IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

URL PHARMA, INC., et al.,	:	
Plaintiffs,	:	
	:	**CIVIL ACTION**
v.	:	
	:	**NO. 15-0505**
RECKITT BENCKISER INC.,	:	
Defendant.	:	

MEMORANDUM

Tucker, C.J. **April 20, 2016**

Presently before the Court are Plaintiffs' Motion for Preliminary Injunction (Doc. 36), Defendant's Response in Opposition (Doc. 50), Plaintiffs' Supplement in Support of Their Motion for Preliminary Injunction (Doc. 97), and Defendant's Supplemental Memorandum in Law in Opposition to Plaintiffs' Motion for Mandatory Preliminary Injunction (Doc. 100). Upon consideration of the parties' submissions and exhibits and for the reasons set forth below, this Court DENIES Plaintiffs' Motion.

I. FACTUAL BACKGROUND

Plaintiffs URL Pharma, Inc., Mutual Pharmaceutical Company, Inc., and United Research Laboratories, Inc. (collectively "Plaintiffs" or "Mutual") filed an antitrust and breach of contract action against Defendant Reckitt Benckiser Inc. ("Defendant" or "Reckitt") for alleged violations of the Sherman Antitrust Act and the Clayton Antitrust Act as well as a breach of a settlement agreement.

Defendant owns the patent for an over-the-counter drug, extended-release guaifenesin ("ERG"), and sells it under the brand name Mucinex® ("Mucinex ERG"). Reckitt's Mucinex ERG was the only ERG product consumers could purchase at the relevant time periods. Though other immediate-release guaifenesin ("IRG") products were available, these IRG products were not directly comparable to the effects of the ERG product because they "provide short-term relief and must be taken every 3 to 4 hours to approach the long-lasting benefit of ERG." Compl. ¶ 32.

Prior to the instant action, Mutual was in the process of developing a generic ERG, but Reckitt sued Mutual for patent infringement on October 4, 2006 and December 15, 2006. Compl. Exh. A at 2. Mutual subsequently brought an antitrust action against Reckitt on January 18, 2007. *Id.* On March 21, 2007, the parties entered into a settlement agreement wherein Mutual agreed to refrain from entering the ERG market until, *inter alia*, another generic manufacturer began offering generic ERG to the public (the "Agreement"). The relevant terms of the 2007 Agreement are as follows:

> 4. Adams[1] hereby grants to Mutual a non-exclusive, royalty-free, perpetual and irrevocable license under the Licensed Patents (the "License") to make, have made, sell or offer for sale to the Retail Trade, use and import each Licensed Product commencing on or after the applicable Marketing License Effective Date for such Licensed Product (as defined below in Section 5).
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> . . . .
>
> 5. (a) *Mutual 600 mg Guaifenesin Product*: Subject to Section 5(b) below, the Marketing License Effective Date for the Mutual 600 mg Guaifenesin Product shall be the later of (i) July 1, 2012 or (ii) the date Mutual obtains FDA approval to market such Licensed Product.
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> . . . .

[1] Adams Respiratory Therapeutics, Inc., Adams Respiratory Operations, Inc., and Adams Respiratory Products, Inc. (collectively "Adams") merged into Reckitt at some point after the execution of the Settlement Agreement. Compl. ¶ 20. "As a consequence of the merger, Reckitt assumed the rights and obligations of Adams under the [Agreement]." *Id.*

(b)(ii) **If Mutual does not obtain approval from FDA to market a Licensed Product prior to the Launch Date of a corresponding Third Party Formulation or Adams Guaifenesin Product, then the Marketing License Effective Date shall be the date on which Mutual obtains FDA approval to market such Licensed Product corresponding to such FDA-approved Third Party Formulation. Mutual, in its sole discretion, may purchase from Adams and Adams shall supply, pursuant to the terms of Section 6 of this Agreement, tablets of the Adams Guaifenesin Product corresponding to such Third Party Formulation, for sale by Mutual**, its Affiliates or a single independent Sublicensee to the Retail Trade under a private label or a brand name other than Adams' brand names for the Adams Guaifenesin Product, in the Territory Date. To the extent that Mutual purchases tablets of Adams Guaifenesin Product pursuant to the Supply Agreement, Adams grants Mutual a non-exclusive, perpetual and irrevocable right to sell and offer for sale to the Retail Trade such tablets supplied by Adams under the Licensed Patents in the Territory and agrees, in a timely manner, to take all steps with respect to the New Drug Applications and/or other marketing authorizations for such Adams Guaifenesin Product that are necessary in order to manufacture and supply such Adams Guaifenesin Product tablets to Mutual hereunder and under the Supply Agreement and to ensure that Mutual and its Affiliates or its single Sublicensee, as the case may be, is authorized to sell such Adams Guaifenesin Product.

. . . .

6. (a) **Mutual shall notify Adams in writing of its election to purchase tablets of Adams Guaifenesin Product pursuant to Section 5(b)(ii)**, **and the Parties shall promptly execute a supply agreement**. . . . The tablets supplied by Adams shall be white and/or in such other reasonable mono-colored configuration mutually agreeable to the Parties, and shall be manufactured using Adams' and its Affiliates' bilayered technology.

Compl., Exh. A. at 10–13 (emphasis added). Thus, pursuant to the Agreement, if Mutual failed to obtain FDA approval to market its generic ERG product, then after a third party launched a third-party formulation of the ERG product, Mutual could arrange to execute a supply agreement with Reckitt (the "Bulk Supply Agreement"). The Bulk Supply Agreement would allow Mutual to purchase from Reckitt tablets corresponding to the third-party formulation of the ERG product. *See* Compl. Exh. B.

Mutual alleges that "[b]y October 2013, a third party, Perrigo Company PLC ("Perrigo") had been legally selling and delivering to the market a generic version of the Mucinex 600 mg

ERG product." Compl. ¶ 22. Mutual had not obtained FDA approval to market an ERG product by this time. Accordingly, Mutual claims that Perrigo's entry into the market with the "generic ERG product triggered Reckitt's obligation to supply Reckitt's 600 mg ERG product to Mutual. *Id.* ¶ 23. Mutual alleges that on October 24, 2013, pursuant to the Settlement Agreement, Mutual provided Reckitt with written notice that it was electing to purchase for resale the generic equivalent of Mucinex ERG from Reckitt. *Id.* ¶ 24. As of this date, Reckitt has not supplied Mutual with the tablets.

