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: May 18, 2010
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" or "defendant"), 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"), seeking 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"), is 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 remaining portion of the 30-month stay, and GlycoLax® entered the market shortly the

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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.

FDA issued its approval on July 2, 2004. Plaintiffs filed the instant suit on March 12, 2007 alleging that the Braintree/Schwarz litigation was a sham litigation designed to delay the FDA's approval of GlycoLax® and to improperly maintain monopoly power with respect to its pioneer drug. Plaintiffs amended their complaint on October 2, 2009. (D.I. 21) In lieu of an answer, defendant filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). (D.I. 22) That motion is presently before the court. For the reasons that follow, defendant's motion is denied.

II. BACKGROUND

A. The Parties and their Products

Plaintiffs in this action are direct purchasers of MiraLax® who allege that they paid overcharges on their purchases of MiraLax® or generic PEG as a result of defendant's monopoly prior to July 2004. (D.I. 21 at ¶ 1) Plaintiffs Meijer, Inc. and Meijer Distribution, Inc. (collectively, "Meijer") are corporations organized under the laws of the State of Michigan, with their principal place of business in Grand Rapids, Michigan. (*Id.* at ¶ 13) Meijer is the assignee of the claims of the Frank W. Kerr Co. which, during the relevant period, purchased MiraLax® directly from defendant. (*Id.*) Plaintiff Rochester Drug Cooperation, Inc. ("RDC") is a drug wholesale cooperative located in Rochester, New York. (*Id.* at ¶ 14) Plaintiff Louisiana Wholesale Drug Company, Inc. ("LWD") is a Louisiana corporation located in Sunset, Louisiana. (*Id.* at ¶ 15)

Defendant Braintree is a privately held corporation organized and existing under the laws of the Commonwealth of Massachusetts and shares its name with its principal

place of business – Braintree, Massachusetts. (*Id.* at ¶ 16) Defendant first discovered the '183 patent while its New Drug Application ("NDA") was pending with the FDA.[4] (*Id.* at ¶ 66; D.I. 23 at 5) After defendant's counsel examined the '183 patent, defendant paid the named inventor, George M. Halow ("Halow"), "a nuisance-value payment of approximately $15,000 for a non-exclusive license." (D.I. 21 at ¶ 68; D.I. 23 at 5) In 1999, while its NDA remained pending, defendant listed the '183 patent in the FDA's Orange Book as covering MiraLax®. (D.I. 21 at ¶ 69) Defendant purchased the '183 patent outright in 2001.[5] (*Id.* at ¶ 70)

Schwarz filed its ANDA for GylcoLax®, a generic PEG, on January 20, 2003, and sent defendant a Paragraph IV certification letter on April 1, 2003. (*Id.* at ¶¶ 70-71) Braintree filed its patent infringement suit against Schwarz on May 16, 2003.[6] (*Id.* at ¶ 73) The only asserted claim in the Braintree/Schwarz litigation was claim 33 of the '183 patent, claiming: "A method for improving bowel function in a mammal, comprising orally administering [PEG] to the mammal, in an amount sufficient to improve bowel motility, stool formation, or both."

Schwarz received a tentative approval letter from the FDA for its ANDA for

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[4]The court presumes a familiarity with the statutory framework of the Hatch-Waxman Act. For a detailed description, the court references a recent opinion by Chief Judge Sleet of this court. *See In re Metoprolol Succinate Direct Purchaser Antitrust Litig.*, Civ. Nos. 06-52 & 06-71, 2010 WL 1485328 (D.Del. April 13, 2010).

[5]The purchase price does not appear to be of record.

[6]*See* 35 U.S.C. § 271(e)(2)(A) ("It shall be an act of infringement to submit . . . 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[.]").

