

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

_____))
IN RE RELAFEN ANTITRUST) MASTER FILE
LITIGATION) NO. 01-12239-WGY
_____)

SUPPLEMENTAL MEMORANDUM
CLARIFYING THE PRESENT STATUS OF THESE PROCEEDINGS
AND
SETTING FORTH THE LEGAL FRAMEWORK FOR FURTHER
JUDICIAL ACTION

YOUNG, C.J.

February 22, 2005

I. INTRODUCTION

This case is a consolidated action against SmithKline Beecham Corporation and GlaxoSmithKline PLC (collectively "SmithKline") by multiple parties. The plaintiffs include SmithKline competitor Eon Labs; pharmaceutical wholesalers that purchased Relafen directly from SmithKline ("direct purchasers"); drugstores that indirectly purchased Relafen and the generic drug nabumetone for resale ("drugstore plaintiffs"); and parties that purchased nabumetone from sources other than SmithKline for purposes other than resale ("end payors") (collectively "Plaintiffs").

Since SmithKline has submitted papers purporting to describe what has and has not been settled in these consolidated actions, it is incumbent upon this Court to clarify the current status of

each of these consolidated cases and to provide further explanation of the legal analysis it has adopted to inform its resolution of the remaining important issues in several of these class actions.

II. BACKGROUND

The background of this case is detailed more completely in Judge Lindsay's opinion resolving the underlying patent infringement action, In re '639 Patent Litig., 154 F. Supp. 2d 157 (D. Mass. 2001) (Lindsay, J.), and in this Court's previous Memoranda and Orders, In re Relafen Antitrust Litig., 286 F. Supp. 2d 56 (D. Mass. 2003); In re Relafen Antitrust Litig., 218 F.R.D. 337 (D. Mass. 2003); Eon Laboratories, Inc. v. SmithKline Beecham Corp., 298 F. Supp. 2d 175 (D. Mass. 2003); and In re Relafen Antitrust Litig., 221 F.R.D. 260 (D. Mass. 2004). For present purposes the relevant background is as follows.

A. Factual Background

On November 2, 1982, the U.S. Patent and Trademark Office (the "Patent Office") rejected SmithKline's sixth application to patent nabumetone, a non-steroidal anti-inflammatory drug also described as methoxy ketone. In re '639 Patent Litig., 154 F. Supp. 2d at 169. In doing so, the Patent Office cited a 1973 article authored by J. N. Chatterjea and R. Prasad ("Chatterjea & Prasad"), who had previously named methoxy ketone and described a method for its synthesis. Id. at 162-63, 169. In light of

Chatterjea & Prasad's prior publication, the Patent Office concluded that SmithKline's claims to solid nabumetone were invalid as obvious and its claim to nabumetone per se was invalid as anticipated. Id. at 169. These conclusions were consistent with the early reports of SmithKline scientists, who had in internal communications, also identified the Chatterjea & Prasad publication as an "existing literature procedure" and described the preparation of nabumetone "following the published methods." Id. at 165-66 (internal quotation marks omitted).

Yet, in its interactions with the Patent Office, SmithKline maintained that the Chatterjea & Prasad publication was distinguishable on two bases. First, SmithKline argued before the Board of Patent Appeals that the Chatterjea & Prasad procedure produced a "thick pale yellow oil" unlike the solid nabumetone claimed by SmithKline. See Defs.' Noerr-Pennington App., Tab 11 (Decision of the Board of Patent Appeals) at 2. SmithKline scientist Dr. Carl Rose ("Dr. Rose") declared that he had obtained solid nabumetone only because he "diverged from [Chatterjea & Prasad's] described processes in that [he] purified the compounds carefully at each stage." Id. at 5 (quoting Rose Decl. ¶ 5). On the issue of anticipation, the Board of Patent Appeals ruled in SmithKline's favor, concluding, without reference to Dr. Rose's declaration, that the Chatterjea & Prasad publication did not disclose nabumetone in "solid form" and therefore did not anticipate SmithKline's solid-form claim. Id.

On the issue of obviousness, however, the Board of Appeals ruled against SmithKline in favor of rejection. Id. at 7. The Board of Patent Appeals cited evidence, including Rose's declaration and SmithKline's report of obtaining solid nabumetone "after purification," which "suggest[ed] that Chatterjea's 'thick pale yellow oil' may well have been an impure form of the claimed compound." Id. at 6. Because "correct and normal chemical procedure" included purifying intermediate and final compounds, the Board of Patent Appeals reasoned that it would have been obvious to the ordinary chemist to purify the oil described by Chatterjea & Prasad "and thereby obtain the compound . . . in solid form." Id. at 6. SmithKline subsequently challenged this finding with an affidavit sworn by J. N. Chatterjea ("Dr. Chatterjea"), who stated that R. Prasad had originally synthesized nabumetone only to convert it to a corresponding derivative. See Defs.' Noerr-Pennington App., Tab 13 (Chatterjea Aff. ¶¶ 4, 5(b)). For this purpose, SmithKline urged, there was no reason to purify the nabumetone.

Second, SmithKline asserted more broadly that the Chatterjea & Prasad publication did not disclose nabumetone at all. SmithKline stated that further review of the Chatterjea & Prasad publication had revealed a flaw. In re '639 Patent Litig., 154 F. Supp. 2d at 163. Although Chatterjea & Prasad described their starting material as methoxy acetate, they then cited an article

authored by R. G. Jones who, due to an error (the "Jones error"), described the synthesis of hydroxy acetate rather than methoxy acetate. Id. SmithKline argued that the ordinary chemist, cognizant of the Jones error, would understand Chatterjea & Prasad to describe a series of reactions that started with hydroxy acetate and ended with hydroxy ketone, not the methoxy ketone claimed by SmithKline's application. Id.

