IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ANTRIM PHARMACEUTICALS LLC,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**Case No. 16 C 784**
	)	
BIO-PHARM, INC.,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

MATTHEW F. KENNELLY, District Judge:

Antrim Pharmaceuticals LLC sought to manufacture and sell generic pharmaceuticals. Antrim began to work with Bio-Pharm, Inc. a contract manufacturer, to produce two drugs, but their arrangement collapsed after Bio-Pharm withheld shipment of one of the products. Antrim has sued Bio-Pharm for breach of contract and unjust enrichment. Bio-Pharm has counterclaimed against Antrim, asserting claims of promissory estoppel and breach of contract. Both have moved for summary judgment.

Background

The present suit arises from a dispute between Antrim and Bio-Pharm involving the production of two generic drugs, escitalopram and ondansetron.[1] The following background focuses on four events leading to the present dispute: the execution of a term sheet outlining a plan to create a new entity, the subsequent dealings between

[1] Escitalopram is the generic form of Lexapro, and ondansetron is the generic form of Zofran.

Antrim and Bio-Pharm, Antrim's navigation of the regulatory barriers to its sale of the pharmaceuticals, and the breakdown of the relationship between the two companies.

I. Term Sheet

In December 2009, Antrim (then doing business as BrianT Laboratories of Illinois LLC), Bio-Pharm, and S. Zhaveri Pharmakem PVT, Ltd. entered into an agreement regarding a prospective venture. The Court refers to this agreement as the Term Sheet. The Term Sheet was drafted to "formaliz[e] the relationship" between the three entities seeking to form a new entity to produce pharmaceutical products. D.E. 77, Def.'s Ex. 2 at Antrim 0002329. Antrim would own sixty percent of the new venture; Zhaveri and Bio-Pharm would each own twenty percent.

According to its terms, the Term Sheet was to be replaced by a "Definitive Agreement" within 90 days. It also provided that, "[i]n case a Definitive Agreement is not entered into within the aforesaid period for reason that any of the Parties is not interested in continuing with the subject matter stated herein, then the Agreement the Term Sheet [sic] shall stand terminated . . . ." *Id.* at Antrim 0002334. Zhaveri departed from the arrangement, but Antrim and Bio-Pharm continued to pursue a business relationship. They never created a new entity.

II. Antrim and Bio-Pharm's relationship

In November 2010, approximately a year after creating the Term Sheet, Brian Tambi, one of the owners of Antrim, e-mailed Amit Shah, Bio-Pharm's Vice President of Corporate Development, stating: "As you know we don't have an Agreement as yet. . . . I suggested that we just follow the [Term Sheet] and I will see about making it an operational Agreement." D.E. 77, Def.'s Ex. 7 at BIO-PHARM 013287. Shah

responded: "I agree that we should not spend anymore money with lawyers and agreement and we are fine with formailizing [sic] and reactivating the [Term Sheet]." *Id*.

The parties continued to discuss the matter in e-mails and otherwise. *See* D.E. 82, Pl.'s Ex. 34 at Antrim 0002551-53 (Mar. 7, 2012 Tambi e-mail to Shah). In August 2012, Shah sent an e-mail to Tambi in which he described the current status of the parties' relationship: "[Y]ou decided you would continue the relationship with Bio-Pharm. We also showed our interest in receiving some type of equity investment/committment [sic] as we felt that would make the most sense for us so as not to have conflicts and also grow each others businesses in the best possible manner." *Id.* at Antrim 0002551.

In January 2013, Shah e-mailed Tambi, writing "[w]e would like to have a final agreement at the moment we just have the Term Sheet." D.E. 77, Def.'s Ex. 8 at Antrim 0001954. Shah also stated: "We feel for the level of work we are putting in to the project during the development and eventual commercialization we would like to have a larger share in the product." *Id.* In response to Shah's first point, Tambi responded: "Agree—I will finalize the Agreement." *Id.* He also wrote: "I regret I cannot change the Terms we agreed unless there is something patently unfair. As I countered on the Phone, Amit, I do not find this to be the case. I have been subject to this type of post-Agreement suggestions by Companies in India and I have recinded [sic] the Agreements." *Id.*

In subsequent e-mails, Shah and Tambi continued to dispute whether Bio-Pharm was entitled to equity. In July 2015, Shah e-mailed a draft agreement to Tambi that contained a section stating that Antrim and Bio-Pharm would "jointly own the products in

a ratio of 75:25%." D.E. 82, Pl.'s Ex. 9 at Antrim 0001252. Tambi deleted the ownership section and replaced it with a term providing for a profit-sharing arrangement in which Bio-Pharm would receive twenty-five percent and Antrim seventy-five percent of the profits over the commercial life of the product. *.Id.*

Antrim contends that, during the same period the e-mails were exchanged, Shah and Tambi engaged in phone conversations about their arrangement. During his deposition, Tambi testified to numerous phone calls he had with Shah, in which he said they agreed to a profit-sharing arrangement, as opposed to an equity share:

> Q. Did Amit ever say to you in writing, I understand that Bio-Pharm does not have any equity in Escitalopram?
>
> A. I think that he – he understood that. There are a number of telephone calls where that was acknowledged.
>
> Q. Okay.
>
> A. Now, whether we put it into an e-mail, I don't know, but I will – we will search for it.
>
> Q. Yeah. That's my question, is: Did he ever say that to you in writing?
>
> A. Not in writing, but I think – I am very positive that he said he said he understood that on telephone calls.

