IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ROCHESTER DRUG CO-OPERATIVE, et. al, INC., on behalf of itself and all others similarly situated,	)	
Plaintiffs,	)	
v.	)	Civ. No. 07-142-SLR
BRAINTREE LABORATORIES,	)	
Defendant.	)	

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MEMORANDUM OPINION

Dated: July 7, 2011
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

This is an antitrust action arising out of a patent infringement case filed on May 16, 2003 by Braintree Laboratories, Inc. ("Braintree"), a pharmaceutical company selling the constipation drug polyethylene glycol 3350 ("PEG") in the United States under the brand name MiraLax®, against a generic drug manufacturer, Schwarz Pharma, Inc. ("Schwarz"), in which Braintree sought to preclude FDA approval for Schwarz's generic PEG drug GlycoLax®. (Civ. No. 03-477-SLR (hereinafter, "the Braintree/Schwarz litigation")) The Braintree/Schwarz litigation commenced when Braintree brought suit pursuant to 35 U.S.C. § 271(e)(2)(A)[1] responsive to Schwarz's filing of an ANDA containing a "Paragraph IV" certification[2] claiming that the patent listed by Braintree in the FDA's Orange Book[3] as covering MiraLax®, U.S. Patent 5,710,183 ("the '183 patent" or the "Halow patent"), was invalid or not infringed by the manufacture, use, or sale of GlycoLax®. That suit triggered the 30-month stay on the FDA's approval of Schwarz's ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii). The Braintree/Schwarz litigation was voluntarily dismissed by Braintree on June 3, 2004. Braintree waived any

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[1]"(2) It shall be an act of infringement to submit – (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent[.]"

[2]*See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

[3]The FDA publishes patent information on approved drug products in its publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book," a register that provides notice of patents covering name brand drugs.

remaining portion of the 30-month stay, and GlycoLax® entered the market shortly after the FDA issued its approval on July 2, 2004. Rochester Drug Cooperative, Inc. ("RDC") filed the instant putative class action against Braintree on March 12, 2007, alleging that the Braintree/Schwarz litigation was a sham designed to delay the FDA's approval of GlycoLax® and to improperly maintain MiraLax®'s monopoly power. Plaintiffs amended their complaint on October 2, 2009. (D.I. 21) In lieu of an answer, Braintree filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). (D.I. 22) The court denied Braintree's motion on May 19, 2010. (D.I. 27, 28) Presently before the court is plaintiffs' motion for a preliminary injunction. (D.I. 117) For the reasons that follow, plaintiffs' motion is granted.

II. BACKGROUND

A. Procedural History

Plaintiffs are wholesalers and direct purchasers of MiraLax® who allege that they paid overcharges on their purchases on MiraLax® and generic polyethylene glycol 3350 ("PEG") as a result of defendant's monopoly prior to July 2004. The Braintree/Schwarz litigation, with which the court presumes familiarity, concluded in July 2008. (Civ. No. 03-477) In short, the facts of that case were as follows. Braintree discovered the '183 patent during a literature search while its NDA was pending with the FDA. It corresponded with the owner and iterated its position that the '183 patent was invalid as anticipated. Braintree succeeded in acquiring an exclusive license to the '183 patent for $15,000, whereupon it listed the '183 patent in the Orange Book (in 1999) and later sued Schwarz for infringement based on Schwarz's ANDA. Braintree later acquired the

'183 patent outright (in 2001). During litigation, the inventor of the '183 patent (Dr. Halow) was deposed for the first time, during which he provided that the clinical trials for MiraLax® were not done under confidentiality agreements. The Federal Circuit law at that time (in 2004) stated that such trials could be used as § 102 anticipatory prior art.[4] Braintree dismissed its suit, granted Schwarz a free license, waived the rest of the stay, and generic approval soon followed.

Schwarz maintained its counterclaims of unfair competition, "tortious interference with business advantage/opportunities," and actual or attempted monopolization of the market for PEG laxatives in the United States in violation of the Sherman Act, 15 U.S.C. § 2. After a bench trial, the court found that Schwarz did not meet its high burden of proof to demonstrate that the sham litigation exception to Noerr-Pennington immunity applied. *Braintree Labs., Inc. v. Schwarz Pharma, Inc.*, 568 F. Supp. 2d 487 (D. Del. 2008). Specifically, Braintree advanced a colorable claim construction under which its claims would be valid. Although not entirely consistent with its infringement position, Braintree's validity position was not frivolous on the record presented, and the court entered judgment for Braintree. *Id.* at 500.