II. PROCEDURAL HISTORY

On February 3, 2015, Plaintiffs filed their complaint against Defendant in this Court (the "Complaint"). Doc. 1. In Count I of its Complaint, Plaintiffs allege monopolization in violation of the Sherman Antitrust Act, 15 U.S.C. § 2, and the Clayton Antitrust Act, 15 U.S.C. § 15, and request treble damages. In Count II, Plaintiffs allege monopolization under the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. § 26, and request injunctive relief in the form of specific performance. In Count III, Plaintiffs allege attempted monopolization in violation of the Sherman Act, 15 U.S.C. § 2, and the Clayton Act, 15 U.S.C. §§ 15, 26, and request treble damages and injunctive relief in the form of specific performance.

In addition to the antitrust claims, Plaintiffs allege that Defendant breached the Agreement by failing to provide the 600 mg version of Mucinex ERG when Perrigo entered the market. Counts IV and V of the Complaint assert a breach of contract claim and requests direct and consequential damages, as well as specific performance. Count VI seeks declaratory judgment as to the validity of the Agreement and Reckitt's duty to perform pursuant to the Agreement.

On April 6, 2015, Defendant filed a motion to dismiss for failure to state a claim upon which relief could be granted. Doc. 20. This Court granted in part and denied in part Defendant's Motion. Doc. 32. Specifically, the Court denied Defendant's motion to dismiss Plaintiffs' antitrust claims, state law claims, and claim for declaratory judgment pertaining to Perrigo's 600 mg ERG formulation of Defendant's ERG product. *Id.* The Court granted Defendant's motion to dismiss Plaintiffs' claim for declaratory judgment relating to all other third-party formulations of Reckitt's Mucinex® product. *Id.*

On September 9, 2015, Plaintiffs filed the instant Motion for Preliminary Injunction. Doc. 36. Plaintiffs request that this Court (1) compel Defendant to commence supply of Plaintiffs' requirements of 600 mg ERG tablets within 30 days and/or (2) prohibit Defendant from continuing to prioritize its own requirements of 600 mg ERG over those of Plaintiffs, which is allegedly in breach of Section 2.7 of the Bulk Supply Agreement. *Id.* at 2.

III. LEGAL STANDARD

The district court will grant a motion for preliminary injunction if the movant can "establish that [it] is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest.'" *Ferring Pharm., Inc. v. Watson Pharm., Inc.*, 765 F.3d 205, 210 (3d Cir. 2014) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). The moving party "bears the burden of showing that these four factors weigh in favor of granting the injunction." *Id.* The movant's "'failure to establish any element ... renders a preliminary injunction inappropriate.'" *Id.* (quoting *NutraSweet Co. v. Vit-Mar Enters., Inc.*, 176 F.3d 151, 153 (3d Cir. 1999)). The court is mindful that the preliminary injunction "is an extraordinary remedy" that is "never awarded as of right." *Winter*, 555 U.S. at 24. Accordingly, a preliminary

injunction, as "an exercise of a court's equitable authority" will only be granted after "taking into account all of the circumstances that bear on the need for prospective relief." *Salazar v. Buono*, 559 U.S. 700, 714 (2010). The court will not issue a preliminary injunction "merely to allay the fears and apprehensions or to soothe the anxieties of the parties." *Grant Heilman Photography, Inc. v. John Wiley & Sons, Inc.*, 864 F. Supp. 2d 316, 325 (E.D. Pa. 2012).

In the present case, Plaintiffs request, *inter alia*, that the Court order Defendant "to commence supply of Plaintiffs' requirements of 600 mg ERG tablets within 30 days." Pl. Mot. for Preliminary Injunction at 2, Doc. 36. An injunction that "require[s] [a] defendant[] to take some affirmative action" is considered a mandatory injunction. *Snyder v. Millersville Univ.*, Civil Action No. 07–1660, 2008 WL 5093140, at *11 (E.D. Pa. Dec. 3, 2008). A mandatory injunction is "'looked upon disfavorably and [is] generally only granted in compelling circumstances.'" *Id.* (quoting *Florham Park Chevron, Inc. v. Chevron U.S.A., Inc.*, 680 F. Supp. 159, 166 (D.N.J. 1988)). Courts rarely grant mandatory injunctions "'because mandatory injunctions are more burdensome than prohibitory injunctions, and disturb the status quo prior to final adjudication.'" *Tri-Realty Co. v. Ursinus Coll.*, Civil Action No. 11–5885, 2013 WL 5298469, at *12 (E.D. Pa. Sept. 19, 2013) (quoting *Christie-Spencer Corp. v. Hausman Realty Co.*, 118 F. Supp. 2d 408, 418 (S.D.N.Y. 2000)). In light of the fact that a mandatory injunction "will alter the status quo, the party seeking the injunction must meet a higher standard of showing irreparable harm in the absence of an injunction." *Bennington Foods LLC v. St. Croix Renaissance Grp., LLP*, 528 F.3d 176, 179 (3d Cir. 2008). Accordingly, the court may only grant a mandatory injunction if the movant's "'right to relief [is] indisputably clear.'" *Trinity Indus., Inc. v. Chi. Bridge & Iron Co.*, 735 F.3d 131, 139 (3d Cir. 2013) (quoting *Communist Party of Ind. V. Whitcomb*, 409 U.S. 1235, 1235 (1972)).

IV. DISCUSSION

Courts will issue a preliminary injunction only if the movant "establish[es] that [it] is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest.'" *Ferring Pharm., Inc.*, 765 F.3d at 210 (quoting *Winter*, 555 U.S. at 20). Accordingly, the Court must determine whether Plaintiffs satisfied these requirements and met their "'particularly heavy'" burden for the Court to grant mandatory injunctive relief. *Trinity Indus., Inc.*, 735 F.3d at 139 (quoting *Punnett v. Carter*, 621 F.2d 578, 582 (3d Cir. 1980)).

A. Likelihood of Success on the Merits

In order "[t]o state a claim for breach of contract under New York law, 'the complaint must allege: (i) the formation of a contract between the parties; (ii) performance by the plaintiff; (iii) failure of defendant to perform; and (iv) damages.'" *Orlander v. Staples, Inc.*, 802 F.3d 289, 294 (2d Cir. 2015) (quoting *Johnson v. Nextel Commc'ns, Inc.*, 660 F.3d 131, 142 (2d Cir. 2011)).[2] In New York, "a plaintiff bears the burden of proving a breach of contract by a preponderance of the evidence." *Meda AB v. 3M Co.*, 969 F. Supp. 2d. 360, 378 (S.D.N.Y. 2013). Plaintiffs contend that "[t]he Agreement is a standard industry agreement including all material terms customarily seen in agreements to supply bulk tablets." Pl. Supp. Br. at 4, Doc. 97. Furthermore, Plaintiffs claim that "[t]he [Settlement] Agreement at issue unambiguously proves Reckitt has breached by failing to supply Mutual." Pl. Mot. for Preliminary Injunction at 15. In contrast, Defendant maintains that "on the face of the [Settlement Agreement] and [Bulk Supply Agreement], shape, color, price, delivery or quantity are missing." Def. Resp. at 22, Doc.

