion to dismiss, a complaint must contain sufficient factual matter . . . to ‘state a claim to relief that is plausible on its face.’” *Id.* (quoting *Twombly*, 550 U.S. at 570). 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). If the plaintiff has not “nudged [his] claims across the line from conceivable to plausible, [the] complaint must be dismissed.” *Twombly*, 550 U.S. at 570.

III. DISCUSSION

Turing seeks dismissal of Impax’s unjust enrichment claim primarily on the basis that the subject matter of the claim is covered by the APA. Def.’s Mem. (Doc. 62) at 6–10.

In New York, it is “well settled” that “[w]here the parties executed a valid and enforceable written contract governing a particular subject matter, recovery on a theory of unjust enrichment for events arising out of that subject matter is ordinarily precluded.” *Simkin v. Blank*, 19 N.Y.3d 46, 55 (2012) (quoting *IDT Corp. v. Morgan Stanley Dean Witter & Co.*, 12 N.Y.3d 132, 142 (2009)); *see also Chiste v. Hotels.com L.P.*, Nos. 08 Civ. 10676 (CM), 08 Civ. 10744 (CM), 08 Civ. 10746 (CM), 10 Civ. 07522 (CM), 2011 WL 2150653, at *2 (S.D.N.Y. May 31, 2011) (same). For that reason, courts in this district routinely dismiss claims for unjust enrichment that are predicated on disputes covered by an agreement between the parties. *See, e.g., Epstein v. N.Y.C. Dist. Council of Carpenters Benefit Funds*, No. 15 Civ. 2866 (PAC), 2016 WL 1718262, at *3 (S.D.N.Y. Apr. 28, 2016); *Bancorp Servs., LLC v. Am. Gen. Life Ins. Co.*, No. 14 Civ. 9687 (VEC), 2016 WL 4916969, at *8 (S.D.N.Y. Feb. 11, 2016).

Although the parties agree that the APA constitutes a valid, enforceable agreement between them, Impax maintains that it should be permitted to proceed on its unjust enrichment claim for two separate reasons, both of which the Court rejects.

First, Impax argues that the APA does not clearly govern Turing's receipt of the shelf stock adjustment from Walgreen, on which the unjust enrichment claim is partially based. Pl.'s Opp'n Mem. at 2 ("At a minimum, Turing was unjustly enriched by its apparent receipt of legal entitlement to millions of dollars in value in the form of a shelf stock adjustment from Walgreen"); *see* Am. Compl. ¶ 103. Pursuant to the APA, however, Turing acquired "all right, title and interest . . . in, to and under" Impax's distribution agreement with Walgreen. APA § 2.1; *see also* APA § 2.2(a)(vi) & sched. 2.2(a). The propriety of Turing's entitlement to any payments due pursuant to that agreement thus falls squarely under the APA.

Second, Impax argues that the Court has not yet determined whether the APA covers all aspects of the Medicaid rebate liability Impax has paid or incurred as a result of Turing's price increase, including, specifically, the allocation of rebate liability assessed on inventory "put into the stream of commerce" by Impax before the Closing Date, but "resulting entirely from Turing's use, marketing and sale" of the drug after the Closing Date. Pl.'s Opp'n Mem. at 2–3. Both parties agree that the APA covers this issue, but Impax asserts that it should not be precluded from pleading an alternative theory of recovery were the Court to find otherwise. *Id.* at 11; Def.'s Reply Mem. at 3.

Having not been presented with the issue directly before, the Court now finds that the APA clearly covers all aspects of the parties' dispute as to Medicaid rebate liability assessed on Daraprim. The APA describes in detail how the parties intended to handle the issue of Medicaid rebate liability, specifically setting forth the parties' respective roles and responsibilities in

connection with Turing's ability to sell Amedra-labeled Daraprim. *See* APA §§ 2.4(a), 8.3, 9.2(d), (e) & Ex. E. The APA also addresses how rebate liability is meant to be allocated between the parties during a period in which both Impax and Turing may be responsible for a portion of the rebates. Exhibit E to the APA states: "Upon Close [Turing] shall be responsible for reimbursing [Impax] for all rebates on utilization that takes place after the Close. In the event that the Close takes place in the middle of a Quarter then [Turing] shall be responsible for a prorated amount of that Quarters [*sic*] rebate invoices."⁶ APA, Ex. E at 5–6. As Impax itself concedes, "[i]f the APA governs this issue, then Impax's breach of contract claim will resolve the dispute, and Impax will succeed or fail on the merits of that claim." Pl.'s Opp'n Mem. at 13. Having found that the APA does govern this issue, Impax's unjust enrichment claim must be dismissed.⁷

IV. CONCLUSION

For the foregoing reasons, Defendant's motion to dismiss with prejudice Plaintiff's unjust enrichment claim (Count V of the Amended Complaint) is GRANTED. Plaintiff's motion for

⁶ Section 9.2(d) of the APA also provides:

[O]n and after the Closing Date, (i) [Turing] shall have responsibility and shall assume all Liabilities for, all Rebates . . . made after the Closing Date for Products sold on or after the Closing Date, and (ii) [Impax] shall have responsibility to process, and assume all Liability for, all Rebates . . . made after the Closing Date for Products sold prior to the Closing Date.


See also APA § 9.2(g) ("In the event there is a conflict between this Section 9.2 and Exhibit E, the provisions of Exhibit E shall govern.").

⁷ Because the Court finds that the APA covers the subject of Impax's unjust enrichment claim, the Court need not consider Turing's alternative argument that Impax failed to adequately plead the claim. *See* Def.'s Mem. at 10–13.

oral argument is DENIED as moot. The Clerk of the Court is respectfully directed to terminate the motions, Doc. 60 & 65.

It is SO ORDERED.

Dated: November 16, 2016
New York, New York



Edgardo Ramos, U.S.D.J.