IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BRAINTREE LABORATORIES, INC.,	)	
Plaintiff and Counterclaim Defendant,	)	
v.	)	Civ. No. 03-477-SLR
SCHWARZ PHARMA, INC.,	)	
Defendant and Counterclaim Plaintiff.	)	

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OPINION

Dated: July 31, 2008
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

This action arises out of the filing of an Abbreviated New Drug Application ("ANDA")[1] by Schwarz Pharma, Inc. ("SPI") to market a generic version of the constipation drug MIRALAX® proprietary to Braintree Laboratories, Inc. ("Braintree"). MIRALAX® has a single ingredient, polyethylene glycol 3350 ("PEG"); the administration of PEG to treat constipation is protected by claim 33 of U.S. Patent No. 5,710,183 ("the '183 patent"). Braintree brought a patent infringement suit pursuant to 35 U.S.C. § 271(e)(2)(A)[2] on May 16, 2003. (D.I. 1) Braintree's suit triggered the 30-month stay on the FDA's approval of SPI's ANDA for its generic drug, GLYCOLAX®. See 21 U.S.C. § 355(j)(5)(B)(iii). On June 3, 2004, the court signed a stipulated order of dismissal whereby Braintree's complaint for infringement was voluntarily dismissed with prejudice, SPI's counterclaim for invalidity was dismissed as moot, and Braintree waived any remaining portion of the 30-month stay on FDA approval of SPI's ANDA. (D.I. 64) Remaining were SPI's 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.[3] (D.I. 259 at 14) A bench trial was held between January

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[1]No. 76-652.

[2]"(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[.]"

[3]The record was relatively unclear as to what counterclaims SPI was pursuing. SPI had originally asserted patent misuse, improper listing in the Orange Book, as well as a Section 1 claim under the Sherman Act. (D.I. 39) SPI omitted these assertions in

29, 2007 and February 2, 2007 on these issues, as well as damages, which were fully briefed post-trial. The court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a) and 1400(b). Having considered the documentary evidence and testimony, the court makes the following findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(1).

II. FINDINGS OF FACT AND CONCLUSIONS OF LAW

A. Background

1. The Parties and the Technology at Issue

1. Braintree is a Massachusetts corporation with its principal place of business in Braintree, Massachusetts. SPI is a Delaware corporation with its principal place of business in Mequon, Wisconsin. Both are pharmaceutical drug companies involved in the manufacture of laxatives.

2. Polyethylene glycol 3350 ("PEG") is an inert chemical that is not well absorbed by the body and tends to absorb water. (D.I. 235 at 106:6-8) In its pure form, PEG is used to treat constipation; it is also used in combination with electrolytes for lavage[4] of the colon. (Id. at 106:25-107:6) Constipation is the difficulty of passage of stool or infrequent stools or both. (Id. at 105:20-21) Braintree sells PEG under the tradename MIRALAX®. (Id. at 107:9-14) SPI sells a generic PEG product under the tradename GLYCOLAX®. (Id. at 112:17-18) The parties agree that MIRALAX® and

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its pre-trial submission (D.I. 230, pt. 2 at p.18), but Braintree included them amongst its list of issues of law to be decided (id. at p. 24). The court limits its consideration to those counterclaims addressed in SPI's post-trial papers (D.I. 259 at 14).

[4]A cleaning of the colon in preparation for a colonoscopy or other rectal exam.

GLYCOLAX® have the same active ingredient (PEG), the same (oral) route of administration, the same dosage form, and have the same strength. (JTX-1 at ¶¶ 35-38)

3. The patient insert for MIRALAX® states that it is for the treatment of "occasional" constipation, and should be used for two weeks or less as directed by a physician. (PTX-737; D.I. 235 at 108:14-18) In practice, MIRALAX® is often used for the treatment of "chronic" constipation, or constipation lasting between three and six months. (D.I. 235 at 108:23-109:8) The usual daily dose is 17 grams, but can be up to 34 grams per day. (Id. at 109:15-110:8) MIRALAX® works by softening the stool, making it easier to pass and increasing the number of bowel movements. (Id. at 110:10-20) The patient insert for GLYCOLAX® also indicates that 17 grams per day may be used for two weeks for occasional constipation, and that it works by softening the stool. (PTX-738; D.I. 235 at 112:23-114:9)

2. The '183 Patent

4. The '183 patent, entitled "Laxative/Antidiarrheal Composition Comprising Polyethylene Glycol and Fiber Bulking Agent," was filed as U.S. Patent Application No. 502,773 ("the '773 application") on July 14, 1995. George M. Halow was named as the sole inventor. Originally-filed claims 1 to 27 of the '773 application claimed a composition for the improvement of bowel function comprising PEG and a fiber bulking agent. Claim 1, the only independant composition claim, required the PEG to be "present in a weight ratio of [PEG] to fiber of at least about 1:2." (PTX-2 at SP004637) Original claims 28 to 32 claimed a dosage for the oral administration of the claimed compositions. Claim 34 of the '773 application was drawn to

> [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.