The present class action litigation was filed by the drug wholesalers on March 12, 2007. Plaintiffs bring a claim for a violation of the Sherman Act based on Braintree's improper maintenance of its monopoly on MiraLax® which, plaintiffs allege, resulted in artificially inflated prices on their PEG purchases. (D.I. 21 at ¶ 104) In

[4] *See Baxter Int'l, Inc. v. Cobe Labs., Inc.*, 88 F.3d 1054, 1058 (Fed. Cir. 1996); *compare Bernhardt, L.L.C. v. Collezione Europa USA, Inc.*, 386 F.3d 1371 (Fed. Cir. 2004) (absence of confidentiality agreements not dispositive on issue of § 102(b) public use).

denying Braintree's motion to dismiss, the court found that: (1) plaintiffs stated a claim for antitrust injury, which could properly be forged as an "overall scheme" to forestall competition; (2) plaintiffs have alleged facts supporting their claim for objective baselessness; (3) plaintiffs at bar may make their own record, and succeed where Schwarz did not; and (4) the prior holding has no estoppel effect, as it was premised on Schwarz's failure to meet its high burden of proof, i.e., Braintree did not obtain a judgment of non-baselessness.[5] *Rochester Drug Co-Operative, Inc. v. Braintree Labs.*, 712 F. Supp. 2d 308 (D. Del. 2010).

B. Facts Relevant to the Preliminary Injunction Motion

Plaintiffs RDC and Louisiana Wholesale Drug Company, Inc. ("LWD") are direct purchasers of MiraLax®. Plaintiffs Meijer, Inc. and Meijer Distribution ("Meijer") are the assignees of the claims of direct purchaser Frank W. Kerr, Co. ("Kerr"). As noted previously, this litigation was initiated on March 12, 2007. The court denied Braintree's motion to dismiss on May 19, 2010, and discovery commenced. (D.I. 27, 28) On March 18, 2011, Harry P. Keegan, III ("Keegan"), President of Braintree, sent a letter to the CEO of RDC, stating as follows:

> The purpose of this letter is to inform you that effective immediately, Braintree Laboratories, Inc. will no longer sell any products to Rochester Drug Co-Operative, Inc.
>
> Braintree no longer wishes to do business with your firm as a result of its pursuit of vexatious and meritless litigation against Braintree in the case of [Civ. No.] 07-

[5]Both parties skew the court's prior holdings vis a vis the current motion. That is, plaintiffs argue that the prior holding indicates that they are likely to succeed on the merits (where Schwarz failed). Braintree argues that the bench ruling in the Schwarz litigation indicates the opposite. Neither party is correct; both must make their own records here.

> 142-SLR. As you know, Judge Robinson already found based on an extensive trial record that Braintree's patent infringement lawsuit against Schwarz Pharma, Inc. was not objectively baseless. In light of that ruling, Braintree views your efforts to pursue follow-on litigation before the same judge on behalf of a purported class of direct purchasers of MiraLax® as an effort to harass Braintree and pressure it to settle rather than incur potentially prohibitive defense costs. Braintree always has treated its customers with the utmost good faith, and expects the same in return.
>
> Accordingly, Braintree will not fill any orders from Rochester Drug for any product.

(D.I. 119 at A-23) Braintree similarly terminated its relationships with LWD and Kerr.[6]

Keegan justifies these actions as follows: (1) RDC, LWD and Meijer have collectively filed more than sixty (60) antitrust complaints as direct purchasers against pharmaceutical companies (D.I. 131 at A12-15); (2) Braintree is a small, privately-held pharmaceutical company with limited resources (*id.* at A4-5, ¶¶ 12-15[7]); (3) litigation is depriving Braintree of essential revenue it needs to reinvest into new products (*id.* at ¶¶ 14-15); and (4) Braintree desires to "limit future litigation exposure from these class litigants" (*id.*). Further, Braintree submits that only 0.53% of its annual gross sales are derived from RDC, LWD and Meijer. (*Id.* at A10, ¶ 7[8]) Braintree states, and plaintiffs do not dispute, that Braintree no longer sells MiraLax®. Braintree's termination, therefore, affects plaintiffs' ability to purchase from Braintree any of its five current product lines: (1) HalfLytely® (a laxative containing PEG); (2) NuLytely® (PEG