Id., Pl.'s Ex. 1 at 245-46. But Tambi also testified that he was not able to "definitively" state that Shah conceded that Bio-Pharm would have no equity share. *Id.* at 110. Tambi testified that an oral agreement between the parties was formed under which Bio-Pharm would obtain twenty-five percent of the profits over the life of the products and would be compensated for its costs in manufacturing the drug through the proceeds of the sale of the drug. Tambi also testified that Bio-Pharm would be compensated upon sale of the drug based on the cost of production, plus ten percent. Shah likewise

testified that Bio-Pharm would be reimbursed from the sales proceeds.

III. Antrim's ability to market

Meanwhile, Antrim was also engaged in the process of obtaining regulatory approval to manufacture and market escitalopram and ondansetron. To obtain approval to market the pharmaceuticals, Antrim was required to successfully complete an Abbreviated New Drug Application (ANDA) for approval by the Food and Drug Administration. Part of the ANDA process includes shipping samples of the products for FDA review. Bio-Pharm produced these samples and supplied them for the ANDA. The FDA approved Antrim's ANDA for escitalopram on February 2, 2012. But the FDA has never approved Antrim's ANDA for ondansetron.

Additionally, Antrim was required to find a third party that could market and distribute the pharmaceuticals that Bio-Pharm produced. At the time, Antrim planned to use Leading Pharmaceuticals, an entity licensed to fulfill this role. The parties dispute whether the relationship was finalized. Antrim also contends that it has secured an agreement with another third-party seller, RxTPL, but it is unclear from the record whether a contract between Antrim and RxTPL exists.

IV. Bio-Pharm withholds escitalopram

After the FDA approved the ANDA for escitalopram and as Leading Pharmaceuticals and Antrim were finalizing a distribution agreement, Bio-Pharm withheld shipment of the escitalopram (Bio-Pharm concedes this). Antrim and Bio-Pharm never sold any of the pharmaceuticals Bio-Pharm produced. Bio-Pharm contends that it incurred $277,000 in manufacturing costs: $152,000 for escitalopram and $125,000 for ondansetron. Bio-Pharm alleges that in manufacturing the products, it

relied on Antrim's purported promise to provide it with an equity share; it says it withheld the products when Antrim declined to extend the promised equity.

In January 2016, Antrim sued Bio-Pharm for breach of contract and conversion. The Court later dismissed the conversion claim. *Antrim Pharms. LLC v. Bio-Pharm, Inc.*, 16 C 784, D.E. 21 (N.D. Ill. June 12, 2016). Bio-Pharm has counterclaimed, asserting claims of promissory estoppel and breach of contract. Both parties have moved for summary judgment.

Discussion

To prevail on a motion for summary judgment, the movant must "show[] that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). When considering a motion for summary judgment, the Court takes all reasonable inferences and construes all facts in favor of the nonmoving party. *Omnicare, Inc. v. UnitedHealth Grp., Inc.*, 629 F.3d 697, 706 (7th Cir. 2011). To defeat summary judgment, the nonmoving party must "produc[e] evidence that is more than 'merely colorable,' that there is a genuine issue for trial." *Id.* (citation omitted).

I. Antrim's motion for summary judgment

Antrim seeks summary judgment on the promissory estoppel and breach of contract claims in Bio-Pharm's counterclaim, which Bio-Pharm asserts in the alternative. In its promissory estoppel claim, Bio-Pharm alleges that Antrim made a promise to provide Bio-Pharm a share of equity in the products, among other benefits, in return for manufacturing the products. In its breach of contract claim, Bio-Pharm alleges that Antrim assented to a contract based upon the Term Sheet that promised Bio-Pharm a

share of equity in the pharmaceuticals. Bio-Pharm further alleges that Antrim breached that contract by denying Bio-Pharm the promised equity.

In seeking summary judgment, Antrim first argues that although Bio-Pharm is looking for damages for the deprivation of an equity stake, it has not introduced evidence of damages from this deprivation. Antrim contends it is entitled to summary judgment on both claims as a result. Bio-Pharm disputes Antrim's characterization of its claim: it says it is seeking damages for the losses it incurred while investing in the manufacturing processes to produce the pharmaceuticals, not for Antrim's refusal to extend an equity stake. Bio-Pharm argues that it has presented sufficient evidence to establish damages. The Court concurs, as Bio-Pharm has introduced adequate evidence of the $277,000 it expended in manufacturing costs for a reasonable jury to find in its favor on this point. *See* D.E. 77, Def.'s Ex. 6 at ¶ 20 (Shah Decl.); D.E. 78, Def.'s Ex. 1 (Breakdown of Costs). Antrim is not entitled to summary judgment on this basis.

Second, Antrim argues it is entitled to summary judgment because the damages Bio-Pharm asserts—unpaid manufacturing costs—only arose because Bio-Pharm refused to ship the drugs. Antrim contends that Bio-Pharm agreed to be paid out of the profits of the sale of the pharmaceuticals and that, by refusing to ship the products, Bio-Pharm caused the very losses of which it complains. Bio-Pharm retorts that it had no obligation to perform because Antrim repudiated the contract by refusing to provide an equity stake, as specified in the contract that Bio-Pharm contends arose from the Term Sheet.