(Id. at SP004640)

5. On February 25, 2005, all 34 claims of the '773 patent were rejected by the examiner. Claims 1-33 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Nos. 5,445,831 to Leis, Jr. et al ("Leis") and 4,321,263 to Powell et al ("Powell"), in combination with U.S. Patent Nos. 3,202,578 to Parker, 5,077,048 to Kimura et al and Abstract No. WO 870212,[5] authored by Fordtran ("the Fordtran abstract"). The examiner addressed claim 34 separately, stating:

> Claim 34 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Kimura et al or [the Fordtran abstract]. Each of the references teach compositions which contain polyethylene glycol as a laxative. The use of these compositions to improve bowel movement is obvious on its face. The instant method is considered to be taught by these references.

(Id. at SP004656)

6. Mr. Halow submitted a response to this office action on July 14, 1995. He did not specifically address the examiner's rejection of claim 34. With respect to the examiner's rejections of claims 1-33, Mr. Halow asserted that Powell disclosed the use of PEG preferably in combination with polyvinyl pyrollidone, in the prefered range of 2 to 5%, by weight of the wettable granules (substantially psyllium). Mr. Halow distinguished Powell on the basis that Powell requires wet granulation of psyllium powder goated with PEG and an organic solvent, followed by dispersion in water; "[n]owhere in the

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[5]This abstract corresponds to the Fordtran (PCT) application discussed in detail infra. The examiner rejected the claims based only on the abstract, which provided that "[c]onstipation may be treated with [aqueous solutions] of PEG alone." (PTX-2 at SP004658)

document is there a discussion of the use of an improved composition for an ongoing regimen in an amount sufficient to improve bowel motility and/or stool formation." (Id. at SP004665) Similarly, Mr. Halow asserted that Leis does not teach "the use of [PEG] in the percentages desired for the intended result of an ongoing treatment." (Id.) Mr. Halow stressed that "[t]he percentages set forth in the claims are critical"; too little PEG approaches the activity level of prior art, while too much PEG causes negative side effects. (Id. at SP004666) In sum,

> the claims as presently set forth provide a unique composition containing [PEG] and a fiber bulking agent wherein the [PEG] is present in a weight ratio of [PEG] to fiber of from about 1 to 2 to no more than 7 to 1. These percentages are critical and nowhere are they discussed in the base references or the alleged equivalence teaching set forth by the secondary references[, nor is the] unique regimen of taking the material on an ongoing basis without adverse side effects[.]

(Id.)

7. The examiner thereafter allowed claims 1-6 and 8-34, reasoning that "[t]he claims are considered to distinguish over the prior art since there is no teaching of the ratio for the two active ingredients. Unexpected results have been shown within the recited ratio." (Id. at SP004668) On August 14, 1997, an examiner's amendment was entered further limiting claim 1 to require PEG to be "present in a weight ratio of [PEG] to fiber of at least about 1:2 and not more than about 7:1."[6] (Id. at SP004670) A Notice of Allowance was issued on August 15, 1997, and the '183 patent issued on January 20, 1998. Original claim 34 of the '773 application issued, without amendment, as claim 33 of the '183 patent.

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[6]Original claim 7 was a dependant claim containing the "and not more than about 7:1" upper ratio limitation; in essence, claim 7 was eliminated when this limitation was incorporated into claim 1.

3. Prior Art

a. The Fordtran PCT

8. On August 1, 1985, Braintree filed U.S. Patent Application No. 762,577, entitled "Low-Sodium Laxative and Lavage Formulation," on behalf of employee-inventor John S. Fordtran. This U.S. application became the priority document for PCT Application No. WO1986US01578 ("the Fordtran PCT"), filed on July 31, 1986.[7] (PTX-36) The Fortran PCT, assigned to Braintree, was the product of work done by Dr. Fordtran in developing MIRALAX®; Braintree subsequently abandoned the application in July 1990. (D.I. 243 at 1576:22-1577:1)

9. The Fordtran PCT discloses the use of a formulation for the treatment of constipation, as well as a method for its use in treating constipation. Specifically,

> [t]he formulation [of the invention] is comprised of [PEG], which, in the treatment of constipation, can be administered alone in an aqueous solution or can be administered in combination with electrolytes in an aqueous solution. . . In treating constipation, the [PEG] solution is administered in sufficient quantities to produce a soft stool.