The Patent Office subsequently reversed its position and on December 13, 1983 issued SmithKline U.S. Patent No. 4,420,639 (the "'639 patent"). Id. at 169. SmithKline submitted a new drug application to the Food and Drug Administration (the "FDA"), and filed with its application a notice that the '639 patent claimed nabumetone. See 21 U.S.C. § 355(b)(1). In February, 1992, after receiving FDA approval, SmithKline commenced sales of nabumetone under the brand name "Relafen." See In re '639 Patent Litig., 154 F. Supp. 2d at 159.

In 1997, several generic drug manufacturers filed abbreviated new drug applications ("ANDAs") seeking approval to market generic nabumetone. Id. at 159-60. Copley Pharmaceutical, Inc. ("Copley") and Teva Pharmaceuticals USA ("Teva") filed first, submitting ANDAs for 750 and 500 milligram tablets on August 5, and August 18, 1997, respectively. Defs.' Stmt. of Noerr-Pennington Facts, App. [Doc. No. 180], Tabs 23-24. Eon Labs, Inc. ("Eon") then filed its ANDA for 500 and 750 milligram tablets on December 18, 1997. Id., Tab 25. In each of

their ANDAs, Copley, Teva, and Eon certified that the '639 patent was, to the best of their knowledge, invalid or unenforceable. See In re '639 Patent Litig., 154 F. Supp. 2d at 160; 21 U.S.C. § 355(j)(2)(A)(vii)(IV). After receiving notice of the certifications, SmithKline initiated patent infringement actions, filing suit against Copley on October 27, 1997, against Teva on November 13, 1997, and against Eon on February 17, 1998. In re Relafen Antitrust Litig., 218 F.R.D. at 341. As provided for by statute, the litigation triggered a thirty-month stay period, during which the FDA's tentative approval of Eon's and Teva's ANDAs could not be made effective. See 21 U.S.C. § 355(j)(5)(B)(iii).

The infringement actions were consolidated and drawn to Judge Lindsay of this District. In re '639 Patent Litig., 154 F. Supp. 2d at 160. In July, 1999, Copley, Teva, and Eon moved for summary judgment, asserting that the '639 patent was invalid as anticipated and unenforceable for inequitable conduct. Judge Lindsay denied the motion on both grounds. Id. at 161. On the question of anticipation, Judge Lindsay noted that SmithKline had submitted affidavits sworn by Dr. Paul Bartlett ("Dr. Bartlett"), who stated that a chemist of ordinary skill would regard the Chatterjea & Prasad publication as describing the synthesis of hydroxy ketone rather than methoxy ketone. In re '639 Patent Litig., Civ. A. No. 97-12416-RCL, 2000 WL 33706441, at *3 (D. Mass. Aug. 16, 2000) (Lindsay, J.). Judge Lindsay concluded that

the "present record," which included both Dr. Bartlett's affidavits and "evidence to the contrary," left the question of anticipation "unresolved." Id.

A sixteen-day non-jury trial commenced on January 8, 2001. In re '639 Patent Litig., 154 F. Supp. 2d at 161. At trial, SmithKline again presented the testimony of Dr. Bartlett, whose "position was that a person of ordinary skill in the art who simply read the Chatterjea & Prasad publication, but did not experiment, would immediately believe that the article described a series of hydroxy, rather than methoxy compounds." Id. at 185 (citing Trial Tr., Day 16 at 8:19-9:2). On this question, Judge Lindsay "did not find his testimony persuasive." Id. Nor did Judge Lindsay credit the testimony of Drs. Anderson or Rose, who in attempting to distinguish the Chatterjea & Prasad publication and SmithKline's earlier opinions, displayed "visible discomfort" and "easy willingness to recant on cross-examination," as well as "obstinacy, evasiveness and occasional sophistry." Id. at 182. Dr. Rose in particular attempted to disclaim earlier statements in a manner that was "generally unconvincing and at times transparently disingenuous." Id. at 185. Rather than crediting SmithKline's witnesses, Judge Lindsay credited the testimony of Dr. Edward C. Taylor, whose opinion that an ordinary chemist "would not rely on a single, flawed reference in one footnote," was supported by the testimony, experimental practices, and initial responses of SmithKline's scientists. Id. at 185-86.

Accordingly, on August 14, 2001, Judge Lindsay entered judgment for Copley, Teva, and Eon, finding, inter alia, that claims 2 and 4 of the '639 patent -- which respectively recited the compound in solid form and the compound per se -- were invalid for anticipation by the Chatterjea & Prasad publication, and that the '639 patent was unenforceable due to SmithKline's inequitable conduct before the Patent Office. Id. at 194-95. On appeal, the Federal Circuit affirmed Judge Lindsay's finding of invalidity, but did not reach the issue of unenforceability. SmithKline Beecham Corp. v. Copley Pharm., Inc., 45 Fed. Appx. 915, 917, 2002 WL 1890708 (Fed. Cir. Aug. 15, 2002) (unpublished opinion).

Shortly after Judge Lindsay entered judgment, Teva's¹ tentative approval was made effective, and it began marketing generic nabumetone during a "180-day exclusivity period" guaranteed to it as the first applicant to submit an ANDA. See 21 U.S.C. § 355(j)(5)(B)(iv). Eon entered the market after the exclusivity period expired in February, 2002. In re Relafen Antitrust Litig., 218 F.R.D. at 341.

B. Procedural Posture

This action consolidates the claims of several plaintiffs, including one of SmithKline's competitors, Eon, and many of SmithKline's customers, described by the parties as "direct

¹ Teva acquired Copley (and its generic nabumetone products) in August, 1999. In re Relafen Antitrust Litig., 218 F.R.D. at 341 n.3.

purchasers," "drugstore plaintiffs," and "end payors." The Court briefly describes each of their claims.