The Court cannot resolve this dispute in Antrim's favor on a motion for summary

judgment, for a reasonable jury could find that the contract that Bio-Pharm contends was formed actually exists. First, under the Term Sheet, Bio-Pharm was to obtain a twenty percent share of equity in the venture that the Term Sheet assumed would be created. Although the joint venture never materialized, there is evidence that Tambi and Shah agreed in November 2010 to "formaliz[e]" and "reactivat[e]" the Term Sheet in lieu of creating another agreement. D.E. 77, Def.'s Ex. 7 at BIO-PHARM 013287. Again, in January 2013, Shah e-mailed Tambi to ask for a final agreement because "at the moment we just have the Term Sheet." *Id.*, Def.'s Ex. 8 at Antrim 0001954. Tambi concurred. *Id.* Even though the Term Sheet specified that it would terminate after a certain period if no final agreement was reached, *id.*, Def.'s Ex. 2 at Antrim 0002334 (Term Sheet), the Court is not convinced that this otherwise forecloses Bio-Pharm's contract argument, as a reasonable jury could find that the parties thereafter expressed their intention to be bound by the terms of the Term Sheet.

Based on this evidence, a reasonable jury could conclude that Bio-Pharm had a contractual right to equity in the products. And if a jury so found, it could reasonably determine that Antrim repudiated the contract by denying Bio-Pharm its ownership stake in the pharmaceuticals.

Antrim relies upon upon *In re Marriage of Olsen*, 124 Ill. 2d 19, 528 N.E.2d 684 (1988), to show that it did not repudiate the contract. In *Marriage of Olsen*, the Illinois Supreme Court held that an anticipatory repudiation "requires a clear manifestation of an intent not to perform the contract[.]" *Id.* at 24, 528 N.E.2d at 686. But here there is evidence that Antrim clearly manifested that it would not extend Bio-Pharm an equity stake, so *Marriage of Olsen* affords Antrim little aid.

For the foregoing reasons, the Court denies Antrim's motion for summary judgment on either of the claims in Bio-Pharm's counterclaim

II. Bio-Pharm's motion for summary judgment

Bio-Pharm has moved for summary judgment on Antrim's breach of contract and unjust enrichment claims. Bio-Pharm argues it is entitled to summary judgment on Antrim's breach of contract claim for four reasons: Antrim cannot establish that an oral agreement superseded the Term Sheet; Bio-Pharm did not cause Antrim damages; Antrim is a new business that, under Illinois law, cannot recover lost profits; and Antrim failed to mitigate its damages. Bio-Pharm also argues Antrim's unjust enrichment claim fails because there is no evidence Bio-Pharm ever benefitted by retaining the products.

A. Superseding agreement

Antrim's breach of contract claim is based on an alleged agreement formed after the execution of the Term Sheet. Bio-Pharm argues that it is entitled to summary judgment because no contract was ever formed after the Term Sheet. (This argument is offered in the alternative to Bio-Pharm's contention that a contract exists that Antrim repudiated.) Antrim argues that a reasonable jury could find that a contract existed, under which (1) Bio-Pharm would manufacture the products for regulatory and commercial use and be compensated for its manufacturing costs upon sale of the products, (2) Bio-Pharm would obtain 25 percent of net profits for the life of the drug, (3) Bio-Pharm would sell the manufactured pharmaceuticals to Antrim at the cost of production plus ten percent, and (4) Antrim would market the drugs. *See* D.E. 82, Pl.'s Ex. 1 at 144-45 (Tambi Dep.) (describing the terms of the purported agreement). Antrim also argues that a reasonable jury could find that the contract did not include a term

under which Bio-Pharm would obtain an equity interest in the products. *Id.* at 245-46.

It is not entirely clear whether Antrim seeks to prove the existence of an express, oral contract or an implied contract. "The [ ] difference between an express contract and an implied contract is the mode of proof. An express contract is proven by an actual agreement or by the expressed words used by the parties. An implied contract is proven by circumstances showing that the parties intended to contract . . . ." *In re Brumshagen's Estate*, 27 Ill. App. 2d 14, 23, 169 N.E.2d 112, 116-17 (1960). The Court will review the evidence that supports each of these theories.

1. Express contract

First, Antrim provides the deposition testimony of Tambi to support the existence of an express, oral contract. During his deposition, Tambi stated that an oral contract between Antrim and Bio-Pharm was formed with the following terms: (1) Bio-Pharm would manufacture the pharmaceuticals and obtain reimbursement for its costs from the net profits, (2) Bio-Pharm would obtain 25 percent of net profits, (3) the price at which Bio-Pharm would sell the products to Antrim was the cost of production, plus ten percent, and (4) Antrim would market the drugs. D.E. 82, Pl.'s Ex. 1 at 144-45. Finally, Tambi also stated that Shah "understood" that Bio-Pharm did not have any equity in the drugs, because "[t]here are a number of telephone calls where that was acknowledged." *Id.* at 245. Tambi was "very positive" that Shah understood Bio-Pharm did not have any equity in the products. *Id.* at 246.