(PTX-36 at 4:10-23, 6:8-15) A PEG solution with a concentration of 75 to 300 grams of PEG per liter, and a preferred concentration of 105 grams per liter, is disclosed. (Id. at 7:9-13) Other embodiments are disclosed with PEG present in water at a concentration of 120 grams per liter of solution, with and without electrolytes.[8] (Id. at 7:22-26) The Fordtran PCT provides that, for "the treatment of constipation, individuals consume

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[7]The Fordtran application was assigned international publication no. WO 87/00754 and published on February 12, 1987.

[8]Where electrolytes are present, each of the ions is present in a concentration of from about 5.0 milli-equivalents per liter to about 50 milli-equivalents per liter. (PTX-36 at 7:22-30)

from about 50 to about 500 milliliters of either the PEG solution or the PEG-electrolyte solution, generally once a day or with meals"; preferably, individuals consume 250 milliliters of a one-liter solution containing 105 grams of PEG. (Id. at 8:17-29)

b. Andorsky

10. An article, entitled "Colonic Lavage Solution (Polyethylene Glycol Electrolyte Lavage Solution) as a Treatment for Chronic Constipation: A Double-Blind, Placebo-Controlled Study," was published by Richard I. Andorsky et al. in the American Journal of Gastroenterology in March 1990 (hereinafter, "Andorsky"). Andorsky discloses that a PEG-electrolyte lavage solution ("PEG-ELS") "can be an effective agent in the treatment of chronic constipation." (PTX-165 at BL00370) Andorsky provides that ingesting small quantities of PEG-ELS "significantly increases stool frequency and decreases stool consistency, compared with placebo." (Id. at BL00373) "PEG-ELS in the amount of 16 o[unces] per day is superior to 8 ounces per day" to treat chronic constipation in this manner. (Id. at BL00373-74)

11. Neither the Fordtran PCT nor Andorsky were before the examiner during prosecution of the '773 application. Both are prior art to the '183 patent.

3. Braintree's activities regarding the '183 patent

12. Braintree learned of the '183 patent in the late summer of 1998 when Dr. Robert Raleigh, Braintree's General Counsel, retrieved the published abstract in a routine patent literature search. (D.I. 235 at 242:7-22; D.I. 236 at 498:1-25) At that time, Braintree's New Drug Application ("NDA") for the use of PEG to treat constipation was pending with the Food and Drug Administration ("FDA"). Dr. Raleigh was surprised

by his discovery of the '183 patent, in view of the fact that Braintree had tried, unsuccessfully, to patent PEG for the treatment of constipation (the Fordtran PCT). (D.I. 236 at 499:21-500:5)

13. About a month prior to the issue date of the '183 patent, on December 23, 1998,[9] Arthur A. Smith, Jr., Esquire, counsel for Braintree, sent a letter to Stu Gitler, Esquire, counsel for Dr. Halow ("the Smith letter"), in which Mr. Smith stated the following:

> Per our discussions, you are aware that my client, Braintree Laboratories, Inc., is interested in obtaining option and licensing rights in [the '183 patent] . . .
>
> After evaluating the file history of this patent, we have concluded that, if this patent were to be reexamined by the USPTO, claim 33 (PEG alone) would be found invalid in view of the prior art (Fordtran PCT publication, WO87000754[, et al.]). It is our opinion that claim 33 . . . is directly anticipated by the claims of Fordtran [et al.]. . . .
>
> With that being said, we also recognize that validity and claim scope can only be ultimately determined by the USPTO and the courts.

(PTX-7) Mr. Smith further noted that Braintree would be interested in licensing claim 33, but in view of its "serious doubts concerning validity," Braintree desired only a non-exclusive license for the lump sum of $15,000. (Id.)

14. On February 5, 1999, Dr. Halow granted Braintree a non-exclusive license to claim 33 of the '183 patent. On or about February 18, 1999, Braintree received approval from the FDA to manufacture and sell a PEG laxative for the treatment of occasional constipation. In May 1999, Braintree began selling its PEG laxative,

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[9]The '773 application was filed on July 14, 1995; it would have published 18 months later, in January 1996.