Eon initiated suit against SmithKline on March 18, 2003, alleging that SmithKline's "course of anticompetitive Conduct" -- from fraudulently procuring to maliciously enforcing the '639 patent -- violated various federal and state laws. Eon's Compl. [Doc. No. 1 in Eon Laboratories, Civ. A. No. 03-10506-WGY] ¶¶ 2-5. On July 11, 2003, SmithKline moved to dismiss Eon's claims as time-barred, or in the alternative, as unasserted compulsory counterclaims. [Doc. No. 5 in Eon Laboratories, Civ. A. No. 03-10506-WGY]. This Court allowed the motion in substantial part on December 23, 2003, concluding that Eon's claims were logically related to SmithKline's earlier claim of patent infringement. Eon Laboratories, 298 F. Supp. 2d at 179. The only exception was Eon's claim for malicious prosecution, which did not mature until the infringement action terminated in Eon's favor. Id. at 183-84.

Direct purchasers -- defined as "persons or entities in the United States or its territories who purchased Relafen directly from [SmithKline]" -- filed a consolidated class action complaint on December 26, 2002. Direct Purchasers Pls.' Compl. [Doc. No. 60 in Master File No. 01-12222-WGY] ¶ 11. Lead plaintiff Louisiana Wholesale Drug Company, Inc. ("Louisiana Wholesale")²

² Former lead plaintiff Meijer, Inc. withdrew as a class representative by notice dated July 10, 2003. [Doc. No. 92].

alleged, on behalf of itself and members of the direct purchaser class, that SmithKline violated Section 2 of the Sherman Act, 15 U.S.C. § 2, with its scheme to mislead the Patent Office and the FDA, and to prosecute "sham litigation" against generic manufacturers. Id. ¶¶ 1, 5. On October 29, 2003, the Court allowed the direct purchaser plaintiffs' motion and certified the following class:

All persons or entities in the United States or its territories who purchased Relafen directly from defendants at any time during the period of September 1, 1998 through December 31, 2002.

Order of 10/29/03 [Doc. No. 151] at 2. Excluded from the class were governmental entities and SmithKline and its officers, directors, management, employees, subsidiaries, and affiliates. Id.; see also In re Relafen Antitrust Litig., 218 F.R.D. 337.

Drugstore plaintiffs Walgreen Co., Eckerd Corporation, The Kroger Co., Albertson's, Inc., Hy-Vee, Inc., Safeway, Inc., CVS Meridian, Inc., and Rite Aid Corporation, filed complaints against SmithKline on March 29, 2002, and January 7, 2003. Walgreen's Compl. [Doc. No. 1 in Walgreen, Civ. A. No. 02-10588-WGY]; CVS's Compl. [Doc. No. 1 in CVS Meridian, Civ. A. No. 03-10040-WGY]. Like the direct purchaser plaintiffs, the drugstore plaintiffs asserted claims under the Sherman Act, 15 U.S.C. §§ 15, 26. The drugstore plaintiffs, however, asserted claims in three different postures, two of which are relevant here. See Walgreen's Compl. ¶ 2; CVS's Compl. ¶ 5. The drugstore

plaintiffs asserted claims first as assignees of national wholesalers that had opted out of the direct purchaser class, Walgreen's Compl. ¶¶ 7-9; Drugstore Pls.' Illinois Brick App. [Doc. No. 201], Exs. A-K, and second as direct purchasers of generic nabumetone, Walgreen's Compl. ¶¶ 7-9.

End payors -- entities that purchased Relafen or generic nabumetone from sources other than SmithKline for purposes other than resale -- filed a consolidated class action complaint on February 11, 2003. End Payors Pls.' Compl. [Doc. No. 68 in Master File No. 01-12222-WGY]. The lead end payor plaintiffs, on behalf of themselves and other health benefit providers, consumers, and consumer organizations, asserted claims under the Sherman Act, 15 U.S.C. § 16, and under the antitrust statutes, unfair competition statutes, consumer protection statutes, and unjust enrichment doctrines of twenty-four states. Id. ¶¶ 1, 4. On November 21, 2003, this Court declined to certify the proposed class of end payor plaintiffs with respect to their federal law claims, but tentatively certified the following exemplar classes with respect to their state law claims:

[As] to their antitrust, unfair competition, and consumer protection claims --

All persons or entities who purchased Relafen or its generic alternatives in the states of Arizona, California, Massachusetts, or Vermont during the period of September 1, 1998 through June 30, 2003 for consumption by themselves, their families, members, employees, insureds, participants, or beneficiaries.

[and as] to their unjust enrichment claims --

All persons or entities in the United States who purchased Relafen in the states of Arizona, California, Massachusetts, Tennessee, or Vermont during the period September 1, 1998 through June 30, 2003 for consumption by themselves, their families, members, employees, insureds, participants, or beneficiaries.

Order of 11/21/03 [Doc. No. 168] at 3, 5; see also In re Relafen Antitrust Litig., 221 F.R.D. 260. Excluded from both classes were "governmental entities; SmithKline and its officers, directors, management, employees, subsidiaries, and affiliates; persons or entities who purchased Relafen or its generic alternatives for purposes of resale; persons or entities who purchased Relafen directly from SmithKline or its affiliates; and persons or entities who suffered no economic harm as a result of SmithKline's alleged conduct." Order of 11/21/03 at 3, 5.

By Memorandum and Order dated October 1, 2003, this Court afforded preclusive effect to certain findings deemed "essential" to Judge Lindsay's judgment in the prior patent litigation. See In re Relafen Antitrust Litig., 286 F. Supp. 2d at 64-70. In limiting the scope of the preclusion, the Court noted that on appeal, the Federal Circuit had affirmed that the '639 patent was invalid for anticipation, but "passed over" whether the patent was also unenforceable for inequitable conduct. See id. at 66; 18 Charles Alan Wright, et al., Federal Practice and Procedure § 4421 (2004) ("As to matters passed over by the appellate court .