[2] Section 28 of the Settlement Agreement provides that "[t]his Agreement and any dispute arising out of or related to this Agreement shall be governed by and construed in accordance with the internal laws of the State of New York." Compl., Exh. A at 21. The Court is required to apply "the ordinary rules of contract construction" to the Agreement. *Texas 1845, LLC v. Kyaw*, 986 N.Y.S.2d 574, 576 (App. Div. 2d Dep't 2014).

50. Additionally, "where, as here, a defendant has substantial, unrebutted defenses to the validity of the contract that require fact-finding, a preliminary injunction is inappropriate." *Id.* at 23. Therefore, the Court will assess, in accordance with New York law, whether Plaintiffs have met their burden of demonstrating a likelihood of success on the merits of the breach of contract claim. The Court is not required to determine that Plaintiffs' "'right to a final decision after trial [is] wholly without doubt; rather, the burden is on [Plaintiffs] to make a Prima [sic] facie case showing a reasonable probability that it will prevail on the merits.'" *Am. Freedom Def. Initiative v. S.E. Pa. Transp. Auth.*, 92 F. Supp. 3d 314, 322 (E.D. Pa. 2015) (quoting *Oburn v. Shapp*, 521 F.2d 142, 148 (3d Cir. 1975)).

1. Existence of a Contract

Under the first prong, "[c]ourts look to the basic elements of the offer and the acceptance to determine whether there is an objective meeting of the minds sufficient to give rise to a binding and enforceable contract." *Silber v. N.Y. Life Ins. Co.*, 938 N.Y.S.2d 46, 50 (App. Div. 1st Dep't 2012). In particular, the courts examine whether "[a]n agreement . . . [has] sufficiently definite terms and the parties . . . express[ed] their assent to those terms." *Id.*; *see also Judal Indus., Inc. v. Welsbach Elec. Corp.*, 526 N.Y.S.2d 154, 156 (App. Div. 2d Dep't 1988) (concluding that "[f]or a contract to be enforceable, it must be definite as to its essential terms."). When the contract is a "'contract for a sale of goods, the essential terms are quantity, price, and time and manner of delivery.'" *Dell's Maraschino Cherries Co. v. Shoreline Fruit Growers, Inc.*, 887 F. Supp. 2d 459, 471 (E.D.N.Y. 2012) (quoting *DiMare Homestead, Inc. v. Alphas Co. of N.Y., Inc.*, No. 09 Civ. 6644(PKC), 2012 WL 1155133, at *24 (S.D.N.Y. Apr. 5, 2012)). If "one or more terms are left open in a contract for sale" it does not automatically follow that the

contract will "fail for indefiniteness if the parties have intended to make a contract and there is a reasonably certain basis for giving an appropriate remedy." N.Y. U.C.C. § 2-204(3).

In *Aiello v. Burns International Security Services, Corp.*, the New York Supreme Court Appellate Division, distinguished contracts that have essential terms missing and that are left for future negotiations that are enforceable and those that are unenforceable. 973 N.Y.S.2d 88, 94 (App. Div. 1st Dep't 2013). The issue before the court was "whether the security service agreement, which disavows any third-party beneficiaries, was rendered unenforceable by the contracting parties' failure to set forth, in writing, the security agency's duties." *Aiello*, 973 N.Y.S.2d at 91. The court found that "'a mere agreement to agree, in which a material term is left for future negotiations, is unenforceable.'" *Id.* at 94 (quoting *166 Mamaroneck Ave. Corp. v. 151 E. Post Rd. Corp.*, 575 N.E.2d 104, 105 (N.Y. 1991). In contrast, the court found that a contract may be enforceable even though "'it expresses the idea that something is left to future agreement.'" *Id.* (quoting *Four Seasons Hotels v. Vinnik*, 515 N.Y.S.2d 1, 6 (App Div. 1st Dep't 1987)). The court explained that, "court[s] shall enforce a contract if the parties have completed negotiations of essential elements, even when 'the parties have expressly left ... other elements for future negotiation and agreement.'" *Id.* (quoting *Vinnik*, 515 N.Y.S.2d at 6). The court ultimately concluded that "the security service agreement here is sufficiently definite to establish that the parties intended to be bound and sufficiently definite to establish the nature of the parties' agreement." *Id.* at 94–95.

As stated above, Defendant's principal contention is that the contract lacks essential terms. Specifically, Defendant maintains that "shape, color, price, delivery, or quantity are missing" from the Agreement. Def. Resp. at 22. The Agreement provided that:

> If Mutual does not obtain approval from FDA to market a Licensed Product prior to the Launch Date of a corresponding Third Party Formulation or Adams

> Guaifenesin Product, then the Marketing License Effective Date shall be the date on which Mutual obtains FDA approval to market such Licensed Product corresponding to such FDA-approved Third Party Formulation. Mutual, in its sole discretion, may purchase from Adams and Adams shall supply, pursuant to the terms of Section 6 of this Agreement, tablets of the Adams Guaifenesin Product corresponding to such Third Party Formulation, for sale by Mutual.

Compl., Exh. A. at 12. Mutual did not obtain FDA approval to market a Licensed Product and instead decided to purchase the tablets from Reckitt after Perrigo entered the market in October 2013. Compl. ¶¶ 22–24. Thus, Mutual was required to "notify [Reckitt] in writing of its election to purchase tablets of [Reckitt's] Guaifenesin Product pursuant to Section 5(b)(ii)." Compl. Exh. A. at 13. The parties were then required to "promptly execute a supply agreement." *Id.*

According to the Agreement, Reckitt was to supply Mutual with tablets that were "white and/or in such other reasonable mono-colored configuration mutually agreeable to the Parties and [that were] manufactured using [Reckitt's] and its Affiliates' bilayered technology." *Id.* Mutual would sell the tablets "under a private label or a brand name other than [Reckitt's] brand names for the [Reckitt] Guaifensin Product." *Id.* at 12. The amount of tablets that Mutual would purchase would be determined "[a]t least ninety (90) days prior to the Mutual Launch Date for a Product" when "Mutual [would] make a good faith estimate of Mutual's projected requirement of such Product for delivery during each of the following six (6) Calendar Quarters." *Id.* at 35. Mutual would then complete a purchase order "at least thirty (30) days before the desired delivery date. . . . [and] [s]uch purchase orders shall specify the quantity of Product ordered and the requested delivery date." *Id.* Mutual was required to "purchase at least one hundred percent (100%) of the Product quantities in the first Calendar Quarter of each Forecast for each such Product." *Id.* Once the tablets were manufactured, Reckitt was to "ship all Product FCA Facility (Incoterms 2000) to Mutual's facilities in Philadelphia, Pennsylvania or such other destination in the Territory mutually agreed upon by [Reckitt] and Mutual." *Id.* Lastly, "[i]n consideration for

such supply, Mutual [would] pay [Reckitt] a supply price equal to the sum of the Fully Allocated Cost basis for such tablets, and a royalty of ten percent (10%) of the Net Sales of Mutual. . . ." *Id.* at 13.