MIRALAX®, in the United States.[10] Also in 1999, Braintree listed the '183 patent in the FDA's Orange Book[11] as covering MIRALAX®. (JTX-1 at Nos. 19, 24, 25; D.I. 235 at 88:23-24)

15. On April 19, 2000, Braintree had a meeting with representatives of McNeil Consumer HealthCare to discuss a possible business deal regarding an over the counter version of MIRALAX®. (JTX-1 at No. 58) Dr. Pelham drafted an internal memo regarding the meeting dated May 4, 2000 ("the Pelham memo"), stating the following:

> Braintree indicated that the Halow patent is weak, but that the courts ultimately judge validity. The information was conveyed also on April 20 by Braintree's counsel, Mr. Arthur Smith, Esq., in a telephone conversation held with McNeil counsel Joe Lightner. In that discussion, Mr. Smith also indicated that Braintree's license with Dr. Halow is non-exclusive.

(PTX-124)

16. Braintree submitted an application for approval of generic MIRALAX® to the FDA by letter dated February 16, 2001. (D.I. 237 at 926:22-25) Subsequently, on August 30, 2001, Braintree obtained an exclusive license to the '183 patent. (JTX-1 at No. 20) Braintree became the assignee of the '183 patent in February of 2002. (Id. at No. 22)

4. Emergence of generics

17. On or about January 30, 2003, SPI filed its ANDA with the FDA, seeking to

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[10]MIRALAX® was approved for over-the-counter usage by the FDA on October 6, 2006.

[11]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.

manufacture and sell GLYCOLAX®, its generic for MIRALAX®. SPI's ANDA contained a "Paragraph IV" certification,[12] asserting that the '183 patent is invalid or not infringed by the manufacture, use, or sale of GLYCOLAX®.

18. SPI notified Braintree of the submission of its ANDA on April 1, 2003. (JTX-1 at No. 34) Braintree initiated the present suit on May 16, 2003, triggering a 30-month stay whereby GLYCOLAX® could not be approved by the FDA.[13] Braintree did not serve its complaint on SPI for several months; service was effected on September 8, 2003. (D.I. 5; JTX-1 at No. 40) SPI was prepared to launch GLYCOLAX® on January 1, 2004 but for Braintree's lawsuit. (D.I. 237 at 791:10-793:20; D.I. 240 at 1436:22-25, 1442:7-1443:10)

19. The FDA granted Braintree's request to market generic MIRALAX® on April 5, 2004. (PTX-80; JTX-1 at No. 27) On May 27, 2004, Braintree voluntarily moved to dismiss its infringement complaint against SPI;[14] the court dismissed Braintree's complaint and SPI's invalidity counterclaim on June 3, 2004. At that time, Braintree

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

[13]See 21 U.S.C. § 355(j)(5)(B)(iii).

[14]Braintree learned at Dr. Halow's deposition in May 2004 that Dr. Halow did not obtain confidentiality agreements for the MIRALAX® clinical trials, which had taken place over a year prior to the filing of the '183 patent. (D.I. 236 at 520:20-521:9; D.I. 243 at 1602:8-12, 1605:2-10) On April 23, 2004, the Federal Circuit issued an opinion in Smithkline Beecham Corporation v. Apotex Corporation, 365 F.3d 1306 (Fed. Cir. 2004), in which it found that clinical trials conducted in the absence of confidentiality agreements constitute a non-experimental public use for the purposes of 35 U.S.C. § 102(b). The Smithkline decision was vacated en banc in April 2005. See Smithkline Beecham Corp. v. Apotex Corp., 403 F.3d 1328 (Fed. Cir. 2005). To avoid the risk of having its '183 patent invalidated under the law as it existed at that time, Braintree moved to dismiss its infringement claims on May 27, 2004.

waived the remaining portion of the 30-month stay (about 16 months). (D.I. 64) SPI received final approval for its ANDA by the FDA on July 2, 2004, and brought GLYCOLAX® to market on or about July 8, 2004. (D.I. 240 at 1441:25-1442:6) Although Braintree had secured its generic approval in April, it was not ready to launch at that time. GLYCOLAX® was the first generic to market.

20. In August 2004, Braintree formed a direct, wholly-owned subsidiary, "Affordable Pharmaceuticals, LLC" ("Affordable"), which was charged with the responsibility for marketing and selling generic MIRALAX®. Affordable entered into a marketing and sales agreement with Granard Pharmaceutical Sales and Marketing, LLC ("Granard") in September 2003, and generic MIRALAX® was introduced to market in mid to late-October 2004. (JTX-1 at Nos. 28-32)

21. Following the parties' entry into the generic market, several other companies informed Braintree of ANDA filings with the FDA for generic MIRALAX®, which filings included Paragraph IV certifications. Teva Pharmaceuticals USA, Inc., YVR Therapeutics LLC, Par Pharmaceutical, Inc., and Coastal Pharmaceuticals, Inc. each had ANDAs approved by the FDA between May 2006 and September 1996. (JTX-1 at Nos. 46-55)

B. Discussion

22. The infringement and invalidity claims have long since been removed from this case. Despite the lack of an infringement charge, SPI has pursued several of its counterclaims to trial. SPI asks the court to find bad faith in Braintree's commencement

of suit under the Hatch-Waxman statutory scheme[15] on the basis that Braintree knew, or should have known, that the '183 patent is invalid.