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[6]Letters evidencing these terminations do not appear to be of record. Plaintiffs cite only the RDC letter in their papers. (D.I. 118 at 5)

[7]The declaration of Keegan in support of Braintree's opposition to plaintiffs' motion was sworn on May 26, 2011.

[8]The declaration of Thomas Kelly, Braintree's CFO, in support of Braintree's opposition to plaintiffs' motion, sworn on May 31, 2011.

solution); (3) GoLytely® (same); (4) SUPREP® (colonoscopy preparative solution); and (5) Axid oral solution (stomach acid reducer). (*Id.* at A9, ¶ 2; D.I. 130 at 2, 10-11)

Plaintiffs aver that Braintree's actions threaten their ability to obtain and retain customers as full-line, full service drug wholesalers – a "one stop shop[ ]." (D.I. 118 at 17) According to RDC's CEO Laurence F. Doud, III ("Doud"), many of RDC's long-term care pharmacy customers belong to Group Purchasing Organizations ("GPOs") which negotiate discount contracts with manufacturers. RDC honors these contract prices, and sells drugs to its contract customers at less than the full price RDC paid to acquire them (the wholesale acquisition cost, or "WAC"). (D.I. 119 at A-3, ¶ 10) Typically, manufacturers will refund wholesalers their WAC (a "chargeback"); Braintree will not honor chargeback submissions from RDC now that RDC has been terminated as an authorized wholesaler. (*Id.* at ¶¶ 11-13) Doud states that RDC has eleven (11) contract customers that have discount contracts with Braintree. (*Id.* at ¶ 14)

According to Gayle R. White ("White"), President and General Manager of LWD, LWD's customers consist primarily of independent retail pharmacies in Louisiana which rely on LWD for a full line of pharmaceutical products. (*Id.* at A-9, ¶ 9) LWD's business operations and good will with its customers "would suffer serious adverse effects" "[i]f LWD is unable to obtain the products of a specified vendor (such as Braintree)[.]" (*Id.*)

Robert Newman ("Newman"), Senior Vice President at Kerr, similarly states that Braintree's termination will cause it to "lose control of its reputation as a full-line drug wholesaler." (*Id.* at A-13, ¶¶ 6, 10) Meijer[9] is still able to purchase Braintree products

[9]Newman does not make clear which Meijer entity (or both) he refers to in this regard.

from other wholesalers – Kerr's direct competitors – resulting in a loss of business. (*Id.* at ¶ 10) Newman "cannot envision a way to calculate the monetary losses Kerr will incur from Braintree's termination," as its future losses are "impossible to calculate." (*Id.* at ¶¶ 6, 9) Finally, Jacquelyn DeBruler ("DeBruler"), Merchandise Manager for Meijer, states that Meijer is "particularly concerned" about Braintree's decision as it "risks sullying Meijer's reputation and its relationship with all of its suppliers."[10] (*Id.* at A-19, ¶ 7)

In their reply papers, plaintiffs characterize RDC's losses as "imminent" insofar as RDC has not made the Braintree termination public in an effort to mitigate its damages. (D.I. 132 at 9-10) While Doud declared that RDC's eleven contract customers "will, I believe, leave RDC" due to Braintree's terimination (D.I. 119 at A5, ¶ 14), and stated at his deposition that his declaration omitted reference to "another contract . . . contain[ing] 11 more stores and sister stores to the ones that are listed [bringing] the total to approximately 31 stores doing approximately $75 million worth of business with [RDC]" (D.I. 133 at RA-73, 10:7-16), plaintiffs do not contest that RDC has not identified any customers that have actually left RDC (D.I. 132 at 10).