. . preclusion is not available on the basis of the trial-court decision. This result is supported by the fact that the appellate choice of grounds for decision has made unavailable appellate review of the alternative grounds."). Accordingly, the Court declined to give preclusive effect to findings regarding "what Smithkline may have known, represented, or misrepresented to the Patent Office." In re Relafen Antitrust Litig., 286 F. Supp. 2d at 70. Preclusive effect was thus limited to the ultimate determination of invalidity and its "necessary intermediate findings." Id. at 68 (emphasis omitted). In relevant part, those findings provide:

The Chatterjea & Prasad Publication was published more than one year prior to the date of SmithKline's application in the United States for the '639 patent. . . .

The Chatterjea & Prasad publication described nabumetone to the ordinary chemist in 1973 and anticipated claim 4 of the '639 patent.

The Chatterjea & Prasad publication anticipates claim 2 as well as claim 4 of the '639 patent. . . .

Evidence related to the validity of the '639 patent was offered at trial that was not before the Patent Office, including research, internal communications and other correspondence. . . .

It is not necessary for the ordinary chemist attempting to replicate a synthesis set forth in a scientific article to derive each of his or her starting materials only from a footnoted reference.

Id. at 68-69 (original alterations omitted).

On November 25, 2003, SmithKline moved for summary judgment on, inter alia, (1) all claims, and (2) the federal claims

asserted by the drugstore plaintiffs. [Doc. Nos. 169, 197]. After hearing oral argument and reviewing the parties' submissions, the Court denied both motions. Order of 12/19/03.

III. CURRENT STATUS OF THESE PROCEEDINGS

The case brought by Eon Laboratories has settled and was closed on February 13, 2004. Order of 2/13/04 [Doc. No. 62 in Eon Labs., Inc. v. SmithKline Beecham Corp., Civ. A. No. 03-10506-WGY]. The class actions brought by the direct purchasers have settled and were closed on April 9, 2004. Order of 4/9/04 [Doc. No. 297]. The actions brought by the drugstore plaintiffs have settled and were closed on January 20, 2004. Order of 1/20/04 [Doc. No. 28 in Walgreen Co. v. SmithKline Beecham Corp., Civ. A. No. 02-10588-WGY]; Order of 1/20/04 [Doc. No. 11 in CVS Meridian, Inc. v. SmithKline Beecham Corp., Civ. A. No. 03-10040-WGY]. The various class actions brought by the end payor plaintiffs, Lynch v. SmithKline Beecham Corp., [Civ. A. No. 02-10163-WGY]; A.F. of L. - AGC Bldg. Trades Welfare Plan v. SmithKline Beecham Corp., [Civ. A. No. 02-10205-WGY]; Twin Cities Bakery Workers Health and Welfare Fund v. SmithKline Beecham Corp., [Civ. A. No. 02-985 (E.D. Pa.)]; Houchins v. SmithKline Beecham Corp., [Civ. A. No. 02-10424-WGY]; Teamsters Local No. 35 Health Plans v. SmithKline Beecham Corp., [Civ. A. No. 02-10487-WGY] Smithfield Foods, Inc. v. SmithKline Beecham Corp., [Civ. A. No. 02-10589-WGY]; Franklin v. SmithKline Beecham Corp., [Civ. A.

No. 02-10671-WGY]; Fox v. SmithKline Beecham Corp., [Civ. A. No. 02-11543-WGY]; Kravitz v. SmithKline Beecham Corp., [Civ. A. No. 02-11806-WGY]; Central States SE Health and Welfare Fund v. SmithKline Beecham Corp., [Civ. A. No. 04-10817-WGY], have not yet settled and, although a preliminary order of settlement has issued certifying a nationwide settlement class, all remain sub judice on this Court's docket. Order of 11/24/04 [Doc. No. 373]. As will be detailed below, much remains to be done.

IV. THE LEGAL FRAMEWORK GOVERNING FURTHER JUDICIAL ACTION

Since SmithKline made a valiant, albeit unsuccessful, attempt to defeat all these cases through summary judgment, the Court here quotes extensively from its reasoning rejecting SmithKline's summary judgment motions as that reasoning most accurately frames the issues for trial,³ and concomitantly frames the triable issues concerning which the parties now ultimately

³ There has been too much loose talk in these cases about the Court making "findings." This is error. The Court never uses that word in the quoted passages and this Court is quite cognizant of the difference between a finding of fact and a ruling of law. See, e.g., United States v. Green, 346 F. Supp. 2d. 259, 281-82 (D. Mass. 2004); Berthoff v. United States, 140 F.Supp.2d 50, 66, 90-91 (D.Mass. 2001); see also Arthur R. Miller, The Pretrial Rush to Judgment: Are the "Litigation Explosion," "Liability Crisis," and Efficiency Clichés Eroding our Day in Court and Jury Trial Commitments?, 78 N.Y.U. L. Rev. 982, 1076-1077, 1082-1086, 1091-1093 (2003). The quoted passages express the Court's considered and careful legal reasoning and are, of course, subject to de novo review on appeal. Straughn v. Delta Air Lines, Inc., 250 F.3d 23, 33 (1st Cir. 2001); see Miller, 78 N.Y.U. L. Rev. at 1082 ("the accepted wisdom about the law-fact spectrum is that judges determine the law and juries the facts").

desire to reach a settlement.