GlycoLax® on December 23, 2003. (*Id.* at ¶ 82) This approval would have become final but for the 30-month stay triggered by the Braintree/Schwarz litigation. (*Id.*)

B. The Braintree/Schwarz Litigation

1. Prosecution history relevant to the parties' claim construction arguments

Claim 33 of the '183 patent was filed as original claim 34. (D.I. 21 at ¶ 57)[7] During prosecution of the '183 patent, on February 25, 1997, the examiner rejected all of the pending claims 1-34. Specifically, claim 34 was rejected as obvious in light of two prior art references teaching compositions containing PEG to improve bowel movement. (*Id.* at ¶ 58) In response, the applicant argued that claims 1-34 "provide a unique composition containing polyethylene glycol and a fiber bulking agent wherein PEG is present in a weight ratio of polyethylene glycol to fiber of from about 1 to 2 to no more than about 7 to 1. These percentages are critical and nowhere are they discussed or taught in the base references or the alleged equivalence teaching set forth by the secondary references." (*Id.* at ¶ 59) The applicant further emphasized that the ratio of PEG to fiber was critical because if "the PEG to fiber ratio is too low, rapid onset of activity of the products of the invention drops off and begins to approach the low onset of a fiber based bulk laxative of the prior art. If the PEG to fiber ratio is too high, the volume of composition which must be ingested to obtain the benefits of the fiber content may be too high and the excess PEG may result in undesirable effects, such as those associated with PEG based bowel lavage compositions, such as those set forth in

[7]The court cites the amended complaint in the current action for these facts, which do not differ from those recited in its Braintree/Schwarz litigation opinion.

[the asserted prior art]." (*Id.* at ¶ 60) The examiner issued a notice of allowance based upon this teaching of "the ratio for the two active ingredients." (*Id.* at ¶ 61) While issuing claims 1-32 included the emphasized PEG-fiber ratio, claim 33 (original claim 34) issued unamended, without this restriction. (*Id.* at ¶ 63)

2. The parties' positions and the court's determination

The labeling literature for GlycoLax® does not include any reference to the improvement of "bowel motility" or "stool formation" as reflected in claim 33 of the '183 patent. (D.I. 21 at ¶ 6; Civ. No. 03-477, D.I. 262 at 19-20) Braintree argued that the term "amount sufficient" as used in claim 33 should be construed to include the purpose of the stated amount of PEG, that is, "to improve bowel motility, stool formation, or both[,]" as this was the "new use discovered by Dr. Halow and the novel portion of the claim." (Civ. No. 03-477, D.I. 262 at 18) It was Schwarz's position that only an "amount sufficient" to "improv[e] bowel function in a mammal" is required, as there is no discussion of improving bowel motility or stool formation in the '183 patent specification. If "amount sufficient" was not limited to the new use advocated by defendant, then several prior art references disclosing the use of PEG to treat constipation would anticipate the claim. Contrarily, if "amount sufficient" were tied to the result of "improv[ing] bowel motility, stool formation, or both," the prior art, omitting any reference to these particular uses, would not invalidate. (*Id.* at 18-19)

Schwarz's principal argument was twofold: (1) MiraLax® does not include in its labeling any reference to bowel motility or stool formation in its packaging, yet Braintree listed the '183 patent in the Orange Book for MiraLax®; and (2) if GlycoLax® can

infringe without such references in its packaging, then the asserted prior art references anticipate without specific reference to bowel motility or stool formation. (*Id.* at 19-20) The court agreed that only one construction applies to both infringement and validity analyses. The court noted that Braintree's construction "reflects the plain meaning of the claim," and that neither asserted prior art reference discuss using PEG to improve bowel motility, stool formation, or both. (*Id.* at 20) Schwarz's anticipation argument, therefore, was premised on "inherent anticipation." (*Id.*) Schwarz did not present clear and convincing evidence that an improvement of bowel motility or of stool formation always and necessarily results from the administration of PEG as disclosed in its asserted prior art references. Both parties' experts agreed that "stool softening," improving "bowel motility" and improving "stool formation" were related benefits to some degree, but the record lacked any clear indication of the nature of this relationship. (*Id.*) Because it was possible that both MiraLax® and GlycoLax® have a use covered by claim 33, and because clear and convincing evidence of inherent anticipation was not provided, the court "decline[d] to find Braintree's infringement claim frivolous **on th[at] record**." (*Id.* at 21) (emphasis added) Essentially, although Braintree's position may have been inconsistent with respect to infringement (by GlycoLax®, as unlabeled for the claimed uses) and anticipation (by prior art not specifically disclosing the claimed uses), the court's decision was premised on Schwarz's failure to meet its high burden of proof.