Based upon the terms of the Agreement, Reckitt was to supply Mutual with white tablets, unless they could agree upon another monocolor, "no earlier than ninety (90) days after the corresponding Launch Date." *Id.* at 12. Price, delivery, and the manner to determine quantity were all contemplated in the Agreement. The language of the Agreement suggests that the Agreement was entered into by two sophisticated parties that endeavored to minimize unnecessary litigation costs and fairly resolve an antitrust dispute. Further, the Agreement does not reflect a mere agreement to agree but rather an intention to enter into a binding agreement that provided Mutual with the option to either pursue FDA approval of its own generic drug or purchase tablets from Reckitt after a third party entered the market. Accordingly, because the essential terms of a contract for the sale of goods are present in the contract and the parties manifested a clear intention to be bound, it is likely that a contract was formed.

2. Plaintiffs' Performance

Since the Court found that the parties did form a contract, Plaintiffs are required to prove that they performed their obligations under the contract. Plaintiffs claim that they performed their obligations under the Agreement by (1) dismissing the pending claims against Defendant in the 2007 litigation and (2) requesting, in writing, the 600 mg ERG tablets from Defendant. Pl. Mot. for Preliminary Injunction at 18–19. The Court agrees. The Agreement provided that "this [Settlement] Agreement and the Consent Judgment and Dismissal Without Prejudice (attached hereto as Appendix B) are the only consideration exchanged by or on behalf of Mutual on the one side, and Adams on the other side, in reaching the agreement to dismiss the Lawsuits."

Compl., Exh. A at 3. After executing the Agreement, Plaintiffs ceased their pursuit of litigation against Adams. On October 24, 2013, Plaintiffs did exercise their right, under the Agreement, to request that Defendant begin to supply Plaintiffs with the 600 mg ERG tablets. Compl. ¶ 24. Consequently, Plaintiffs sustained their burden of proving that they performed their obligations under the Agreement.

3. Defendant's Failure to Perform

Next, Plaintiffs are required to prove that Defendant failed to perform its obligation under the Agreement. Plaintiffs argue that "[d]espite its unambiguous contractual obligations, Reckitt refuses to supply Mutual and is in breach of the Agreement." Pl. Mot. for Preliminary Injunction at 20. In contrast, Defendant claims that it "attempted to negotiate, offered terms, dates, and quantities that Mutual deemed unacceptable." Def. Resp. at 25. Further, Defendant maintains that "[n]one of [Plaintiffs'] witnesses could testify, or even identify, the factual basis of RB's[3] purported breach and 'repudiation' of the Agreements—because none exists." Def. Supp. Br. at 7, Doc. 100. There are, however, facts to support each party's contentions.

It is true that as of the present date, Defendant has failed to supply Plaintiffs with the 600 mg ERG tablets and execute a supply agreement. It is also true, however, that the parties have been unable to reach an agreement as to the volume of the initial forecast and the characteristics of the tablets, thus precluding Defendant from initiating the supply of the tablets. The parties disagreed that Plaintiffs' projection for 28 million tablets in its first year was reasonable. Plaintiff avers that "[d]espite Mutual's effort to get Reckitt to change its position by reducing its initial year volume forecast from 90 million to 28 million tablets, . . . Reckitt never agreed to supply Mutual more than 9 million tablets per year." Pl. Supp. Br. at 3. On the other hand, Defendant alleges that Plaintiffs' "witnesses confirmed under oath that despite RB's repeated

[3] In its supplementary brief, Defendant refers to itself as "RB." Def. Supp. Br. at 1.

request for a commitment for the volume of Tablets [Plaintiffs] did not place an Order, as required under [Bulk Supply Agreement] § 2.3, stating a definitive amount; they discussed various options with RB but went no further." Def. Supp. Br. at 4.[4]

Additionally, and perhaps more importantly, besides color, it is unclear as to what the tablet would look like in finished form. For example, shape is not contemplated in the Agreement. Plaintiffs contend that "Mutual was clear from the beginning, it preferred the oval tablets described in Reckitts's NDA, but would accept whatever would get Mutual in the market ASAP[,]" however Defendant maintains that shape is still an open item. Pl. Supp. Br. at 3. Moreover, there is no mention as to whether there will be embossing on the tablets. The Agreement does state that "Mutual, in its sole discretion, may purchase from Adams and Adams shall supply, pursuant to the terms of Section 6 of this Agreement, tablets of the Adams Guaifensin Product corresponding to such Third Party Formulation, for sale by Mutual . . . *under a private label or a brand name other than Adams' brand names for the Adams Guaifensin Product*" but it does not mention whether the tablets would be embossed and if so, what the embossing would entail. Compl., Exh. A at 12 (emphasis added).

According to the Agreement, once Mutual notified Reckitt in writing that it sought to purchase the 600 mg ERG tablets, the parties were to "promptly execute a supply agreement." Compl., Exh. A. at 13. Prior to the filing of the instant motion, the parties were discussing the remaining open terms. As noted by Plaintiffs, "Reckitt *wants* to honor the contract." Pl. Supp. Br. at 6. There is no indication that the parties have ceased communication and that Reckitt intends to breach the Agreement by not executing a supply agreement with Mutual. Accordingly, because Defendant has not affirmatively breached the agreement and there is the

[4] Defendant acknowledges that Plaintiffs did send a purchase order after they filed the instant Motion, however the purchase order "fails to identify the Material terms." Def. Supp. Br. at 4.

possibility that the parties can, in good faith, continue to engage in talks to resolve the open items, Plaintiffs have not proven beyond a preponderance of the evidence that Defendant breached the Agreement.[5]

4. Damages

Lastly, Plaintiffs are required to prove that they were damaged by Defendant's breach of the Agreement. Plaintiffs allege that they have not only suffered monetarily in the form of lost sales and lost profit, but also "Mutual's ability to compete is completely foreclosed and it is losing the opportunity to gain a firm foothold in the OTC market by offering ERG." Pl. Mot. for Preliminary Injunction at 22. Thus, if Plaintiffs were able to prove that Defendant breached the Agreement, it is also likely that they will be able to prove that they suffered damages as a result of the breach.