A. Legal Standard

This Court may grant a motion for summary judgment only if the record, "construed in the light most favorable to the party opposing summary judgment," reveals no genuine issue of material fact. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 261 n.2 (1986); Fed. R. Civ. P. 56(c). The party seeking summary judgment must first make a preliminary showing that there are no issues worthy of trial. Celotex Corp. v. Catrett, 477 U.S. 317, 323, 330 (1986). Upon such a showing, the burden of production shifts to the nonmovant, who must identify specific evidence demonstrating a genuine issue of material fact. Id. at 324 (citing Fed. R. Civ. P. 56(e)).

Unlike the burden of production, the ultimate burden of persuasion remains on the moving party. Id. at 330. This burden is a "stringent one." Id. at 331 n.2 (citations omitted). "Summary judgment should not be granted unless it is clear that a trial is unnecessary, and any doubt as to the existence of a genuine issue for trial should be resolved against the moving party." Id. (citing Anderson, 477 U.S. at 255, and Adickes v. S.H. Kress & Co., 398 U.S. 144, 158-59 (1970)). The Court proceeds to apply this standard to the record, addressing SmithKline's motions in turn.

B. All Claims

SmithKline most broadly asserted that all of the plaintiffs' claims were barred by the Noerr-Pennington doctrine. Defs.' Noerr-Pennington Mot. at 2. Articulated in Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961), and examined in Mine Workers v. Pennington, 381 U.S. 657 (1965), the Noerr-Pennington doctrine generally shields those who petition the government from antitrust liability. In Noerr, the Supreme Court held that "the Sherman Act does not prohibit . . . an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or monopoly." 365 U.S. at 136. In thus interpreting the Sherman Act, the Supreme Court declined to "impute to Congress an intent to invade" the First Amendment right to petition. Id. at 138. Pennington later emphasized that Noerr's application "was not at all affected by any anticompetitive

purpose'" motivating the petitioning. Pennington, 381 U.S. at 669 (quoting Noerr, 365 U.S. at 140). Rather, "Noerr shields from the Sherman Act a concerted effort to influence public officials regardless of intent of purpose." Id. at 670.

Here, the parties did not dispute that initiating and prosecuting a patent infringement action was the type of petitioning activity generally protected by the Noerr-Pennington doctrine. See California Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 510 (1972) (extending the "philosophy" of Noerr and Pennington to "the approach of citizens or groups of them to administrative agencies . . . and to courts"). The parties instead disputed whether the immunity that would otherwise apply to SmithKline's conduct should be withheld under an exception to the Noerr-Pennington doctrine.³ These exceptions, commonly termed the "sham" and "Walker Process fraud" exceptions, respectively deny immunity to petitioning that is mere "sham" and to conduct before the Patent Office that is materially fraudulent.

FN3. The plaintiffs asserted two other challenges to the application of Noerr-Pennington, neither of which requires extended discussion. Eon first contended that Noerr-Pennington immunity "stems from an interpretation of the Sherman Act," and as such, does not apply to state law claims. Eon's Noerr-Pennington Opp'n at 4-6. As was largely true of the plaintiffs' Sherman Act claims, however, Eon's remaining state law claim was premised on SmithKline's initiation and prosecution of patent infringement lawsuits. Because Eon's state law claim thus implicated significant First Amendment and patent law concerns, the Court assumed, for purposes of this analysis, that the Noerr-Pennington doctrine applied with equal force to Eon's state law claim. See Globetrotter Software, Inc. v. Elan Computer Group, Inc., 362 F.3d 1367, 1376-77 (Fed. Cir. 2004); cf. BE & K Constr. Co. v. NLRB, 536 U.S. 516, 531-32 (2002); see also Robert P. Faulkner, The Foundations of Noerr-Pennington and the Burden of Proving Sham Petitioning: The Historical-Constitutional Argument In Favor of a "Clear and Convincing" Standard, 28 U.S.F. L. Rev. 681, 638 (providing a

"historical-constitutional foundation" for the proposition that Noerr-Pennington is a "First Amendment doctrine").

In addition, the end payor plaintiffs challenged the application of Noerr-Pennington to claims based on SmithKline's listing the '639 patent with the FDA. End Payor Pls.' Noerr-Pennington Opp'n at 25-26 (arguing that in listing the '639 patent, SmithKline did not "petition" the FDA, but rather, secured its merely ministerial action). While this challenge was not without force, see In re Buspirone Patent Litig., 185 F. Supp. 2d 363, 372-73 (S.D.N.Y. 2002), the Court considered SmithKline's initiation and prosecution of patent infringement lawsuits to be the more direct cause of the complained-of generic delay. See 21 U.S.C. § 355(j)(5)(B)(iii) (providing that approval of an ANDA for a generic version of a patented drug "shall be made effective immediately unless, before the expiration of 45 days . . . , an action is brought for infringement of the patent").

1. "Sham" Exception

In Noerr, the Supreme Court suggested that immunity may be justifiably withheld from petitioning conduct that, while "ostensibly directed toward influencing governmental action," is "mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." 365 U.S. at 144. As subsequently "adapted to the adjudicatory process," California Motor Transport, 404 U.S. at 516, this sham exception has a "two-part definition," Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 50, 60 (1993). To constitute sham, the lawsuit first "must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." Id. This "objective prong" incorporates "the notion of probable cause, as understood and applied in the commonlaw tort of wrongful civil proceedings." Id. at 62. In that context, "[p]robable cause to institute civil proceedings requires no more than a 'reasonable belief that there is a chance that a claim may be held valid

upon adjudication.'" Id. at 62-63 (quoting Hubbard v. Beatty & Hyde, Inc., 343 Mass. 258, 262 (1961) (internal quotation marks omitted) (alterations omitted)). Just as the existence of probable cause establishes an "absolute defense" to the tort of wrongful civil proceedings, so too does it "irrefutably demonstrate[]" that an antitrust defendant is "entitled to Noerr immunity." Id. at 63.