C. Termination of the Braintree/Schwarz Litigation

The Braintree/Schwarz litigation proceeded until May 21, 2004, at which time

Braintree wrote to Schwarz that it had decided to voluntarily dismiss its patent infringement claim with prejudice and without costs. Braintree also offered Schwarz a royalty-free license to claim 33 of the '183 patent. (D.I. 21 at ¶ 83) Braintree states that its dismissal was prompted by "certain unexpected discovery from Mr. Halow." (D.I. 23 at 6) The court effectuated the dismissal on June 3, 2004 (Civ. No. 03-477, D.I. 64), and the FDA issued its final approval to Schwarz for GlycoLax® on July 2, 2004. (D.I. 21 at ¶ 86) GlycoLax® was first shipped "within days" of the FDA's approval. (*Id.*)

The Braintree/Schwarz litigation was not terminated, however. Schwarz maintained its state law counterclaims of unfair competition and tortious interference with business relations, as well as its claim that defendant violated Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2, by engaging in sham patent infringement litigation for the purpose of unlawfully extending defendant's market monopoly on MiraLax®. Following a bench trial, the court issued its findings of fact and conclusions of law. (Civ. No. 03-477, D.I. 262)[8] On the record before it, the court drew an inference that Braintree "obtained and relied upon an admittedly 'weak' patent for protection from other generic competition." (*Id.* at 14) However, insofar as even a potentially "weak" patent enjoys a presumption of validity, 35 U.S.C. § 282, the court concluded that Braintree had "advanced at least a colorable argument for validity and for infringement under its reading of claim 33" and, therefore, Braintree was immune from antitrust liability pursuant to the *Noerr-Pennington* doctrine, discussed in detail *infra*. (Civ. No. 03-477, D.I. 262 at 18)

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[8]*Braintree Labs., Inc. v. Schwarz Pharma, Inc.*, 568 F. Supp. 2d 487 (D.Del. 2008).

III. LEGAL STANDARDS

A. Motions to Dismiss

In reviewing a motion filed under Federal Rule of Civil Procedure 12(b)(6), the court must accept all factual allegations in a complaint as true and take them in the light most favorable to plaintiff. *See Erickson v. Pardus*, 551 U.S. 89, 127 S.Ct. 2197, 2200 (2007); *Christopher v. Harbury*, 536 U.S. 403, 406 (2002). A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 1964 (2007) (hereinafter, "*Twombly*") (interpreting Fed. R. Civ. P. 8(a)) (internal quotations omitted). A complaint does not need detailed factual allegations; however, "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 1964-65 (alteration in original) (citation omitted). The "[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true." *Id.* at 1959.

B. Antitrust Liability

Section 2 of the Sherman Act makes it unlawful to monopolize, attempt to monopolize, or conspire to monopolize, interstate or international commerce.[9] It is "the

[9]"Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court." 15

provision of the antitrust laws designed to curb the excesses of monopolists and near-monopolists." *LePage's Inc. v. 3M*, 324 F.3d 141, 169 (3d Cir. 2003) (en banc). Liability under § 2 requires "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966); *Schuylkill Energy Resources v. Pennsylvania Power & Light Co.*, 113 F.3d 405, 412-13 (3d Cir. 1997). Monopoly power is the ability to control prices and exclude competition in a given market. *Id.* at 571. If a firm can profitably raise prices without causing competing firms to expand output and drive down prices, that firm has monopoly power. *Harrison Aire, Inc. v. Aerostar Int'l, Inc.*, 423 F.3d 374, 380 (3d Cir. 2005).

To support an inference of monopoly power, a plaintiff typically must plead and prove that a firm has a dominant share in a relevant market, and that significant "entry barriers" protect that market. *Harrison Aire*, 423 F.3d at 381; *United States v. Microsoft*, 253 F.3d 34, 51 (D.C. Cir. 2001). Barriers to entry are factors, such as regulatory requirements, high capital costs, or technological obstacles, that prevent new competition from entering a market in response to a monopolist's supracompetitive prices. *Microsoft*, 253 F.3d at 51; *Rebel Oil Co. v. Atlantic Richfield Co.*, 51 F.3d 1421, 1439 (9th Cir. 1995); *see also Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 591 n.15 (1986) ("[W]ithout barriers to entry it would presumably be

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U.S.C. § 2.

impossible to maintain supracompetitive prices for an extended time.").