Bio-Pharm identified a number of other statements in which Tambi was more equivocal about the absence of an agreement to give Bio-Pharm equity. *See id.* at 110 ("Q: I am asking whether you recall whether Amit ever said in his own words that he

understood Bio-Pharm did not have an equity ownership position in Escitalopram. A: My understanding to that: He may have."). But when considered on a motion for summary judgment, with all inferences taken in favor of a non-moving party, Tambi's deposition testimony was not so equivocal that no reasonable jury could find that an oral contract was formed in the way that Tambi described.

2. Implied contract

Antrim also introduces evidence to support a claim of an implied contract. A contract "may be . . . implied when it is inferred from the acts or conduct of the parties instead of their spoken words." *In re Brumshagen's Estate*, 27 Ill. App. 2d at 23, 169 N.E.2d at 116-17. For each term of the purported contract, Antrim has introduced evidence of the parties' conduct that supports its existence.

First, a reasonable jury could conclude, based on the parties' conduct, that they agreed that Bio-Pharm would manufacture the products for regulatory and commercial use and would be compensated for its manufacturing costs upon sale of the products. Antrim introduced the letter from the FDA approving its escitalopram ANDA, in which the FDA lists Bio-Pharm as the manufacturer. D.E. 66, Pl.'s Ex. 8 at Antrim 0003140 (regulatory letter approving ANDA). This letter supports a contention that Bio-Pharm had agreed to manufacture the samples that the FDA analyzed in the ANDA. *See also* D.E. 82, Pl.'s Ex. 3 at 283 (Shah Dep.).

Next, Antrim has also introduced evidence that the parties acted consistently with the existence of the alleged profit-sharing term of the contract. For instance, in a March 2012 e-mail, Shah told Tambi that "we would like to have more of an association than just a product partnership/nominal profit share etc." *Id.*, Pl.'s Ex. 2 at Antrim 0002557.

One could reasonably infer from this that Shah and Tambi had agreed to a profit-sharing arrangement and that Shah was trying to change that term. Indeed, in response, Tambi stated "we agreed to a 20% Share in the Net Profit of each product BioPharm manufactures." *Id.* at Antrim 0002556. The parties continued to work together after this e-mail exchange. A reasonable jury could conclude that the conduct of the parties implies the existence of an agreement in which Bio-Pharm would share in the profits of the products sold.

As to the third term—the price of the goods—a reasonable jury could also find that the conduct of the parties implies an agreement on price. In at least two e-mails, Tambi mentioned that the price of the goods would be calculated as the cost plus ten percent, to which Shah either assented, *id.*, Pl.'s Ex. 10 at BIO-PHARM 000399 (Nov. 25, 2015 Shah e-mail to Tambi), or did not object. *Id.*, Pl.'s Ex. 5 at Antrim 0000999 (July 23, 2015 Shah e-mail to Tambi). A reasonable jury could infer that, because both Tambi and Shah exchanged e-mails that referenced this formula, the parties had agreed that the formula would be used to calculate the price.

Bio-Pharm argues that there was no agreement on price, because Antrim's expert used $4 as the unit cost for escitalopram in his expert report, whereas Bio-Pharm contends the proper unit cost was $6.78. Bio-Pharm also argues that because the expert report relies on a price different from the term it views as the proper price, the report must be excluded. The Court overrules both arguments for the same reason: there is evidence that the parties agreed on a formula for calculating price, even if not on a specific dollar amount.

Antrim also argues that the Court should exclude Shah's affidavit because it

contradicts his prior deposition testimony about the price term. *See Bank of Ill. v. Allied Signal Safety Restraint Sys.*, 75 F.3d 1162, 1168 (7th Cir. 1996) (a party cannot submit an affidavit that (1) contradicts a prior deposition to (2) create a "sham" dispute of fact). But these statements can be reconciled, as Shah's testimony that the parties agreed on how to calculate price, D.E. 66, Pl.'s Ex. 7 at 219-20, does not contradict his later declaration that the parties did not agree that $6.78 per bottle was the correct price. D.E. 77, Def.'s Ex. 6 at 4. Additionally, Shah's affidavit does not create a "sham" issue of fact. The parties did dispute whether $6.78 was the proper cost per unit, even if a reasonable jury could conclude that the parties agreed on how to calculate the cost. The Court concludes that a reasonable jury could find from the conduct of the parties that they reached an agreement on price.

Likewise, a reasonable jury could conclude that the parties' conduct indicated agreement on Antrim's marketing responsibilities. For instance, the Term Sheet indicated each of Antrim's responsibilities, D.E. 77, Def.'s Ex. 2 at Antrim 0002332, and Antrim acted on those responsibilities by pursuing a distribution agreement with Leading Pharmaceuticals. D.E. 82, Pl.'s Ex. 44 (distribution agreement).