The second, subjective prong of the sham definition thus becomes relevant "[o]nly if a challenged litigation is objectively meritless." Id. at 60. Under these circumstances, a court may examine the litigant's motivation to determine whether the lawsuit "conceals 'an attempt to interfere directly' with the business relationships of a competitor." Id. at 50 (quoting Noerr, 365 U.S. at 144). The sham exception applies if the litigant sought to "use the governmental process -- as opposed to the outcome of that process -- as an anticompetitive weapon." Id.; City of Columbia v. Omni Outdoor Advertising, Inc., 499 U.S. 365, 380 (1991).

Under Federal Circuit precedent, which governs "all antitrust claims premised on the bringing of a patent infringement suit," Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1069 (Fed. Cir. 1998), plaintiffs must establish the first, objective prong of the sham definition by clear and convincing evidence. See id. at 1064; Mitek Surgical Prods., Inc. v. Arthrex, Inc., 230 F.3d 1383, 1383 (Fed. Cir. 2000) (unpublished table disposition⁴); see also Globetrotter Software, 362 F.3d at 1377 (explaining that the sham exception, as applied to cease-and-desist letters, requires clear and convincing evidence that the patentee had no reasonable basis to believe that the accused devices were infringing). SmithKline asserted that the Court could determine this issue as matter of law because as in Professional Real Estate Investors, "there [was] no dispute over the predicate facts of the underlying legal proceeding." Defs.' Noerr-Pennington Mem. at 8 (quoting Professional Real Estate Investors, 508 U.S. at 63). SmithKline maintained that the relevant "predicate facts" were those contained in the record of the prior litigation: the arguments, facts, procedural history, and issues. Defs.' Noerr-Pennington Reply at 7. "[O]nce the prior litigation [i]s [complete]," SmithKline reasoned, "objective baselessness is a question of law." Id. at 8.

FN4. For the propriety of citing an

unpublished opinion, see Alshrafi v. American Airlines, Inc., 321 F. Supp. 2d 150, 159-160, n. 9-10 (providing that, “[a]t an absolute minimum, unpublished First Circuit decisions, such as Azubuko, represent persuasive authority in the district courts”). Citing an unpublished opinion raises a number of difficult questions. See Anastasoff v. United States, 223 F.3d 898, 899-905 (8th Cir. 2000) (Arnold, J.) (holding that unpublished opinions have precedential effect), vacated as moot, 235 F.3d 1054 (8th Cir. 2000) (en banc), Giese v. Pierce Chem. Co., 43 F. Supp. 2d 98, 103 n.1 (D. Mass. 1999) (relying on unpublished opinions’ persuasive authority); Hon. Richard S. Arnold, Unpublished Opinions: A Comment, 1 J. App. Prac. & Process 219 (1999); see also Proposed Fed. R. App. P. 32.1; Anne Coyle, Note, A Modest Reform: The New Rule 32.1 Permitting Citation to Unpublished Opinions in the Federal Courts of Appeals, 72 Ford. L. Rev. 2471 (2004). But see Hon. Alex Kozinski, Letter, Fed. Law., June 2004, at 37.

Professional Real Estate Investors, however, suggests a somewhat narrower conclusion. As discussed earlier, in defining the first, objective prong of the sham exception, the Supreme Court drew upon the concept of “probable cause, as understood and applied in the commonlaw tort of wrongful civil proceedings.” Professional Real Estate Investors, Inc., 508 U.S. at 60. In the tort context, as the cases cited in Professional Real Estate Investors make clear, the relevant “predicate facts” are not only the facts determined in the prior lawsuit, but also those facts tending to “prove or disprove the existence of probable cause.” Stewart v. Sonneborn, 98 U.S. 187, 194 (1878), cited in Professional Real Estate Investors, 508 U.S. at 62. When the latter facts are in dispute, “it becomes the duty of the trial court to submit the question to the jury.” Nelson v. Miller, 227 Kan. 271, 277-78 (1980), cited in Professional Real Estate Investors, 508 U.S. at 63; accord Stewart, 98 U.S. at 194 (“It is, therefore, generally the duty of the court, when evidence has been given to prove or disprove the existence of probable cause, to submit to

the jury its credibility"). Thus, although "[t]he respective functions of court and jury in actions for malicious prosecution differ in one important particular [t]he determination of reasonableness] from their respective functions in other actions of tort," deciding disputed issues of fact clearly remains a function of the jury. See Restatement (Second) of Torts § 673 cmt.e; see also Byrd v. Blue Ridge Rural Elec. Coop., Inc., 356 U.S. 525, 537 (1958) ("An essential characteristic of [the federal] system is the manner in which, in civil common-law actions, it distributes trial functions between judge and jury and, under the influence -- if not the command -- of the Seventh Amendment, assigns the decisions of disputed questions of fact to the jury.") (footnote omitted). In light of its "unique and central" role in the American system, the jury's traditional function of "establishing the truth" must be respected, notwithstanding courts' apparent apprehension over jurors' competence to make the ultimate determination of probable cause. Arthur R. Miller, The Pretrial Rush to Judgment: Are the "Litigation Explosion," "Liability Crisis," and Efficiency Cliches Eroding Our Day in Court and Jury Trial Commitments?, 78 N.Y.U. L. Rev. 982, 1077, 1078-79, 1104-10 (2003); accord Hernon v. Revere Copper & Brass, Inc., 494 F.2d 705, 707 (8th Cir. 1974); William G. Young, An Open Letter to United State District Judges, Fed. Law., July 2003, at 30; see also Roberts v. Federal Express Corp., 842 S.W.2d 246, 249 (Tenn. 1992) (rejecting the "historical apprehension" that in determining probable cause for prosecution, juries "might not sufficiently safeguard the rights of defendants" (internal quotation marks omitted)).