Anticompetitive conduct may take a variety of forms, but it is generally defined as conduct to obtain or maintain monopoly power as a result of competition on some basis other than the merits. *LePage's*, 324 F.3d at 147. Conduct that impairs the opportunities of rivals and either does not further competition on the merits or does so in an unnecessarily restrictive way may be deemed anticompetitive. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 604-05 & n.32 (1985). Conduct that merely harms competitors, however, while not harming the competitive process itself, is not anticompetitive. *See Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 224 (1993) ("It is axiomatic that the antitrust laws were passed for 'the protection of competition, not competitors.' ") (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962)); *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993) ("The law directs itself not against conduct which is competitive, even severely so, but against conduct which unfairly tends to destroy competition itself.")

C. *Noerr-Pennington* Immunity

A patent owner asserting its rights through patent infringement litigation is generally immune from antitrust liability. *Eastern R.R. Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965). Commonly referred to as the *Noerr-Pennington* doctrine, this immunity extends to persons who petition all types of government entities, including legislatures, administrative agencies, and courts. *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972). *Noerr-Pennington* immunity, however, is

subject to an exception for "sham" litigation. In this regard, the Supreme Court has outlined a two-part test to determine whether the "sham litigation" exception applies. *See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Ind.*, 508 U.S. 49 (1993). As an objective first part, "the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Id.* at 60. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, then the suit does not qualify as sham litigation and is immunized under the *Noerr-Pennington* doctrine. *Id.* The subjective second part of the definition arises only if the challenged litigation is objectively meritless. In such a case, the court must decide whether the "baseless lawsuit conceals 'an attempt to interfere directly with the business relationships of a competitor.'" *Id.* at 60-61. To invoke the "sham" exception, plaintiffs must prove, by clear and convincing evidence, that defendant's activities were not really efforts to vindicate its rights in court. *See C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1368-69 (Fed. Cir. 1998) ("sham litigation requires more than a failed legal theory") (quoting *Handgards, Inc. v. Ethicon, Inc.*, 743 F.2d 1282, 1288 (9th Cir. 1984)); *MCI Communications v. Am. Telephone and Telegraph Co.*, 708 F.2d 1081, 1155 (7th Cir. 1983).

IV. DISCUSSION

Plaintiffs frame their Section 2 claim in terms of one improper "course of conduct" by Braintree comprising several distinct acts, specifically, knowingly and intentionally: (1) procuring the '183 patent despite its belief that the '183 patent was

invalid;[10] (2) improperly listing the '183 patent in the Orange Book; and (3) improperly filing and prosecuting objectively baseless patent infringement actions against companies seeking to market generic MiraLax®.[11] (D.I. 21 at ¶ 103) As a result of Braintree's patent monopoly, plaintiffs allege that they paid artificially inflated prices for their PEG purchases ("overcharge" antitrust damages) during the extended monopoly period. (*Id.* at ¶¶ 104-05) Braintree disaggregates plaintiffs' theory into its constituent parts, arguing that: (1) plaintiffs' Orange Book allegations fail because they did not result in direct injury; and (2) the court's prior opinion establishes that its suit against Schwarz was not objectively baseless as a matter of law and, therefore, *Noerr-Pennington* immunity applies here to bar plaintiffs' claim.

A. Plaintiffs Have Alleged Antitrust Injury

Antitrust injury, or "an injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendants' acts unlawful," is a requisite to antitrust standing. *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). In its reply brief, Braintree argues (for the first time) that plaintiffs' improper Orange Book listing allegation fails because it resulted in no direct injury to plaintiffs. Insofar as the existence of antitrust injury is a threshold issue, the court

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[10]As Braintree did not prosecute the '183 patent, plaintiffs do not claim that Braintree committed a fraud on the PTO.

[11]Although the allegation is written broadly to encompass other litigation, the complaint identifies only the Braintree/Schwarz litigation as the basis for plaintiffs' claim. "A single lawsuit can violate antitrust law as long as it is both an objective and subjective sham." *See In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 686 (2d Cir. 2009). Notwithstanding, as discussed in the following section, plaintiffs have alleged an overall scheme comprising more than the filing of the Braintree/Schwarz litigation.

briefly addresses it here.