Finally, Antrim has introduced evidence of the parties' conduct sufficient to permit a reasonable jury to find that the parties agreed that Bio-Pharm would not get equity in return for its manufacture of the products but instead would get a share of the profits. In support of this proposition, Antrim notes that Shah e-mailed Tambi in August 2012 to state that Bio-Pharm "showed our interest in receiving some type of equity investment/committment [sic] . . . ." *Id.*, Pl.'s Ex. 34 at Antrim 0002551. As indicated earlier, this suggests that Bio-Pharm was interested in changing the agreement's terms

to obtain an equity stake but had previously agreed to proceed without that. In further support of this inference is a January 2013 e-mail exchange. On January 11, Shah e-mailed Tambi: "We feel for the level of work we are putting in to the project during the development and eventual commercialization we would like to have a larger share in the product." D.E. 77, Def.'s Ex. 8 at Antrim 0001954. Tambi responded on January 12, stating "I regret I cannot change the Terms we agreed unless there is something patently unfair. As I countered on the Phone, Amit, I do not find this to be the case. I have been subjected to this type of post-Agreement suggestions by Companies in India and I have recinded [sic] the Agreements." *Id.* After this January 2013 exchange, the parties continued to work together until 2016. These e-mails support a reasonable inference that an agreement preexisted the e-mails and the parties had agreed that Bio-Pharm would not obtain an equity share in the pharmaceuticals.

A reasonable jury could infer that in seeking an equity share, Shah was trying to change the terms of an existing agreement, rather than trying to reach agreement on a not-yet-formed contract. For example, in a July 27, 2015 e-mail, Tambi wrote to Shah that Bio-Pharm would receive a share of the profits, not a share of the equity, and that Bio-Pharm had previously agreed to these terms. *Id.*, Def.'s Ex. 4 at BIO-PHARM 0000086-87. Antrim also offers e-mails from Shah that support this inference. Shah drafted an e-mail that was to be sent to Tambi as part of an e-mail exchange regarding Bio-Pharm's claimed equity stake in the products. Shah forwarded the e-mail to his father for review and stated that he wanted to "threaten" Tambi. D.E. 82, Pl.'s Ex. 10 at BIO-PHARM 000392-95. His father stated in a separate e-mail that Tambi was a "tough cookie to break." *Id.*, Pl.'s Ex. 40 at BIO-PHARM 000555. A jury might reasonably infer

from this conduct that Shah was attempting to add an equity share to an existing contract that did not include one. The Court finds that Antrim presented evidence sufficient to support the existence of an implied contract.

For these reasons, the Court is unpersuaded by Bio-Pharm's contention that no reasonable jury would find an enforceable contract including the terms argued by Antrim. Bio-Pharm notes that, when the parties attempted to reduce their agreement to writing, every draft agreement Shah offered included an equity stake. Bio-Pharm also relies on e-mails to show that the parties had not concluded an agreement as of January 2013, May 2014, or June 2015, as they were still exchanging proposals for a written agreement. But the absence of a final writing does not mean that there can be no enforceable contract. Tambi testifies that these e-mails arose in a context in which the parties had already orally agreed over phone calls to the terms of an agreement. A reasonable jury could conclude that Bio-Pharm assented to an arrangement in which it did not have an equity stake, even though it kept trying to add an equity share after the fact.

Taken together, the e-mails and Tambi's deposition testimony provide an adequate foundation for a reasonable jury to conclude that the parties had an enforceable agreement, express or implied. Accordingly, Bio-Pharm is not entitled to summary judgment on this ground.

B. Damages

Bio-Pharm argues that Antrim cannot obtain damages, because, even if Bio-Pharm had properly delivered the products, regulations barred Antrim from selling either ondansetron or escitalopram. "[T]he party requesting damages must show causation . .

. [or] that the alleged breach is the cause of those damages, with reasonable certainty." *TAS Distrib. Co. v. Cummins Engine Co.*, 491 F.3d 625, 633 (7th Cir. 2007). First, Bio-Pharm contends that Antrim cannot obtain damages relating to ondansetron: because the FDA never approved the ondansetron ANDA, Antrim could not have lawfully sold the product, even if Bio-Pharm had produced it. Second, Bio-Pharm argues that Antrim cannot obtain damages relating to escitalopram. Even though Antrim's ANDA escitalopram was approved, Bio-Pharm contends that Antrim was not licensed to directly market pharmaceuticals and had not obtained an agreement with a third party marketer. Because no agreement was formed, Bio-Pharm argues, Antrim could not distribute the escitalopram Bio-Pharm withheld and thus suffered no damages.

1. Ondansetron

First, Bio-Pharm argues that it could not have caused Antrim any recoverable damages with respect to lost profits for ondansetron because the FDA never approved the ondansetron ANDA. A company that wishes to market a drug must obtain government approval through a successful ANDA. *See* D.E. 66, Pl.'s Ex. 9 (example of an ANDA). Antrim concedes that the FDA never approved its ondansetron ANDA.

To prevail on a breach of contract claim, a plaintiff must establish both that the defendant breached a contract and that an injury resulted from the breach. *Hess v. Kanoski & Assocs.*, 668 F.3d 446, 452 (7th Cir. 2012) (citing *Henderson-Smith & Assoc., Inc. v. Nahamani Family Serv. Ctr., Inc.*, 323 Ill. App. 3d 15, 27, 752 N.E.2d 33, 43 (2001)). Antrim's failure to obtain approval of an ANDA for ondansetron means that it was not authorized to market the ondansetron that Bio-Pharm produced. Thus no injury could have resulted from Bio-Pharm's purported breach of the agreement with

respect to that product.