1. SPI's Sherman Act Counterclaims & Tortious Interference Counterclaim

23. A party who petitions the government for redress generally is 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). Although originally developed in the antitrust context, courts have applied this doctrine universally to business torts. See Cheminor Drugs, Ltd. v. Ethyl Corp., 168 F.3d 119, 128-29 (3d Cir. 1999) (applying the doctrine to common law claims of malicious prosecution, tortious interference with contract, tortious interference with prospective economic advantage, and unfair competition); see also IGEN Int'l, Inc. v. Roche Diagnostics GmbH, 335 F.3d 303, 310 (4th Cir. 2003). 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

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[15]Braintree was not only permitted, but expressly required by statute, to list its '183 patent in the Orange Book for MIRALAX® so long as the '183 patent "claims a method of using such drug and with respect to which a claim of patent infringement could **reasonably** be asserted" against a non-licensee. See 21 U.S.C. § 355(b)(1) (emphasis added). Once the '183 patent was listed in the Orange Book, SPI was required to file a Paragraph IV certification in its ANDA; when this occurred, SPI committed an act of patent infringement. Braintree's suit, therefore, was expressly contemplated by statute. See 35 U.S.C. § 271(e)(2); Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990).

"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, a defendant must prove, by clear and convincing evidence, that a plaintiff'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).

24. SPI asserts that the totality of the circumstances demonstrates that Braintree's infringement suit was both objectively baseless and brought in bad faith. (D.I. 259 at 20-45) As an initial matter, the court agrees that the chronology of events supports the inference that Braintree's infringement suit was motivated primarily by business considerations, rather than legal ones. Braintree obtained an exclusive license to the '183 patent in August 2001, six months prior to the expiration of the FDA's period of exclusivity for MIRALAX® (in February 2002). SPI notified Braintree of

its Paragraph IV certification in April 2003, and Braintree filed suit in May 2003. Braintree did not meet with Dr. Halow until November 2003. Dr. Halow was deposed on May 20, 2004, and Braintree dismissed its suit a week later. GLYCOLAX® launched thereafter in July 2004, and Braintree's own generic did not launch until October 2004.

25. The inference to be drawn from this chronology is that, instead of directing its efforts to launching a generic, Braintree obtained and relied upon an admittedly "weak" patent for protection from other generic competition. Braintree tries to distance itself from the Smith memo, characterizing Mr. Smith as a "solo practitioner" who downplayed the '183 patent in order to negotiate an inexpensive license. (D.I. 260 at 48-49) According to Braintree, Mr. Smith was tasked with obtaining a license to the '183 patent, and "achieved that result without discussing with his client exactly how it was done." (Id. at 50) Braintree's witnesses testified that Mr. Smith did not share any invalidity opinion with them, despite the fact that Mr. Smith was acting directly on Braintree's behalf. (D.I. 236 at 364:11-365:1, 453:5-456:5,[16] 573:15-574:19) Mr. Keegan admitted that this purported "don't ask, don't tell" scenario was not a usual business practice. (Id. at 572:1-21) Braintree's ignorance as to Mr. Smith's activities and/or opinion is further belied by the Pelham memo, which indicates that Braintree representatives recognized that the '183 patent is "weak" and communicated this on several occasions to a potential business partner.

26. Braintree relies upon the analysis of Dr. Mark Cleveland, its top scientist, to support its validity position. Dr. Cleveland concluded in early 1999 (prior to the launch

[16]Dr. Pelham claimed to be "surprised" by the Smith letter. (D.I. 236 at 455:8-9)

of MIRALAX®) that the '183 patent was valid. (D.I. 235 at 258:9-17; D.I. 236 at 362:22-364:10) Upon revisiting the validity issue in 2000, and again after receiving SPI's Paragraph IV certification in April 2003, Dr. Cleveland reached the same conclusion. (D.I. 236 at 367:18-372:17, 382:12-384:2) Dr. Russ Pelham, Braintree's director of licensing, indicated that he shared Dr. Cleveland's conclusion (in 2000). (Id. at 487:14-25)