LWD did notify its purchasers of Braintree's termination, and is now purchasing pharmaceuticals solely from AmerisourceBergen (its former alternate source) at a higher rate than LWD paid Braintree. (D.I. 132 at 7; D.I. 133 at RA-59, 58:11-19; RA-60, 63:22-23) White testified that LWD is vulnerable to emerging state "pedigree" legislation that would not allow wholesalers to sell to other wholesalers. (D.I. 133 at

[10]DeBruler also testified, however, that Meijer has not considered terminating its relationship with Kerr to date. (D.I. 131 at A50, 17:4-6)

RA-61, 66:25-67:24) Plaintiffs do not call out any specific lost customers or (non-prospective) damages with respect to LWD.

Kerr adds that it has recently obtained certification as a Verified-Accredited Wholesale Distributor ("VAWD") from the National Association of Boards of Pharmacy, requiring Kerr to purchase pharmaceuticals only from the manufacturer. (*Id.* at RA-114, 30:4-15) Per its new agreement with Kerr, Meijer cannot purchase drugs through a secondary supplier and, in Michigan, Meijer has no source for Braintree's offered products. (*Id.* at RA-133, 30:2-31:21, 33:4-18) While DeBruler stated that Kerr lost sales in Michigan as a result, she did not provide details. (*Id.*)

III. STANDARD

Traditional rules of equity apply to requests for injunctive relief. *See eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). The moving party for injunctive relief must establish: "(1) a likelihood of success on the merits; (2) that it will suffer irreparable harm if the injunction is denied; (3) that granting preliminary relief will not result in even greater harm to the nonmoving party; and (4) that the public interest favors such relief." *Id.* (citation omitted). The burden lies with the movant to establish every element in its favor or the grant of a preliminary injunction is inappropriate. *See P.C. Yonkers, Inc. v. Celebrations, the Party and Seasonal Superstore, LLC*, 428 F.3d 504, 508 (3d Cir. 2005). If either or both of the fundamental requirements – likelihood of success on the merits and probability of irreparable harm if relief is not granted – are absent, an injunction cannot issue. *See McKeesport Hosp. v. Accreditation Council for Graduate Med. Educ.*, 24 F.3d 519, 523 (3d Cir. 1994). "The decision to grant or deny

. . . injunctive relief is an act of equitable discretion by the district court." *Id.* The grant of a preliminary injunction is considered an "extraordinary remedy" that should be granted only in "limited circumstances." *See Kos Pharm., Inc. v. Andrx Corp.*, 369 F.3d 700, 708 (3d Cir. 2004) (citation omitted).

IV. DISCUSSION

Plaintiffs' primary support for their motion to return the status quo is the Third Circuit's decision in *Bergen Drug Company, Inc. v. Parke, Davis & Company*, 307 F.2d 725 (3d Cir. 1962). In *Bergen*, the plaintiff commenced a private antitrust action against the defendant, seeking treble damages and a permanent injunction enjoining the defendant from refusing to sell its products to plaintiff upon the same terms as they are sold to other purchasers. The Third Circuit determined both that the district court "possessed equity powers to compel the parties to continue their relationship pending disposition of the main claim" and that the district court should have exercised those powers under the circumstances of record. *Id.* at 726.

In granting the relief sought, the Third Circuit focused its analysis on three factors. First, the permanent injunction sought by plaintiff was "identical to the temporary relief requested." *Id.* at 727. Second, the balance of harms weighed in favor of plaintiff.[11] Third, and perhaps most significantly, defendant's conduct should not

[11]In this regard, the Third Circuit noted that "[i]t would be impossible to estimate or compute plaintiff's damages for the loss of good will which it will suffer as a result of being unable to provide its retail customers with service at least equally as good as that furnished by other wholesalers who have a continuing access to defendant's products." 307 F.2d at 728. In weighing the harm, "[t]he inconveniences, if any, that defendant will undergo if called on to continue to deal with plaintiff are slight, while those that plaintiff has and will experience in the future are burdensome." *Id.*

negatively impact the litigation, as private actions "are a vehicle for serving not only the immediate interests of the litigants, but the continuing interest of the public in a smoothly functioning and unobstructed system of commerce." *Id.*