Plaintiffs allege that, as a result of Braintree's scheme, the ANDA approval process was delayed by the FDA. (D.I. 21 at ¶ 88) The FDA approved Schwarz's ANDA for PEG less than a month after Braintree dismissed its claim against Schwarz. (*Id.* at ¶ 90) "But for Braintree's misconduct, one or more competitors would have begun marketing A-rated generic versions of MiraLax® much sooner than such versions actually were marketed." (*Id.* at ¶ 87) Braintree's "scheme to delay the introduction into the U.S. marketplace of any generic version of MiraLax® caused plaintiffs and the class to pay more than they otherwise would have paid for [PEG]" during the exclusionary period. (*Id.* at ¶ 91) More specifically, the emergence of generics typically results in price competition which enables drug purchasers to both purchase generics at a substantially lower price and to purchase the brand name drug at a reduced price. (*Id.* at ¶ 92)

Braintree's argument that the causal link between its Orange Book listing and delayed generic entry is too attenuated to maintain an antitrust scheme is misplaced. As discussed in detail *infra*, plaintiffs' claim is premised on an overall scheme. It is sufficient, therefore, for plaintiffs to allege injuries that occurred as a result of the entire scheme, rather than any particular component therein.

The Third Circuit has generally sanctioned claims of antitrust injury including, as in this case, allegations that prescription drug consumers, the "foreseeable and necessary victims" of a pioneer drug company's efforts to exclude a generic from the market, pay overcharges during the exclusion period. *See gen. In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 400-01 (3d Cir. 2000) (stating that "[i]t is difficult to

imagine a more formidable demonstration of antitrust injury") (reversing district court's dismissal of indirect purchasers' claim for injunctive relief under the Clayton Act for lack of standing).

Taking plaintiffs' allegations as true, the court finds that the amended complaint sufficiently conveys a causal nexus between the alleged injury and Braintree's purportedly monopolistic behavior. Plaintiffs' allegations in this regard are of the type that generally pass muster in this context. *See id.; see also In re Gabapentin Patent Litig.*, 649 F. Supp. 2d at 355 (citing *Abbott Labs. v. Mylan Pharm., Inc.*, Civ. No. 05-6561, 2007 WL 625496 at *4-5 (N.D. Ill. Feb. 23, 2007)). As "the existence of antitrust injury is not typically resolved through motions to dismiss," the court declines to analyze any further disputes with respect to causation and injury on this motion. *See Schuylkill Energy Res.*, 115 F.3d at 417; *see also gen. Knevelbaard Daries v. Kraft Foods, Inc.*, 232 F.3d 979, 989 (9th Cir. 2001).

B. Plaintiffs Have Alleged an "Overall Scheme" to Forestall Competition

Plaintiffs may make their antitrust case by establishing an "overall scheme" to forestall generic competition. "[C]ourts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation"; "[i]f [plaintiffs] can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the antitrust laws, that series of actions, as an overall scheme, may trigger antitrust liability." *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 358-59 (D.N.J. 2009) (citing *LePage's Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2001)). This rationale applies equally in the patent context as in other antitrust contexts. *See id.* (citing *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522 (D.N.J. 2004)); *see also In re*

Neurontin Antitrust Litig., Civ. Nos. 02-1830, 02-2731, & 02-5583, MDL No. 1479, 2009 WL 2751029 at *15-16 (D.N.J. Aug. 28, 2009) (citations omitted).

Plaintiffs have alleged that during and prior to the proposed class period, Braintree held a 100% share of the PEG market in the United States and, therefore, had monopoly power. (D.I. 21 at ¶ 101) Plaintiffs have alleged in detail how Braintree engaged in a multifaceted scheme to unlawfully maintain its monopoly on the MiraLax® (PEG) market. The scheme comprised paying "a nuisance value payment of approximately $15,000" for a non-exclusive license to the '183 patent, which Braintree considered to be invalid. (*Id.* at ¶¶ 67-68) Braintree nevertheless listed the '183 patent in the Orange Book for MiraLax® in 1999 and purchased the patent outright in 2001, "shortly before MiraLax® would lose its marketing exclusivity on February 18, 2002." (*Id.* at ¶¶ 68-70) The Orange Book listing forced Schwarz to file a Paragraph IV certification. Braintree commenced suit against Schwarz to obtain the benefits of the 30-month stay and extend its market monopoly on MiraLax® beyond that allowed by the patent laws. (*Id.* at ¶¶ 69-73, 88)