Here, "the facts tending to establish the existence or want of existence of probable cause" were disputed, rendering the question inappropriate for decision as matter of law. See Nelson, 227 Kan. at 277. Most significantly, the parties disputed the facts that "appeared to [the defendants] when they filed their petition." Stewart, 98 U.S. at 195.⁵ SmithKline maintained that at the time of filing, it appeared that the ordinary chemist, aware of the Jones error in the Chatterjea & Prasad publication, would "mentally disregard" the article's prior naming of nabumetone. See Defs.' Noerr-Pennington Mem. at 18 (citing In re Yale, 434 F.2d 666, 668-69 (C.C.P.A. 1970), and concluding that a person of ordinary skill,

if confronted with a publication's obvious typographical error, would do nothing more than "mentally disregard" the misnamed compound or "mentally substitute" the proper compound in its place). In response, the plaintiffs argued that SmithKline could not realistically expect success based on the Jones error, because its own scientists did not "mentally disregard" the description of nabumetone. See Eon's Noerr-Pennington Opp'n at 15; Direct Purchaser Pls.'⁶ Noerr-Pennington Opp'n [Doc. 177] at 9-13; End Payor Pls.' Noerr-Pennington Opp'n at 11. Rather, "all of the Beecham chemists confronted with the Chatterjea & Prasad publication during the relevant time period -- including Drs. Rose, Anderson, Marton, Goudie, Miller, Cole and Ms. Gaster -- initially believed the article to have identified nabumetone." End Payor Pls.' Noerr-Pennington Opp'n at 11 (quoting In re '639 Patent Litigation, 154 F. Supp. 2d at 174) (alteration omitted). The state of SmithKline's knowledge at the time of filing -- whether as the plaintiffs suggest, SmithKline scientists continued to believe that the Chatterjea & Prasad publication described nabumetone, or as SmithKline argued on appeal, its scientists had revised their opinions after discovering the Jones error, Defs.' Noerr-Pennington App., Tab 38 (Federal Circuit Brief) at 32-34 -- was thus a disputed factual issue that the Court was duty-bound to submit to the jury.⁷

FN5. Although the "standard applied to defendant's consciousness" is a legal one, see Dir. Gen. of R.R. v. Kastenbaum, 263 U.S. 25, 27-28 (1923) ("The question is not whether he thought the facts to constitute probable cause, but whether the court thinks they did."), the "state of the defendant's knowledge" is nevertheless a factual question, see id.

FN6. Although referred to as the direct purchaser plaintiffs', the opposition was jointly submitted by the direct purchaser plaintiffs and the drugstore plaintiffs.

FN7. The disputed issue of SmithKline's knowledge distinguished the present action from Professional Real Estate Investors. There, the defendant's knowledge was not material. The relevant "predicate facts"

included only the defendant's copyright and the "unsettled condition of the law." 508 U.S. at 63-64; see James B. Kobak, Jr., Professional Real Estate Investors and the Future of Patent-Antitrust Litigation, 63 Antitrust L.J. 185, 187 (1994) (explaining that the underlying action in Professional Real Estate Investors "turned on a pure question of law"). The existence of probable cause would have been far less plain, however, if the plaintiffs had alleged, for example, that the defendant knew that its copyright was invalid. See Stewart, 98 U.S. at 194 (recognizing that probable cause may present a factual question for the jury "when the question of the defendants' belief of the facts relied upon to prove want of probable cause is involved"); cf. Wyatt v. Cole, 504 U.S. 158, 173-74 (1992) (Kennedy, J., concurring) ("It seems problematic to say that a defendant should be relieved of liability under some automatic rule of immunity if objective reliance upon a statute is reasonable but the defendant in fact had knowledge of its invalidity.").

With the exception of Eon, the parties nevertheless urged the Court to determine probable cause as matter of law. SmithKline emphasized that its lawsuits "survived extensive testing at summary judgment," and suggested that this established probable cause. Defs.' Noerr-Pennington Mem. at 10-14. Consistent with SmithKline's argument, several courts, including the Federal Circuit, have suggested that denial of a summary judgment motion precludes a finding of objective baselessness. See, e.g., Beckman Instruments, Inc. v. LKB Produkter AB, 892 F.2d 1547, 1551 (Fed. Cir. 1989) ("In particular, we find it difficult to agree that the inequitable conduct defense was 'baseless' when it survived a motion for summary judgment and was rejected only after findings were made on disputed facts."); Skinder-Strauss Assoc. v. Massachusetts Continuing Legal Educ., Inc., 870 F. Supp. 8, 11 (D. Mass. 1994) (Saris, J.) ("If, on the other hand, Skinder survives a summary judgment motion or the court concludes that the suit was not objectively meritless, then Skinder is entitled to judgment in its favor on the [antitrust] counterclaims and no further proceedings are needed.").

However appropriate these suggestions might be as a general matter, the specific circumstances here compelled a different conclusion. As described above, in denying summary judgment on the issue of anticipation, Judge Lindsay cited the affidavits sworn by Dr. Bartlett "to the effect that the person of ordinary skill . . . would disregard the erroneous use of the name methoxy acetate as the starting compound in the process taught by the Chatterjea & Prasad publication and thereby conclude that the publication teaches only hydroxy ketone." In re '639 Patent Litig., 2000 WL 33706441, at *3. The plaintiffs argued that in light of the contrary views expressed by company scientists, SmithKline could not have realistically expected success based on Dr. Bartlett's opinion. In re '639 Patent Litig., 154 F. Supp. 2d at 185. See Direct Purchaser Pls.' Noerr-Pennington Opp'n at 19 (reasoning that "GSK had to have known that Bartlett's opinion was unreliable and not based on sufficient facts or data" because its internal documents acknowledged that the Chatterjea & Prasad publication disclosed nabumetone); End Payor Pls.' Noerr-Pennington Opp'n at 17 ("[T]he fact questions concocted by GSK as part of the summary judgment motion arise out of the same falsehoods presented to the PTO."). The plaintiffs' arguments highlighted the fact that -- contrary to SmithKline's assertion -- evidence suggesting a genuine issue of material fact does not undergo "extensive testing" on summary judgment, and significantly, undergoes no testing with respect to the credibility of the witnesses. Anderson, 477 U.S. at 255 ("Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge, whether he is ruling on a motion for summary judgment or for a directed verdict.").