At this stage, Plaintiffs are not required to prove that their "'right to a final decision after trial [is] wholly without doubt.'" *Am. Freedom Def. Initiative*, 92 F. Supp. 3d at 322 (quoting *Oburn*, 521 F.2d at 148). Rather, Plaintiffs are only required to demonstrate "'a reasonable probability'" that they will prevail on the merits of the breach of contract claim. *Id.* (quoting *Oburn*, 521 F.2d at 148). As previously discussed, there is some doubt as to whether Plaintiffs

[5] Plaintiffs also argue that Defendant "is also prioritizing its own requirements of 600 mg ERG over those of Mutual, in direct breach of Section 2.7 of the Supply Agreement." Pl. Mot. for Preliminary Injunction at 20–21. This argument is without merit. Section 2.7, entitled "Problems with Supply" provides:

> Adams shall promptly notify Mutual of any circumstances that result or are likely to result in any failure or delay in the supply or delivery of any Product. . . . Adams shall allocate to Mutual an amount of such Product proportionate to Mutual's requirements divided by the total demand for such Product for the ensuing one–year period. In making any such allocation, Adams shall not give any priority to its own requirements of those or of its Affiliates.

Plaintiffs fail to cite where Defendant indicated that it would be unable to supply Plaintiffs with the tablets because there were problems with the supply. Rather, the issue is that the parties have yet to execute a supply agreement. Therefore, Plaintiffs fail to demonstrate that Defendant breached the Agreement by prioritizing its supply requirements over Plaintiffs' requirements.

will ultimately succeed on their breach of contract action. However, they have demonstrated a reasonable probability that they could succeed on the merits of the breach of contract claim. Therefore, the Court will proceed to the second prong of the preliminary injunction analysis.

B. Irreparable Harm

The Third Circuit has "stressed that '[b]efore granting a preliminary injunction, a district court *must* consider the extent to which the moving party will suffer irreparable harm without injunctive relief.'" *Liberty Lincoln-Mercury, Inc. v. Ford Motor Co.*, 562 F.3d 553, 557 (3d Cir. 2009) (quoting *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578, 595 (3d Cir. 2002)). The movant will sustain its burden if it "demonstrates a potential harm which cannot be redressed by a legal or an equitable remedy following a trial." *Grant Heilman Photography, Inc.*, 864 F. Supp. 2d at 325. In cases such as the instant matter, where

> "the claim is based on a breach of contract, irreparable injury may be found in two situations: (1) where the subject matter of the contract is of such a special nature or peculiar value that damages would be inadequate; or (2) where because of some special and practical features of the contract, it is impossible to ascertain the legal measure of loss so that money damages are impracticable."

EUSA Pharma (US), Inc. v. Innocoll Pharm. Ltd., 594 F. Supp. 2d 570, 581 (E.D. Pa. 2009) (quoting *ECRI v. McGraw-Hill, Inc.*, 809 F.2d 223, 226 (3d Cir. 1987)). Nevertheless, "establishing the risk of irreparable harm is not enough to support a preliminary injunction." *Grant Heilman Photography*, 864 F. Supp. 2d at 325. Rather, the movant "has the burden of proving a 'clear showing of immediate irreparable injury.'" *Id.* (quoting *ECRI*, 809 F.2d at 226). Further, the irreparable injury must not be "'remote or speculative, but actual and imminent and for which monetary damages cannot adequately compensate.'" *FMC Corp. v. Control Sols., Inc.*, 369 F. Supp. 2d 539, 573 (E.D. Pa. 2005) (quoting *Air Transp. Int'l L.L.C. v. Aerolease Fin.*

Grp., Inc., 993 F. Supp. 118, 123 (D. Conn. 1998)). Accordingly, courts may not grant preliminary injunctions "'unless the moving party shows that it specifically and personally risks irreparable harm.'" *Liberty Lincoln-Mercury, Inc.*, 562 F.3d at 557 (quoting *Adams v. Freedom Forge Corp.*, 204 F.3d 475, 487 (3d Cir. 2000)).

Plaintiffs argue that the Agreement presented Plaintiffs with "a unique, non-replicable business opportunity. . . . [and] Reckitt's continuing failure to supply Mutual with 600 mg ERG tablets is causing Mutual irreparable harm and preventing it from benefiting from this unique, bargained for business opportunity." Pl. Supp. Br. at 8. Further, Plaintiffs allege that "[b]ecause there are currently so few players in the ERG market, Mutual's ability to offer a generic version of the 600mg ERG product would instantly create its credibility as supplier of generic [over-the-counter] products." Pl. Mot. for Preliminary Injunction at 23. In particular, Mutual contends that "by offering a generic 600 mg ERG product Mutual could build relationships, create new ones, gain market share, and dramatically advance its reputation as a generic [over-the-counter] marker." *Id.* In contrast, Defendant claims that "Mutual is only alleging that it has lost an opportunity to sell goods, i.e., lost profits. . . . [which] are not irreparable harm and do not form the basis for an injunction motion." Def. Resp. at 26. Plaintiffs rely on *Allegheny Energy, Inc. v. DQE, Inc.*, 171 F.3d 153, 154 (3d Cir. 1999) and *Tom Doherty Associates Inc. v. Saban Entertainment Inc.*, 869 F. Supp. 1130, 1132 (S.D.N.Y. 1994), *inter alia*, to support their argument that if the Court does not enter the preliminary injunction Plaintiffs will suffer irreparable harm.

In *Allegheny Energy, Inc. v. DQE, Inc.*, the plaintiff and the defendant were "utility companies whose shares [were] traded on the New York Stock Exchange [and who] entered into a merger agreement on April 7, 1997." 171 F.3d 153, 154 (3d Cir. 1999). Section 8.2(a) of the

merger agreement provided that each party "reserved the right to terminate the contract on October 5, 1998 in the event that the merger was not consummated by that date." *Allegheny Energy*, 171 F.3d at 157. Section 8.2(a) also provided that "the October 5, 1998 date is automatically moved forward six months, to April 5, 1999, if, on October 5, 1998, certain conditions have been met, among them that 'each of the other conditions to the consummation of the Merger ... has been satisfied or waived or can readily be satisfied.'" *Id.* (quoting App. At 42). On October 5, 1998, the defendant informed the plaintiff that the defendant was terminating the merger agreement pursuant to Section 8.2(a). *Id.* The plaintiff then filed an action in the Western District of Pennsylvania and a motion seeking a temporary restraining order and a preliminary injunction. *Id.* at 158.

The court examined precedent outside this circuit to assess whether specific performance was appropriate for an alleged breach of a merger agreement. *Id.* at 161–163. The Third Circuit found that the case law "could be interpreted as imposing upon a plaintiff (the would-be acquirer) the burden of showing with some particularity that the business to be acquired is either inherently unique or offers a unique opportunity to the buyer." *Id.* at 163. The court determined that "the agreed-upon Allegheny–DQE merger constitutes a unique, non-replicable business opportunity for Allegheny." *Id.* The court found the Joint Proxy Statement that was filed with the SEC and distributed to both Allegheny's and DQE's shareholders to be particularly illustrative of the "considerable business opportunities" that the merger presented for both companies. *Id.* at 163–64. The Third Circuit held that "Allegheny would be at serious risk of irreparable harm if preliminary injunctive relief were withheld" and vacated the district court's judgment denying the preliminary injunction. *Id.* at 166–67. The Third Circuit remanded the matter to the District Court to "reassess—in light of [the] opinion—the three

remaining factors in the four-factor determination of whether a preliminary injunction should issue." *Id.* at 167.