As explained *infra*, plaintiffs describe in detail why they believe that the Braintree/Schwarz litigation was objectively baseless. In view of the foregoing, plaintiffs have sufficiently alleged an overall scheme by Braintree to forestall competition on generic MiraLax®. *See In re Gabapentin Patent Litig.*, 649 F. Supp. 2d at 359 ("If a plaintiff can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the antitrust laws, that series of actions, as an overall scheme, may trigger antitrust liability.") (denying motion to dismiss). The court need not, and declines to, analyze whether each facet of this

scheme constitutes a separate antitrust violation. *Id.* at 359.

C. Objective Baselessness

1. Plaintiffs' allegations

The majority of Braintree's papers is devoted to its assertions that *Noerr-Pennington* immunity bars plaintiffs' claim because its positions in the Braintree/Schwarz litigation were objectively reasonable. Plaintiffs' allegations with respect to the baselessness of the Braintree/Schwarz litigation are as follows. First, Braintree knew or should have known that claim 33 was invalid for reading on the prior art. Braintree itself attempted to patent the use of PEG for the treatment of constipation but its applications claiming this use were consistently denied by the PTO. (D.I. 21 at ¶ 64) When Braintree learned of the '183 patent while its NDA for MiraLax® was pending, its counsel examined the '183 patent "and concluded, in a December 23, 1998 letter sent to Halow, that claim 33 of the '183 patent was directly anticipated by the prior art, and hence invalid."[12] (*Id.* at ¶ 67)

Aside from anticipation, plaintiffs allege that the '183 patent is invalid on its face because there is no disclosure of PEG (without fiber) in the specification of the '183 patent in accordance with the requirements of 35 U.S.C. § 112. (*Id.* at ¶ 77) As noted previously, Braintree paid "a nuisance value payment of approximately $15,000" for a non-exclusive license prior to purchasing the '183 patent outright prior to the expiration of the MiraLax® exclusivity period. (*Id.* at ¶¶ 68-70)

Plaintiffs aver that Braintree's lawsuit against Schwarz was "objectively baseless

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[12]The contents of the letter to Halow, i.e., Braintree's grounds for its statement that the '183 patent was invalid, are not specified in the amended complaint.

on its face because, to prevail, Braintree was required to advance a claim construction position for purposes of validity that precluded any reasonable argument of inducement by [Schwarz], and vice versa." (*Id.* at ¶ 76) First, reading claim 33 to cover PEG without fiber would be inconsistent with the examiner's basis for allowing the claims in the first instance, and would compel a finding of anticipation (or obviousness) in view of a plethora of prior art teaching the use of PEG (without fiber) to treat constipation. (*Id.* at ¶ 77) Construing the claim consistent with the applicant's arguments results in noninfringement, as GlycoLax® does not contain fiber. (*Id.*)

Secondly, to overcome the prior art, Braintree was forced to distinguish improving constipation from both bowel motility and stool formation. Braintree argued: (1) "[m]ost patients with constipation do not have a bowel motility or stool formation problem;" (2) "[p]atients with normal transit constipation may still have dismotility of the bowel, meaning alterations in the neuromuscular contractions of the bowel, but would not necessarily have bowel motility problems; " and (3) "giving PEG to soften stool would not necessarily improve stool formation [–] softening the stool of a person having a stool form of five would make that person's stool formation worse." (*Id.* at ¶ 79) (internal citations omitted). Plaintiffs argue that, if the treatment of constipation does not necessarily require improving bowel motility or stool formation, then Schwarz could not reasonably be viewed as encouraging patients to utilize GlycoLax® for these purposes simply by encouraging patients to utilize GlycoLax® for constipation. (*Id.*)

Finally, plaintiffs aver that the ruling in *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003), preceded Braintree's suit by four months and contravened the grounds for Braintree's infringement claim. (*Id.* at ¶ 75) That is, a method of

treatment claim may only be directly infringed by patients who perform the claimed method. (*Id.* at ¶ 76) Schwarz could infringe only if it induced patients to infringe, and GlycoLax® labeling is directed to constipation, which was distinguished by Braintree. (*Id.* at ¶¶ 76, 78, 79)