Antrim argues that as a result of Bio-Pharm's refusal to ship the product, Antrim must restart the ANDA process for ondansetron, which will delay its ability to sell the product in the future. But this theory of damages assumes that the FDA would have approved Antrim's ondansetron ANDA but for Bio-Pharm's purported breach and that the FDA will approve Antrim's ondansetron ANDA once it re-applies. Both of these points are speculative. Accordingly, Antrim has not "demonstrat[ed] actual damage," as required to sustain a claim for breach of contract. *TAS Distrib. Co.*, 491 F.3d at 631. The Court concludes Bio-Pharm is entitled to summary judgment on Bio-Pharm's breach of contract claim pertaining to ondansetron.

2. Escitalopram

Bio-Pharm also argues that Antrim suffered no damages with regard to escitalopram because it never reached an agreement with any entity licensed to distribute the product. The parties agree that Antrim needed a third party to distribute the product on its behalf. They dispute, however, whether Antrim had an agreement with a third party to distribute escitalopram. Antrim argues it had a distribution agreement with Leading Pharmaceuticals, a licensed entity. D.E. 82, Pl.'s Ex. 44 (distribution agreement). Tambi testified that Antrim entered into an agreement with Leading Pharmaceuticals to distribute the escitalopram that Bio-Pharm manufactured. *Id.*, Pl.'s Ex. 1 at 44. Antrim also offers a January 5, 2016 e-mail that Brian Shapiro, an employee of Leading Pharmaceuticals, sent to Tambi and Shah, stating that "[the] agreements are simply awaiting signature by Antrim." *Id.*, Pl.'s Ex. 16 at LEADING-00000575. Antrim argues the agreements were not finalized only because, on January

6, Tambi e-mailed Shapiro with "bad news": Bio-Pharm had withheld the escitalopram as a result of the dispute over the equity share. *Id.*, Pl.'s Ex. 20 at LEADING-00001990.

Bio-Pharm disputes this contention. It cites the deposition testimony of Shapiro, the Rule 30(b)(6) witness for Leading Pharmaceuticals. Shapiro testified that Leading Pharmaceuticals was not prepared to distribute escitalopram on Antrim's behalf: "We never reached a point to allow that to happen, the shipment. You know you can't ship without an audit, you can't ship without a purchase order, so none of those things ever took place because we never got to the execution point of the agreement." D.E. 77, Def.'s Ex. 14 at 20. Shapiro also stated that it could not distribute on Antrim's behalf, because Leading Pharmaceuticals did not have access to the final unit costs of escitalopram or the amount to be sold. *Id.* at 64-65.

A reasonable jury could conclude that the barriers to an agreement with Leading Pharmaceuticals that Bio-Pharm has identified exist only because Antrim and Leading stopped moving towards an agreement once it became apparent that Bio-Pharm would withhold the escitalopram. The Court declines to grant summary judgment on this ground, because a reasonable jury, taking all inferences in Antrim's favor, could conclude that Leading Pharmaceuticals and Antrim would have had a final agreement, but for Bio-Pharm's decision not to ship the escitalopram.

Antrim also argues it had a relationship with another third-party seller, RxTPL, but the Court does not need to resolve the status of this relationship, as Antrim has presented adequate evidence of a relationship with Leading Pharmaceuticals to defeat Bio-Pharm's motion.

C. New business rule

Bio-Pharm's third argument for summary judgment is that, under the so-called new business rule, Illinois law does not permit Antrim to recover lost profits. "The general rule under Illinois law is that a new business has no right to recover lost profits." *TAS Distrib. Co.*, 491 F.3d at 634. The rationale is that new businesses have no history of profits, so any lost profits damages would be speculative. *Id.* at 633-34. The rule, however, is not "inviolate." *Tri-G, Inc. v. Burke, Bosselman & Weaver*, 222 Ill. 2d 218, 249, 856 N.E.2d 389, 407 (2006). Illinois courts applying the new business rule permit an exception if a plaintiff offers expert testimony featuring "convincing and non-speculative evidence sufficient to prove lost profits." *TAS Distrib. Co.*, 491 F.3d at 633.

In *Milex Products, Inc. v. Alra Laboratories, Inc.*, 237 Ill. App. 3d 177, 603 N.E.2d 1226 (1992), the Illinois appellate court allowed a new business to pursue lost profits because the loss could be proved to a "reasonable degree of certainty" by "proof [that] was neither speculative nor the product of conjecture." *Id.* at 193, 603 N.E.2d at 1237. Milex, a company that wished to produce a generic version of a fertility drug, entered into an agreement with a pharmaceutical contract manufacturer. *Id.* at 179-80, 603 N.E.2d at 1228. Milex had not previously entered the pharmaceutical industry. *Id.* at 179, 603 N.E.2d at 1228. Milex later sued its manufacturer for breach of contract after the manufacturer insisted on terms different from the purported original terms. *Id*. Milex introduced expert testimony regarding the profits it contended it lost from the defendant's purported breach. The expert considered the price of the pharmaceuticals, the total number of prescriptions in the market, and the average size of a prescription. *Id.* at 184-85, 603 N.E.2d at 1231-32. He also used data from IMS, "the largest data

collection and information business in the pharmaceutical industry." *Id.* at 184, 603 N.E.2d at 1231. The Illinois appellate court concluded that the Milex expert provided credible testimony, which provided "a reasonable degree of certainty," so the new business rule did not bar Milex from pursuing lost profits. *Id.* at 193, 603 N.E.2d at 1237.