27. Both Drs. Cleveland and Pelham, however, were in direct and frequent contact with Braintree's patent counsel during this time. (D.I. 235 at 246:2-247:3, 250:3-18; D.I. 236 at 438:14-25, 441:15-442:2; PTX 40[17]) Dr. Pelham testified that he spoke to Braintree's patent counsel regarding the '183 patent five to ten times per month. (D.I. 236 at 441:21-24) Dr. Cleveland acknowledged that the substance of his dicussions with counsel remained "in the back of [his] mind"; Dr. Pelham admitted that conversations with counsel "influenced [his] opinion" regarding the '183 patent. (D.I. 235 at 275:20-276:20; D.I. 236 at 452:5-453:3) Mr. Harry Keegan, President of Braintree, who made the ultimate decision to sue SPI after receiving Dr. Cleveland's opinion, testified that he did not know whether or not Dr. Cleveland's recommendation was based in part on any advice from counsel. (D.I. 236 at 582:7-583:6)

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[17]Braintree's privilege log indicates that Dr. Cleveland received a "letter for the purpose of providing legal advice concerning the '183 patent" from Jeffrey Auerbach, Esquire, from the law firm of Howrey & Simon, on November 30, 1998. (PTX-40 at 5) Dr. Pelham both authored and received many communications with Thomas O'Konski, Esquire, of the law firm of Ceceri & McKenna, in the summer of 2001, concerning the '183 patent. Dr. Cleveland was copied on some letters, while Drs. Cleveland and Pelham corresponded directly concerning legal advice received concerning the '183 patent on other occasions. Dr. Pelham also communicated with Mr. Robert Raleigh, Braintree's general counsel, regarding the '183 patent during this time frame. (Id. at 6-11)

28. Braintree did not waive its attorney-client privilege in this case by asserting an advice of counsel defense and, therefore, the nature of its counsel's advice remains unknown. To establish good faith in filing suit, but keep the nature of its communications with counsel confidential, Braintree has orchestrated an "advice of scientist" defense – the immediate flaw of which is that these scientists' views were admittedly tainted, on some level, by the confidential advice of counsel.[18]

29. Braintree's pre-suit consultation with Dr. Fordtran, named inventor on the Fordtran PCT, does not suffer from the same flaw. According to Dr. Peura, Dr. Fordtran advised Braintree in 2001 that the prior art failed to teach the use of PEG to improve bowel motility and stool formation as claimed in the '183 patent. (D.I. 238 at 1179:9-10) Dr. Fortran executed a declaration in 2002 to this effect. (DTX-509[19]) Braintree points to no testimony, however, by Mr. Keegan or otherwise, specifically indicating that Braintree relied upon Dr. Fordtran's opinion in filing suit against SPI. (D.I. 260 at 40-41)

30. Braintree also asserts that it consulted with Dr. David Peura, Braintree's technical expert, between the date suit was filed (May 16, 2003) and the date Braintree actually served its complaint on SPI (September 3, 2003). (D.I. 260 at 40-41; D.I. 259

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[18]The court notes that Braintree's trial counsel, in objecting to a question asked Mr. Keegan regarding the validity of the '183 patent, stated that "Mr. Keegan is not an attorney. The only way he would have any information about the validity or invalidity of claim 33 is on the advice of counsel he received." (D.I. 236 at 596:21-24)

[19]"It was not obvious to me at the time that the '578 application was filed and prosecuted that the administration of PEG in appropriate amounts or dosages to mammals, either alone or with a fiber-bulking agent, would have the effect of improving bowel motility, stool formation, or both. I know of no other work or publication that predates the Halow patent that teaches these effects of PEG." (DTX-509 at ¶ 10)

at 29-30 (collecting citations)) Dr. Peura, however, consulted only with counsel. (D.I. 238 at 1065:6-13) Braintree did not permit SPI discovery on the nature of counsel's communications with it regarding Dr. Peura's views, and cannot use Dr. Peura's advice to refute SPI's bad faith allegations without having permitted discovery regarding the precise nature of the advice that "filtered back" from Dr. Peura to counsel to Braintree.[20]

31. Notwithstanding the foregoing, to proceed with its antitrust and tortious interference counterclaims, it is SPI's burden to establish, by clear and convincing evidence, that Braintree's lawsuit was "objectively baseless" such that "no reasonable litigant could realistically expect success on the merits," i.e., a sham. In this respect, the court finds that SPI has not satisfied its burden.[21]

32. Even a potentially "weak" patent enjoys a presumption of validity. 35 U.S.C. § 282. The validity of the '183 patent has not been adjudicated by any court (or the USPTO on reexamination). This court has no occasion to judge the merits of SPI's invalidity arguments, and declines to issue a finding that Braintree "should have known" of its patent's invalidity absent such findings. As discussed previously, the evidence demonstrates that Braintree appreciates that its '183 patent is "weak." Notwithstanding,

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[20]As Braintree points out, the record indicates that Dr. Peura was deposed upon the substance of his conversations with counsel, with no objection due to the fact that Dr. Peura is a testifying expert. (D.I. 238 at 1168:14-1169:3) As SPI asserts, "the issue is not what Dr. Peura told Wilmer Hale," which was presumably discovered at deposition, "but rather that Wilmer Hale told Braintree about Dr. Peura's views." (D.I. 261 at 12) Braintree has not waived the substance of its conversations with counsel on its privilege log and, therefore, cannot have it both ways.