In *Tom Doherty Associates Inc. v. Saban Entertainment Inc.*, the plaintiff brought a breach of contract action against the defendant and

> moved for a preliminary injunction requiring Saban to offer TOR the right to publish juvenile story books based on the Mighty Morphin Power Rangers ("Power Rangers"), prohibiting Saban from licensing or facilitating the publication of books based on the Power Rangers (except coloring, comic or activity books), and prohibiting Saban from licensing the publication of juvenile story books based on other Saban properties unless TOR is first offered the right to publish such books.

869 F. Supp. 1130, 1132 (S.D.N.Y. 1994). The plaintiff was "a major publisher of fantasy and science fiction books for adults." *Tom Doherty Assocs. Inc.*, 869 F. Supp. at 1132. The defendant was a "creator, producer, and distributor of video entertainment for children." *Id.* The parties entered into an agreement which provided that the plaintiff "would immediately publish six books based on Saban properties" and that there was a possibility of "publication of further books in the future." *Id.* at 1132–33. After the defendant gained popularity with its creation of the Power Rangers, the defendant "entered into a variety of licensing agreements with companies in various fields of children's merchandising, including children's book publishing." *Id.* at 1134. The plaintiff then filed a breach of contract action in the district court and moved for a preliminary injunction. *Id.* at 1135.

The district court determined that the plaintiff "demonstrated that it will suffer irreparable harm unless Saban is ordered to license to it publishing rights to Power Ranger books." *Id.* The court found that "[t]he loss of the opportunity to distribute and market a commodity may constitute irreparable harm. . . . [and] [w]here the property is unique, injunctive relief is appropriate." *Id.* After examining precedent, the court concluded that "the determination to grant

injunctive relief when a source refuses to supply a commodity is necessarily fact sensitive." *Id.* at 1136. Therefore, "[t]he issue can be resolved by asking whether the plaintiff seeks something more than lost profits." *Id.* The court reasoned that the plaintiff not only sought lost profits, but also "the opportunity to establish itself in the children's publishing industry as a reputable and responsible publisher of books." *Id.* Therefore, "[a]s a relative unknown and unproven entity in the industry" there could have been "few better opportunities than as the exclusive publisher of Power Rangers books." *Id.* The court ultimately granted the motion for preliminary injunction and held that "when, in circumstances such as those in the present case, the supplier of a unique, lucrative, and possibly short-lived property refuses to supply that property in breach of a contract, the distributor is entitled to an injunction compelling performance." *Id.* at 1141.

Conversely, Defendant relies on *Bennington Foods LLC v. St Croix Renaissance Group, LLC*, 528 F.3d 176, 179 (3d Cir. 2008), *inter alia*, to support its contention that Plaintiffs failed to demonstrate that they were irreparably harmed. In *Bennington Foods*, the plaintiff argued "that it has a reputation for delivering scrap metal on time and that this reputation will be irreparably harmed if it is not allowed to remove the scrap metal at issue here." 528 F.3d at 179. The district court agreed with Plaintiff and "concluded that this represented an irreparable harm analogous to those faced by the plaintiffs in *Pappan Enterprises, Inc. v. Hardee's Food Systems, Inc.*, 143 F.3d 800 (3d Cir. 1998) and *Fitzgerald v. Mountain Laurel Racing, Inc.*, 607 F.2d 589 (3d Cir.1979)." *Bennington Foods LLC*, 528 F.3d at 179. The Third Circuit disagreed and concluded that "[i]n both of those cases the reputation of the plaintiff was directly endangered by the defendant's actions—the misleading use of trademarks and a suspension based on suspicion of cheating can, in and of themselves, harm plaintiffs' reputations." *Id.* at 179–80. The Third Circuit found that unlike in *Pappan* and *Fitzgerald*, "any damage to Bennington's reputation will

result only indirectly from SCRG's actions." *Id.* at 180. The court reasoned that the defendant was "not doing anything (or refraining from doing anything) that will directly harm Bennington's reputation with its suppliers in India." *Id.* Moreover, "the claim is a two-step one: (1) because SCRG is not delivering (allegedly breaching the contract), Bennington is unable to deliver, and (2) lack of delivery harms Bennington's reputation with third parties with whom Bennington has contracted to resell the scrap." *Id.* Accordingly, the Third Circuit found that the plaintiff could not demonstrate irreparable harm. *Id.* at 179–80.

The Court also finds *EUSA Pharma (US) Inc. v. Innocoll Pharmaceuticals Ltd.*, 594 F. Supp. 2d 570, 573 (E.D. Pa. 2009) to be instructive. In *EUSA Pharma*, the plaintiff "requested a preliminary injunction to prevent Innocoll from beginning a clinical trial that might trigger EUSA's option to purchase the exclusive license to commercialize a product being developed by Innocoll." 594 F. Supp. 2d at 573. The district court initially "entered a temporary restraining order preventing the option's expiration" and then held an evidentiary hearing and oral argument to determine whether issuance of a preliminary injunction was appropriate. *EUSA Pharma (US) Inc.*, 594 F. Supp. 2d at 573. The court reasoned that the plaintiff "show[ed] a threat of immediate harm because Innocoll clearly intends to begin the OLSS immediately and not to recognize EUSA's Option once that occurs." *Id.* at 581. Further, "[i]f Innocoll's refusal prevents EUSA from exercising the Option, EUSA will suffer irreparable harm by losing 'a unique, non-replicable business opportunity.'" *Id.* at 582 (quoting *Allegheny Energy, Inc.*, 171 F.3d at 163). The court concluded that "the uniqueness of the B–Implant, a novel innovation in post-surgical pain relief still under development, cannot be denied." *Id.*

The present case is analogous to *Allegheny Energy*, *Tom Dougherty Associates*, and *EUSA Pharma*. In those cases, the courts identified a "unique, non-replicable business

opportunity" that the movant would be denied if the preliminary injunction was not entered. In the instant matter, when the parties executed the Agreement, Plaintiffs were not only expecting to cease litigation with Defendant, but to also have the opportunity to become the generic supplier of the Mucinex 600 mg ERG tablet. Consequently, "[t]he market for generic, over the counter . . . alternatives to Reckitt's Mucinex® family of ERG products is one of the largest [over-the-counter] markets existing today." Pl. Mot. for Preliminary Injunction at 9. Thus, if Defendant fails to execute a supply agreement and supply the 600 mg ERG tablets, Plaintiffs would be denied the unique, non-replicable business opportunity to enter the over-the-counter market by supplying the 600 mg ERG tablets at a time when there are few alternative providers.[6]