Defendant in *Bergen*, like defendant at bar, argued that it had "a right to refuse to deal with plaintiff [under the Supreme Court's decision in *United States v. Colgate & Co.*, 250 U.S. 300 (1919)] and, therefore, temporary relief should be denied." *Id.* at 727. The Third Circuit declined to expand the scope of *Colgate* beyond its facts, a criminal case in which the district court dismissed an indictment against a defendant accused of entering into a combination with wholesale and retail dealers for the purpose of fixing resale prices, "on the basis that a manufacturer can specify resale prices to its wholesalers and retailers and refuse to deal with anyone who fails to maintain them without violating the antitrust laws." *Id.* Moreover, according to the Third Circuit,

> the Supreme Court qualified its statement concerning a seller's freedom to choose customers in indicating that the rule would not apply where there is a purpose to create or maintain a monopoly. The undisputed facts here are that the buyer-seller relationship was discontinued because of the filing of the main action. True enough, the defendant can choose customers, but it should not be permitted to do so in order to stifle the main action, especially where it is apparent that such conduct will further the monopoly which plaintiff alleges defendant is attempting to bring about and which, if proved, would entitle plaintiff to permanent relief.

Id. (citation omitted). Consistent with the above, the plaintiff in *Bergen* convinced the Third Circuit that plaintiff would be "unable to secure the cooperation of other wholesalers and of retailers to be witnesses because they fear the same sort of retaliatory action that plaintiff has experienced." *Id.* at 728. The Court concluded that,

"[c]ertainly, a court can act where a party's conduct is calculated to frustrate litigation." *Id.*

Although there is no dispute that defendant at bar terminated its business relationship with plaintiffs[12] specifically as a result of plaintiffs' pursuit of litigation, the facts at bar are otherwise distinguishable from those analyzed in either *Bergen* or *Colgate.* The instant relief sought by plaintiffs – to continue the seller-buyer relationship with defendant – has no bearing on the ultimate relief sought by plaintiffs, that is, to be reimbursed for the cost of defendant's branded MiraLax® product if the court were to find that the Braintree/Schwarz litigation was a sham designed to delay the FDA's approval of generics. To put the point another way, the relief ultimately sought at bar is money damages for past conduct, which conduct has not been found to be violative of the antitrust laws. Moreover, plaintiffs have not demonstrated any specific harm caused by defendant's business termination,[13] relying instead on the possible harms generally described by the Third Circuit in *Bergen.* (D.I. 132 at 8-9) The court is left, then, with the Third Circuit's concern that a defendant's termination of its business relationship with an antitrust plaintiff would make it difficult, if not impossible, for the plaintiff to prosecute the action successfully. The Third Circuit, again, did not refer to

[12]Like the plaintiff in *Bergen,* plaintiffs at bar are "full-line, full-service wholesalers" with whom pharmacies prefer to deal to meet all of their need at once. 307 F.2d at 728.

[13]In *Bergen*, 25% of the orders received by plaintiff called for at least one of defendant's products, many of which were indispensable to the operation of a retail pharmacy. 307 F.2d at 728. There is no indication in the present record that defendant's products constitute as large a percentage of plaintiffs' orders. (D.I. 119 at A5, ¶ 15; D.I. 131 at A10, ¶ ¶ 9-10; A24-27)

any specific evidence of record to find this factor compelling.

In weighing the general principles involved, that is, the right of a business to choose its customers with the importance Congress has assigned to private antitrust actions, the Third Circuit has come out on the side of the plaintiffs. Nevertheless, given the lack of a compelling record at bar and the differences between the immediate and ultimate relief sought by plaintiffs, the court will grant plaintiffs' request for an injunction (i.e., force defendant to resume doing business with plaintiffs) only if plaintiffs are willing to post a bond for the cost of the instant litigation. *See gen., Sprint Comm's Co. L.P. v. CAT Comm's Co. L.P.*, 335 F.3d 235, 240 (3d Cir. 2003) (district court may condition its grant of a preliminary injunction on the applicant's posting of a bond). That is, if plaintiffs seek the "extra" relief of defendant's continued business, as compared to "early" relief on its claims in this action, plaintiffs must bear the risk of costs going forward.

V. CONCLUSION

For the foregoing reasons, the court grants plaintiffs' motion for a preliminary injunction on the conditions described above. An order shall issue scheduling a teleconference to discuss the manner of setting an appropriate amount of bond.