[21]Because the court concludes that the suit was not objectively baseless, it does not reach the subjective second part of the Supreme Court's test, i.e., any bad faith on the part of Braintree.

the test for objective baselessness is an objective one. That is, "[i]t is not what the parties think of the merits of their positions that matters; it is whether there are, in fact, sufficient bases for the positions taken." In re Busiprone Patent Litig., 185 F. Supp. 2d 363, 375 (S.D.N.Y. 2002) (citations omitted).

33. Braintree has advanced at least a colorable argument for validity and for infringement under its reading of claim 33. As noted previously, claim 33 discloses

> [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.

Braintree argues that the "amount sufficient" must be construed to include the purpose of the stated amount, here, to "improve bowel motility, stool formation, or both[,]" as this is the "new use discovered by Dr. Halow and the novel portion of the claim."[22] (D.I. 260 at 22 & n.26) That is,

> PEG was previously thought to be an inert osmotic compound used to soften stool. The fact that it could be used to improve the neuromuscular activity of the bowel was entirely new.

(Id. at 22-23)

34. SPI disagrees with Braintree's claim construction. According to SPI, because there is no discussion of the invention of claim 33 anywhere in the body of the '183 patent, SPI asserts that "the alleged invention of claim 33 does not represent any sort of 'breakthrough' or 'revolutionary' new insight into the field of constipation

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[22]Under Braintree's theory, the prior art does not disclose using PEG for these purposes. That is, neither the Fordtran PCT nor Andorsky mention that their subject patients suffered from bowel motility or stool formation problems; the Fordtran PCT examples describe testing on presumably normal "subjects," and the Andorsky patients suffered from chronic constipation. (D.I. 260 at 6-7)

treatment[.]" (D.I. 259 at 34) Accordingly, "all that matters is that the numeric amount of PEG works to treat the specified condition[,]" i.e., "improving bowel function in a mammal." (D.I. 261 at 6)

35. The court does not decide whether Braintree's construction is correct, but finds that Braintree's proposed construction is not frivolous and is sufficiently reasonable to support its validity position.[23] See Q-Pharma, Inc. v. Andrew Jergens Co., 360 F.3d 1295, 1301 (Fed. Cir. 2004) (pre-filing claim interpretation that "followed the standard canons of claim construction and was reasonably supported by the intrinsic record" insufficient to establish objective baselessness). Braintree's construction reflects the plain meaning of the claim. Neither the Fordtran PCT nor Andorsky disclose using PEG to improve bowel motility, stool formation, or both. Neither reference mentions in its examples or otherwise that the subject patients suffered from bowel motility or stool formation problems; the Fordtran PCT examples describe testing on presumably normal "subjects," and the Andorsky patients suffered from chronic constipation. (D.I. 260 at 6-7) Under Braintree's claim construction, therefore, there is a sufficient basis to conclude that claim 33 is not invalid as anticipated.

36. SPI's chief complaint is that it was sued for infringement of claim 33 notwithstanding the lack of any mention of "bowel motility" or "stool formation" in the

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[23]Ultimately, it is Braintree's position that the court must scrutinize; SPI's claim construction is not at issue. The court notes, however, that SPI's position is untenable. The phrase "sufficient to improve bowel motility, stool formation, or both" cannot be ignored; to hold otherwise would render the "amount sufficient" limitation superfluous. SPI offers no support from the intrinsic record for reading out the stated purpose of the administration of PEG from the claim.

labeling or literature for GLYCOLAX®; similarly, Braintree listed the '183 patent in the Orange Book for MIRALAX® notwithstanding the absence of any such mention in its own product literature. (D.I. 261 at 37) SPI asserts that, if GLYCOLAX® can infringe despite the words "bowel motility" or "stool formation" being absent from its packaging, then the Fordtran PCT or Andorsky can anticipate the '183 patent without those words being present. The court agrees that only one claim construction applies to both infringement and validity analyses. SPI's argument, however, is essentially one of "inherent anticipation" by the Fordtran PCT or by Andorsky. In this regard, SPI has not pointed to evidence that an improvement of bowel motility or of stool formation always and necessarily results from the administration of PEG as disclosed in either reference.