The 600 mg ERG tablets are "'of such a special nature or peculiar value that damages would be inadequate.'" *EUSA*, 594 F. Supp. 2d at 581 (quoting *ECRI*, 809 F.2d at 226). Furthermore, the parties contemplated the "special nature" and "peculiar value" of the Agreement when they included a provision in the Agreement that "there is no adequate remedy at law for the damage which either Party might sustain for breach of this Agreement and, accordingly, each Party shall be entitled, as its option, to specific performance, in addition to any other remedy at law or in equity, to enforce the terms hereof." Compl., Exh. A at 20. Accordingly, Plaintiffs' ability to penetrate the over-the-counter market and establish itself as a legitimate generic provider of a top-selling drug by selling the 600 mg ERG tablets is not quantifiable. Therefore, Plaintiffs have sustained their burden of proving that if the Court did not enter the injunction and require Defendant to begin to supply the 600 mg ERG tablets they would suffer irreparable harm.

[6] Presently, the only other provider of a 600 mg ERG product is Perrigo. *See* Pl. Mot. for Preliminary Injunction at 13 (explaining that "Reckitt became obligated to supply Mutual on October 24, 2013 after Perrigo launched a 600 mg ERG product"). In 2015, Actavis also "announced the FDA approved its ANDA for guaifenesin/pseudophedrine tablets ('combination product'), and that it plans to work with Perrigo to start shipping its product." *Id.* at 23.

The Court's inquiry does not end with a finding of irreparable harm. The Court must also determine whether Plaintiffs' injury is not "'remote or speculative, but actual and imminent.'" *FMC Corp.*, 369 F. Supp. 2d at 573 (quoting *Air Transp. Int'l L.L.C.*, 993 F. Supp. 118 at 123). Plaintiffs have the burden of demonstrating "a 'clear showing of immediate irreparable injury,' or a 'presently existing actual threat'" because an injunction "'may not be used simply to eliminate a possibility of a remote future injury.'" *Acierno v. New Castle Cty.*, 40 F.3d 645, 655 (3d Cir. 1994) (quoting *Cont'l Grp., Inc. v. Amoco Chems. Corp.*, 614 F.2d 351, 358 (3d Cir. 1980)); *see also Grant Heilman Photography*, 864 F. Supp. 2d at 325. A party's delay in seeking a preliminary injunction could "belie[] its claim of irreparable injury." *Laminations, Inc. v. Roma Direct Mktg. LLC*, 516 F. Supp. 2d 404, 420 (M.D. Pa. 2007); *see also MNI Mgmt., Inc. v. Wine King, LLC*, 542 F. Supp. 2d 389, 403 (D.N.J. 2008) (explaining that "inexcusable delay in seeking a preliminary injunction may defeat a movant's assertion of irreparable harm").

Plaintiffs argue that "[t]here is an imminent risk of what Mutual bargained for disappearing completely." Pl. Mot. for Preliminary Injunction at 23. More specifically, Plaintiffs allege that "while Reckitt's motion [to dismiss] was pending, Actavis announced the FDA approved its ANDA for guaifenesin/pseudoephedrine tablets ('combination product'), and that it plans to work with Perrigo to start shipping its product 'in time for the cough/cold season.'" *Id.* (quoting Press Release, Actavis, Actavis and Perrigo Receive FDA Approval of Guaifenesin/Pseudoephedrine, The Store Brand Equivalent to Mucinex® D Tablets (June 2, 2015), http://www.actavis.com/news/news/thomson-reuters/actavis-and-perrigo-receive-fda-approval-of-guaife). On September 15, 2015, Actavis released another press release[7] that it received FDA "approval for its Abbreviated New Drug Applications for three Mucinex®

[7] Actavis and Allergan merged and is now identified as Allergan PLC. Press Release, Allergan, Actavis PLC is Now Allergan PLC (June 15, 2015), http://www.allergan.com/news/news/thomson-reuters/actavis-plc-is-now-allergan-plc.

equivalent products . . . [and] Perrigo [would] begin shipments of the products to its retail and wholesale customers in the U.S. in time for the 2016 cough and cold season." Press Release, Allergan, Allergan and Perrigo Receive FDA Approval of Three Extended Release Products Equivalent to Mucinex® and Mucinex® DM (Sept. 10, 2015), http://www.allergan.com/news/news/thomson-reuters/allergan-and-perrigo-receive-fda-approval-of-three. Thus, Plaintiffs contend that if they have to "wait until trial before Reckitt is ordered to enter into a supply agreement, the generic ERG market will be dominated by Perrigo and Actavis and Mutual's chance to instantly establish itself in the generic OTC market will be gone." Pl. Mot. for Preliminary Injunction at 24.

On the other hand, Defendant contends that Plaintiffs "have not offered ***any*** proof that there is an 'emergency,' so as to compel issuance of a preliminary injunction." Def. Supp. Br. at 9. For example, "[i]f Mutual truly believed it was facing irreparable harm, it had plenty of time to seek a preliminary injunction shortly after it sent the notice in October 2013." Def. Resp. at 28. Defendant maintains that instead of seeking a preliminary injunction, "Mutual negotiated for a year, filed a state court action for breach of contract in August 2014, the same breach of contract claim later filed in this Court. . . . [and] it filed still another action: this antitrust action in this Court." *Id.* Therefore, "Mutual's delay of 13 months after it first filed suit against RB belies its newly claimed need for a preliminary injunction and demonstrates that, at best, it was sleeping on its rights, thereby precluding preliminary injunctive relief." *Id.*

By seeking this mandatory preliminary injunction, Plaintiffs are held to a "higher standard of showing irreparable harm in the absence of an injunction." *Bennington Foods LLC*, 528 F.3d at 179. Plaintiffs failed to sustain this burden. Plaintiffs waited to bring the motion for preliminary injunction until September 10, 2015—seven months after the filing of the suit in this

Court and almost two years after Perrigo began selling the generic Mucinex ERG. This delay, alone, does not preclude a finding that Plaintiffs would suffer immediate irreparable harm. However, together, the delay and the speculative nature of the irreparable harm weigh against a finding that Plaintiffs would be immediately harmed. Plaintiffs contend that if they have to ""wait until trial before Reckitt is ordered to enter into a supply agreement, the generic ERG market will be dominated by Perrigo and Actavis." Pl. Mot. for Preliminary Injunction at 24. However, Plaintiffs concede that "[a]t this time, Perrigo would be Mutual's only generic competition." Pl. Supp. Br. at 8. Plaintiffs have not sufficiently demonstrated that Allergan has entered the market or will enter into the market shortly, thereby diluting Plaintiffs' ability to capture a portion of the market and receive the benefits of the Agreement. Therefore, Plaintiffs failed to sustain its burden of "a 'clear showing of immediate irreparable injury,' or a 'presently existing actual threat.'" *Acierno,* 40 F.3d at 655 (quoting *Cont'l Grp., Inc.*, 614 F.2d at 358.