2. Effect of the prior opinion

The court addresses at this juncture Braintree's argument that, in view of the court's opinion in the Braintree/Schwarz litigation, the court should decide that the Braintree/Schwarz litigation was not a sham as a matter of law. The court disagrees for several reasons. As discussed above, although the court previously found that the *Noerr-Pennington* doctrine barred Schwarz's antitrust counterclaim, it did so on the record before it at that time, mainly, in view of the fact that "[Schwarz did not] demonstrate[ ], by clear and convincing evidence, the lack of any objectively reasonable argument that the '183 patent is valid." (Civ. No. 03-477, D.I. 262 at 21; *see also id.* ("[T]he court declines to find Braintree's infringement claim frivolous **on this record**." (emphasis added))

Issue preclusion, also called collateral estoppel, applies when "(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action." *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006) (citations omitted). The Third Circuit has also considered whether the party being precluded had "a full and fair opportunity to litigate the issue in question in the prior litigation" and, in addition, whether the issue was determined by final judgment. *Id.* (citations omitted).

Plaintiffs, direct purchasers of MiraLax®, were not represented in the Braintree/Schwarz litigation.[13] Plaintiffs at bar seek to make their own record, and insist that they will overcome the deficiencies in proof suffered by Schwarz. The court will not divest these plaintiffs of their day in court. All that is required to defeat Braintree's motion is that the amended complaint allege facts which, if proven, show that Braintree is not entitled to *Noerr-Pennington* immunity under the sham litigation exception. *See In re Gabapentin Patent Litig.*, 649 F. Supp. 2d at 363 (citation omitted). The court is satisfied that plaintiffs have alleged facts sufficient to establish that Braintree's suit against Schwarz was both objectively and subjectively baseless.

D. *Noerr-Pennington* Immunity Vis-a-Vis the "Overall Scheme" Claim

As noted previously, having found that plaintiffs have alleged an "overall scheme" on the part of Braintree that resulted in antitrust injury, the court does not parse plaintiffs' theory into its component parts. In analyzing the litigation component of plaintiffs' alleged monopolistic scheme, the court has not lost sight of this determination. For the reasons discussed above, the court does not exclude Braintree's bringing suit against Schwarz from the asserted scheme.[14]

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[13]This is likely the reason Braintree specifically avoids framing its argument as one of issue preclusion or collateral estoppel, notwithstanding its urging the court to apply preclusively the prior holding in a manner consistent with the doctrine.

[14]Although it need not consider the Orange Book listing component of the asserted scheme independently for purposes of deciding the present motion, the court notes its agreement with the caselaw holding that "improper listing" in the FDA's Orange Book is not an act of petitioning for *Noerr-Pennington* purposes, under the rationale iterated in *In re Buspirone Patent Litigation*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002). Braintree's motion would be alternatively denied on this ground.

E. Discovery Should be Tailored to the Issues to be Decided on Summary Judgment

"Objective baselessness," the threshold issue with respect to *Noerr-Pennington* immunity, is primarily a legal question requiring the court to evaluate the reasonableness of Braintree's litigation positions vis-a-vis the patent laws. To this end, the litigation record of the Braintree/Schwarz litigation has already been forged; only limited additional discovery may be necessary. For example, it would aid the court's review on summary judgment to have scientific evidence shedding light on the credibility of Braintree's positions in that litigation.

Antitrust standing, the second prong of the *Noerr-Pennington* inquiry, and the merits of plaintiffs' Section 2 claim, are determinations that flow from factual allegations and, as a result, are better addressed at the summary judgment stage upon a developed record. *See In re Gapapentin Patent Litig.*, 649 F. Supp. 2d at 360 n.23; *In re Neurontin Antitrust Litig.*, 2009 WL 2751029 at *22-23; *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d at 528. A scheduling conference will be set in due course. The parties shall be prepared to discuss focusing discovery so as to streamline this litigation.

V. CONCLUSION

For the foregoing reasons, Braintree's motion is denied. An appropriate order shall issue.