Antrim has presented the expert testimony of Sean Brynjelsen in support of its claim for lost profits. D.E. 82, Pl.'s Ex. 25 at 5, App. C (Brynjelsen Expert Rep.). Brynjelsen's testimony is quite similar to the expert testimony discussed in *Milex*. In his report, Brynjelsen states that, to reach an opinion on lost profits, he considered the average price of escitalopram, the total volume of escitalopram sales in the market, and the estimated number of units that Antrim would sell. *Id.* Like the expert in *Milex*, Brynjelsen also relied upon IMS data. *Id.* at 4. For the same reasons described in *Milex*, the Court concludes that Antrim has offered evidence sufficient to establish a lost profits estimate with "a reasonable degree of certainty," and thus the new business rule does not bar its lost profits claim.

Bio-Pharm argues that lost profits cannot be reasonably predicted because the corporate organization of Antrim renders it unlike the other companies that Brynjelsen relied upon in his expert report. Bio-Pharm contends that Tambi describes Antrim as a "virtual business," which is unlike the other pharmaceutical companies that Brynjelsen analyzed. The Court finds this argument unpersuasive. This point may bear on the weight to be given to Brynjelsen's testimony, but it does not support its exclusion or suggest that the testimony is insufficient as a matter of law to support Antrim's lost profits claim. Nothing in *Milex* suggests that the sort of identity of structure or

functioning that Bio-Pharm advocates is required. The relevant comparison in *Milex* is between the plaintiff's claimed lost profits and the profits of other similar businesses, using "actual products in the marketplace as well as authoritative sources for the data [that the expert] used." *Milex*, 237 Ill. App. 3d at 192, 603 N.E.2d at 1236. Bio-Pharm has not established that Antrim's supposed status as a "virtual company" undermines the validity of the comparison that Brynjelsen performed.

For this reason, the Court finds unconvincing Bio-Pharm's reliance upon *Kinesoft Development Corp. v. Softbank Holdings Inc.*, 139 F. Supp. 2d 869 (N.D. Ill. 2001). In *Kinesoft*, the court concluded that *Milex* was inapplicable to a business that unsuccessfully produced PC games, as the PC game industry was "hit driven," meaning that some games did very well while others did not, and companies must find a "formula" to repeatedly produce successful games. *Id.* at 887. The plaintiff's expert, considering a new business that never issued a product, was thus unable to base his profit projections on a "comparable company selling comparable games." *Id.* at 888, 910. Bio-Pharm offers nothing to suggest that pharmaceutical companies similarly need to find a unique approach to obtain success in the generic pharmaceuticals market. Indeed, the pharmaceutical products at issue are, by definition, generic; they are the opposite of a "hit driven" product.

The Court concludes that Antrim has presented expert evidence that satisfies the *Milex* standard and declines Bio-Pharm's motion for summary judgment.

D. Failure to mitigate

Bio-Pharm next argues that it is entitled to partial summary judgment on Antrim's breach of contract claim, as Antrim failed to mitigate its damages. "[A]n injured party

has an obligation to take reasonable steps to minimize his damages and thus avoid heaping up additional losses for which the tortfeasor may be held liable." *Toledo Peoria & W. Ry. v. Metro Waste Sys., Inc.*, 59 F.3d 637, 640 (7th Cir. 1995) (citations omitted). Bio-Pharm argues that Antrim did not need more than a year to find another contract manufacturer to replace it, so it should not be permitted to obtain damages for any injuries beyond one year after the purported breach.

The process of obtaining a new manufacturer and FDA approval for the change in manufacturing is known as a "site change." Bio-Pharm contends that Antrim could complete a site change in approximately a year. In support of its contention, Bio-Pharm has introduced the expert testimony of Mark Schwartz.[2] D.E. 66, Pl.'s Ex. 3 (Schwartz Expert Rep.). Schwartz characterized the site change as a six-step process: (1) find a new contract manufacturer, which should take no more than two months; (2) source materials to manufacture the drug, which should take no more than two months; (3) submit additional regulatory documentation, which should take no more than "a couple of days"; (4) prove to the FDA that the manufacturing process is reliable, which should take no more than a month; (5) provide information on the stability of the drugs, which takes about six months; and (6) submit a supplemental document, known as a CBE-30, which should take no more than a month. *Id.* at 4-7.

The length of two steps in this process—finding a new manufacturer and submitting supplemental documents to the FDA—are the source of particular dispute between the parties. First, Bio-Pharm and Antrim dispute the amount of time it takes to

[2] Antrim challenges the admissibility of Schwartz's testimony in its Local Rule 56.1 statement, but its argument is insufficiently developed to preserve the point for purposes of the present motions.

find a new contract manufacturer. Bio-Pharm offers Schwartz's expert report, in which he notes that Tambi testified that finding a new manufacturer would take a month, *id.* at 4 n.4, and opines it would take approximately two months. *Id.* at 4. But Schwartz's report mischaracterizes Tambi's testimony, the relevant excerpt of which is as follows:

> A. . . . [W]e are still trying to get a company to – that we can trust. You can get companies to market – to manufacture this. There are tons of companies, but can you trust these guys.
>
> Q. How long does it usually take to find a good manufacturer?
>
> A. It's difficult to find a good manufacturer. As I'm saying you can find a manufacturer.
>
> Q. Well, *setting aside the trust issue*, which I understand, but, I mean, just if you were to – you were looking for any manufacturer to manufacture a product, how long do you think that would take?
>
> A. Oh, *it would take about a month*.