C. Balance of Harms

The third prong of the preliminary injunction analysis requires the Court to "balance the relative harm to the parties, *i.e.*, the potential injury to the plaintiff if an injunction does not issue versus the potential injury to the defendant if the injunction is issued." *Novartis Consumer Health, Inc.*, 290 F.3d at 596. This "balancing test is intended to ensure that the issuance of an injunction would not harm the [non-moving party] more than a denial would harm the party seeking an injunction." *MarbleLife, Inc. v. Stone Res., Inc.*, 759 F. Supp. 2d 552, 563 (E.D. Pa. 2010).

Plaintiffs claim that "[t]he Court's issuance of a preliminary injunction will do Reckitt no harm, but simply force it to do that which it agreed to do." Pl. Mot. for Preliminary Injunction at 26. More specifically, Plaintiffs allege that because "Reckitt's witnesses testified they want to

comply with the Agreement, . . . [this] illustrat[es] Mutual's point [that] there is no harm to Reckitt by requiring it to fulfill its contractual obligations." Pl. Supp. Br. at 9. In contrast, Defendant argues that "as the holder of the NDA[,] [it] is given the responsibility, indeed the obligation, to assure [the] FDA that any drug produced under its NDA is safe and effective and meets all requires specifications." Def. Resp. at 19. Defendant maintains that it

> cannot possibly bring a 600 mg ERG Product to market **within 30 days**. There are manufacturing steps required to modify the Mucinex tablets in color, logo embossing and shape which take approximately 18 weeks. There are new product specifications and a Quality Agreement for shared responsibility to package the drug under [Bulk Supply Agreement] ¶ 4.7 to prepare; there is punch tooling and obtaining drawing approval from Mutual. There are trial/results evaluations to test whether when the dye is removed and replaced with a buffer, the blend as slightly altered still performs properly. There are issues involved with FDA compliance, including FDA bulk validation production, and whether Mutual has an approved and fully validated packaging and labeling plant as required by FDA's cGMPs. There are studies to be made for reports that RB must keep on hand in the event that the FDA performs a site inspection.

Id. at 17.

The Court finds that the harm Defendant would incur if required to comply with the entry of the preliminary injunction exceeds the harm Plaintiffs would incur absent the entry of the injunction. If Defendant hastily completes the production of the tablets in thirty days, Defendant jeopardizes its reputation as a reputable provider of over-the-counter drugs. Further, Plaintiffs misinterpret Defendant's obligations under the Agreement. While it is true that in executing the Agreement Defendant committed to supplying Plaintiffs with the 600 mg ERG tablets if a third party entered the market, the Agreement does not provide that Defendant must produce the tablets in thirty days. The Agreement only states that the Plaintiffs can begin purchasing and Defendant can begin supplying the tablets "no earlier than ninety (90) days after the corresponding Launch Date." Compl., Exh. A at 12. Thus, Defendant could suffer irreparable damage to its reputation and financial security if it is required to swiftly produce these tablets

and suffer the prospect of an ineffective drug, FDA investigation, and litigation from consumers. Therefore, the harm to Defendant if the injunction is entered surpasses the harm that Plaintiffs would suffer if the injunction was not entered.

D. Public Interest

Lastly, the Court is required to consider the public interest in granting Plaintiffs' motion for preliminary injunction. In a breach of contract action, "the public interest favors enforcing valid contracts and making parties live up to their agreements." *MarbleLife, Inc.*, 759 F. Supp. 2d at 563. Additionally, "the public . . . has a well-recognized interest in 'receiving generic competition to brand-name drugs as soon as is possible,' *Boehringer Ingelheim Corp. v. Shalala*, 993 F.Supp. 1, 3 (D.D.C.1997), and a 'delay in the marketing of [the generic] drug could easily be against the public interest in reduced prices.'" *Biovail Corp. v. U.S. Food & Drug Admin.*, 519 F. Supp. 2d 39, 50 (D.D.C. 2007) (quoting *Schering Corp. v. Sullivan*, 782 F.Supp. 645, 652 (D.D.C.1992)). On the other hand, "[t]he public will suffer harm if the FDA does not follow proper procedures in approving generic drugs and if harmful drugs enter the marketplace as a result." *Id.*

The Court agrees with Plaintiff that "[i]f . . . Reckitt was ordered to perform its bargained-for contractual duties, Mutual would be able to offer a generic product to consumers. . . . [which] would increase competition and consequently lower costs for consumers." Pl. Mot. for Preliminary Injunction at 28. The Court also agrees that "[t]he public interest is also served by enforcing settlement agreements." *Id.* The Court cannot agree, however, that the production of 600 mg ERG tablets in thirty days would serve the public's interest. As noted by Defendant, "were RB to be ordered to produce pills on [a] shorter . . . timeframe . . . without any of the required tests, reports, validation studies or Quality Agreements, it will be doing so in direct

violation of the FDA regulations, putting the consumer in harm's way." Def. Resp. at 31. Furthermore, the Court would usurp the FDA of its role as the administrative body tasked with ensuring generic drug safety. The FDA explained that

> [g]eneric drugs are important options that allow greater access to health care for all Americans. They are copies of brand-name drugs and are the same as those brand name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Health care professionals and consumers can be assured that FDA approved generic drug products have met the same rigid standards as the innovator drug. All generic drugs approved by FDA have the same high quality, strength, purity and stability as brand-name drugs. And, the generic manufacturing, packaging, and testing sites must pass the same quality standards as those of brand name drugs.

Understanding Generic Drugs, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/default.htm (last updated Feb. 5, 2016). Accordingly, ordering Defendant to produce the 600 mg ERG tablets in thirty days would not be in the public's interest and would not ensure that this generic drug "met the same rigid standards as the innovator drug." *Id.* Thus, it is not in the public's interest to grant this injunction.

V. CONCLUSION

For the reasons explained herein, Plaintiffs have not sustained their burden in proving that they have suffered immediate irreparable harm, that the balance of the harms tips in their favor, and that granting the injunction would serve the public's interest. Plaintiffs' "'failure to establish any element ... renders a preliminary injunction inappropriate.'" *Ferring Pharm., Inc.*, 765 F.3d at 210 (quoting *NutraSweet Co.*, 176 F.3d at 153). Accordingly, this Court DENIES Plaintiffs' motion for preliminary injunction. An appropriate order follows.