37. The evidence of record indicates that both MIRALAX® and GLYCOLAX® improve bowel function, but there is no evidence of record that patients or physicians know, or care to know, why (i.e., whether the laxative improves bowel motility, stool formation, or stool softness). Dr. Cleveland testified that Braintree sued SPI for infringement "[b]ecause the numeric amount of PEG [present] would, as a matter of science, [treat bowel motility and stool formation.]"[24] (D.I. 236 at 387:6-18) SPI's expert, Dr. Lembo, agreed that it is possible to soften stool without improving bowel motility or stool formation, but that these benefits are related to some degree. (D.I. 235 at 192:5-16) If stool softening and stool formation are related benefits, it follows that MIRALAX® and GLYCOLAX®, known stool softeners, could have a use claimed in

[24]Dr. Cleveland's opinion as to the science of how PEG works on the bowels is within his own realm of expertise, unlike his legal conclusions of infringement and validity which, as discussed previously, were possibly tainted by the opinions of Braintree's outside counsel.

claim 33. Although Braintree points to no other evidence of record further illustrating the mechanism by which PEG relieves constipation, the court declines to find Braintree's infringement claim frivolous on this record.

38. In sum, SPI has not demonstrated, by clear and convincing evidence, the lack of any objectively reasonable argument that the '183 patent is valid.[25] There has been no finding of invalidity by this, or any other, court. Braintree has advanced a colorable claim construction, under which the '183 patent is not anticipated by the Fordtran PCT or Andorsky. SPI has neither asserted nor demonstrated that improved bowel motility or stool formation always and necessarily results from either disclosure. This does not preclude the possibility, however, that GLYCOLAX® could be demonstrated to infringe (by the lower, preponderance of the evidence, standard). Because its suit was not objectively baseless,[26] Braintree is immune from SPI's Sherman Act and tortious interference counterclaims under the Noerr-Pennington doctrine.

2. Unjust enrichment

39. The court also finds against SPI's unjust enrichment counterclaim. Under Delaware law, unjust enrichment

> is the unjust retention of a benefit to the loss of another, or the retention of money or property of another against the fundamental principles of justice or equity and good conscience. The elements of unjust enrichment have also been

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[25]SPI did not specifically address obviousness, written description, or enablement in its post-trial papers. (D.I. 259 at 21-24)

[26]The court notes that it is unaware of any instance in which a court has found that the assertion of a valid patent following a Paragraph IV certification constituted a "sham" litigation. Indeed, SPI has not pointed to any caselaw in this regard.

> stated in this way: (1) an enrichment, (2) an impoverishment, (3) a relation between the enrichment and impoverishment, (4) the absence of justification and (5) the absence of a remedy provided by law.

Cantor Fitzgerald, L.P. v. Cantor, 724 A.2d 571, 585 (Del. Ch. 1998) (internal quotation and citations omitted). For the reasons discussed above, the court declines to find that Braintree's activities were devoid of justification such that equity warrants this court's award of restitutionary damages.[27]

III. CONCLUSION

40. SPI has failed to prove, by clear and convincing evidence, that Braintree is not entitled to Noerr-Pennington immunity for SPI's Sherman Act and tortious interference counterclaims. The court finds against SPI on its unjust enrichment counterclaim. The parties will bear their own costs. An appropriate order shall issue.

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[27]SPI's right to recovery under prong (3) is questionable insofar as the injury sustained by SPI "was a general injury that was likewise sustained by every other manufacturer of the generic [PEG] drugs[.]" See Barr Labs, Inc. v. Quantum Pharmics, Inc., 827 F. Supp. 111, 119-20 (E.D.N.Y. 1993) (dismissing unjust enrichment claim under New York law, requiring an enrichment at plaintiff's expense, brought by one generic competitor against its generic competitor that allegedly gained market exclusivity through the filing of deceptive ANDAs). Nevertheless, SPI's claim fails under prong (4) as explained above.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

BRAINTREE LABORATORIES, INC.,	)	
Plaintiff and Counterclaim Defendant,	)	
v.	)	Civ. No. 03-477-SLR
SCHWARZ PHARMA, INC.,	)	
Defendant and Counterclaim Plaintiff.	)	

ORDER

At Wilmington this 31st day of July 2008, consistent with the opinion issued this same date;

IT IS ORDERED that SPI has failed to prove its counterclaims by clear and convincing evidence. The Clerk of Court is directed to enter judgment in favor of plaintiff and against defendant.

United States District Judge