D.E. 82, Pl.'s Ex. 1 at 174-75 (Tambi Dep.) (emphasis added). In short, Tambi did not concede that it would take a month to find a replacement contract manufacturer; he said it would take a month to find a replacement *if he did not try to confirm that the manufacturer could be trusted*. Tambi also stated that many pharmaceutical companies in India had been closed after failing to comply with FDA regulations. *Id.* at 299-300. A reasonable jury faced with Schwartz's expert opinion (which may be based in part on a miscitation of Tambi's deposition testimony) and Tambi's own testimony (which describes potentially significant issues in finding a trustworthy manufacturer in India) could conclude that the process takes more than the two months that Bio-Pharm contends.

Additionally, Bio-Pharm and Antrim dispute the amount of time that it would take for Antrim to complete the sixth step, updating the FDA on the change in manufacturers.

Bio-Pharm contends that this process could be completed in approximately one month through the use of a regulatory document known as a CBE-30. Schwartz opined that the FDA would require the CBE-30, not the more involved prior approval supplement (PAS), which takes longer to complete. D.E. 66, Pl.'s Ex. 3 at 7 n.13. But, as the expert report states, a PAS could be required in a number of situations: if the new manufacturer had never produced escitalopram; if the manufacturer had discontinued escitalopram production for more than two years; if the manufacturer lacked an FDA certificate of good standing; or if the replacement manufacturer would use a different process from the previous manufacturer. *Id.* From the record, the Court cannot determine definitively how long a PAS takes to complete, but it appears evident that it is longer than the process for a CBE-30. In short, it is not clear that Antrim would have been able to avail itself of the expedited CBE-30 process. (Bio-Pharm attempts to argue that Antrim agreed that it was eligible for a CBE-30 in a response to a request to admit, but the Court reads Antrim's answer as affirming that the CBE-30 was an *available* channel, not the *definitive* channel it could employ. Antrim LR 56.1 Resp. Stmt. ¶ 70.)

The record shows that a reasonable jury could find that it would take Antrim more than two months to locate a new manufacturer and more than one month to obtain FDA approval for the change in manufacturer. For these reasons, the Court concludes that Bio-Pharm is not entitled to summary judgment, as a reasonable jury could find that Antrim reasonably would have taken longer than one year to mitigate its losses.

E. Unjust enrichment

Bio-Pharm urges the Court to grant summary judgment on Antrim's unjust

enrichment claim, because there is no evidence that Bio-Pharm benefited by retaining the medications. "[U]njust enrichment does not seek to compensate a plaintiff for loss or damages suffered but seeks to disgorge a benefit that the defendant unjustly retains." *Blythe Holdings, Inc. v. DeAngelis*, 750 F.3d 653, 658 (7th Cir. 2014) (citation omitted). Bio-Pharm argues that Antrim has failed to show what benefit Bio-Pharm derived by withholding the escitalopram.

The Court agrees. First, Antrim has offered no evidence or case law to support the proposition that withholding a shipment is sufficient to establish an unjust enrichment claim. Second, though Antrim argues that Bio-Pharm unjustly benefited by selling the withheld products through other channels, no reasonable jury could find in Antrim's favor on this point. Antrim cites to "Shah Ex. 17," which the Court construes as D.E. 77, Def.'s Ex. 17. That exhibit consists of a chain of e-mails from 2014 that predate Bio-Pharm's decision to withhold the escitalopram; it is unclear what relevance they have on this issue. The only other "Exhibit 17," D.E. 82, Pl.'s Ex. 17, is an e-mail from Shapiro, the Leading Pharmaceuticals employee, which also does not support Antrim's contention on this point. Antrim also cites to a July 2016 e-mail chain between Shah and an unidentified third party, Mayur Khamar, *see* D.E. 82, Pl.'s Ex. 31 at BIO-PHARM 021842, but these e-mails lack any context and, standing alone, they do not show that Bio-Pharm is unjustly benefitting from the retention of the products. *Id.* No reasonable jury could conclude from this evidence that Bio-Pharm was unjustly enriched by withholding the products. Bio-Pharm is entitled to summary judgment on this claim.

Conclusion

For the foregoing reasons, the Court denies Antrim's motion for summary

judgment [dkt. no. 63]. The court grants Bio-Pharm's motion for summary judgment on Antrim's unjust enrichment claim (count 3 of Antrim's complaint), partially grants the motion on Antrim's breach of contract claim (count 1) to the extent the claim applies to ondansetron, and otherwise denies the motion [dkt. no. 75]. The case is set for a status hearing on April 24, 2018 at 9:30 a.m. to set a trial date and discuss the possibility of settlement.

MATTHEW F. KENNELLY
United States District Judge

Date: April 19, 2018