In an analogous context -- the imposition of sanctions under Federal Rule of Civil Procedure 11, see Professional Real Estate Investors, 508 U.S. at 64 -- the First Circuit⁸ has recognized that "successful opposition to a summary judgment motion does not always conclusively establish the reasonableness of the claim in question." Media Duplication Servs., Ltd. v. HDG Software, Inc., 928 F.2d 1228, 1240 n.10 (1st Cir. 1991); cf. FilmTec Corp. v. Hydranautics, 67 F.3d 931, 938 (Fed. Cir. 1995) (stating that "a preliminary success on the merits," there a preliminary injunction granted in the plaintiffs' favor, "does not necessarily

preclude a court from concluding that litigation was baseless"). In Media Duplication Services, the First Circuit noted that the Second Circuit had similarly "rejected the argument that a district court's denial of summary judgment shields the nonmoving party from the imposition of sanctions." 928 F.2d at 1240 n.10 (citing Calloway v. Marvel Entertainment Group, 854 F.2d 1452, 1472 (2d Cir. 1988), rev'd on other grounds, 493 U.S. 120 (1989)). The Second Circuit reasoned that "[i]t is . . . entirely possible that a baseless factual claim will survive a motion for summary judgment, particularly where an attorney prepares an affidavit for a client stating a material fact for which there is no basis." Calloway, 854 F.2d at 1473. As in Calloway, the plaintiffs argued that the evidence submitted to demonstrate a genuine issue of material fact was undermined by matters not properly before the court on the summary judgment motion, including the credibility of the affiant and the weight of contrary evidence. The Court thus rejected SmithKline's assertion that its survival of summary judgment, without more, compelled the conclusion that its claim was not objectively baseless.

FN8. Although Federal Circuit law applies to "antitrust claims premised on the bringing of a patent infringement suit," Nobelpharma, 141 F.3d at 1068, regional circuit law applies to motions brought under Rule 11, even if asserted against a patent infringement plaintiff, Phonometrics, Inc. v. Economy Inns of Am., 349 F.3d 1356, 1361 (Fed. Cir. 2003).

The plaintiffs asserted the inverse, suggesting that SmithKline's loss on the merits established that a reasonable litigant could not have realistically expected success. More precisely, the direct purchaser plaintiffs maintained that certain factual findings, made by Judge Lindsay and given preclusive effect by this Court, foreclosed any argument that SmithKline's claims were not objectively baseless. Judge Lindsay determined, after all, that "[t]he Chatterjea & Prasad publication described nabumetone to the ordinary chemist in 1973." Direct Purchaser Pls.' Noerr-Pennington Mem. at 8. The end payor plaintiffs highlighted other excerpts from Judge Lindsay's opinion, including sections in which he described the

"visible discomfort" and "unreasonable pertinacity" of SmithKline witnesses and characterized portions of their testimony as "difficult to credit," "generally unconvincing and at times transparently disingenuous." End Payor Pls.' Noerr-Pennington Opp'n at 6-7 (quoting In re '639 Patent Litig., 154 F. Supp. 2d at 182, 184-85).

Although a court may, in the course of resolving the underlying litigation, make findings "tantamount to a finding that the [litigant's conduct] was objectively baseless," see Theofel v. Farey Jones, 359 F.3d 1066, 1079 (9th Cir. 2004), Judge Lindsay's findings were not clearly and convincingly of this sort. Judge Lindsay's findings did not, for example, describe conduct that was indefensible "on its face." Compare id. at 1071-72. Rather, Judge Lindsay discredited SmithKline's claims only after the careful testing of trial. See, e.g., In re '639 Patent Litigation, 154 F. Supp. 2d at 184 (discussing the "demeanor," "attitude," and "inconsistencies" that "made it difficult . . . to credit" a witness's testimony).

As to Judge Lindsay's findings on the "ultimate factual issue" of anticipation, Direct Purchaser Pls.' Noerr-Pennington Opp'n at 8, this Court must "resist the understandable temptation to engage in post hoc reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation." Professional Real Estate Investors, 508 U.S. at 60 n.5 (quoting Christiansburg Garment Co. v. EEOC, 434 U.S. 412, 421-22 (1978)) (internal quotation marks omitted). Moreover, as SmithKline noted, every determination that a patent is invalid for anticipation will, by definition, rest on a finding that a prior reference described the claimed invention to a person of ordinary skill in the art. See, e.g., In re Paulsen, 30 F.3d 1475, 1479 (Fed. Cir. 1994). As such, were the Court to consider this finding conclusive evidence of objective baselessness, every patentee who unsuccessfully litigated the issue would be potentially stripped of immunity. For these unsuccessful litigants, application of the sham exception would turn on a "purely subjective" test, a result plainly inconsistent with Professional Real Estate Investors. See 508 U.S. at 60 & n.5. Accordingly, the Court declined to conclude that Judge Lindsay's prior findings, without more, established that SmithKline's prior claims were not only ultimately unpersuasive, but also objectively baseless.

In sum, the Court concluded that in light of the disputed factual issues, the parties had not established the existence or want of probable cause as matter of law. Nor had SmithKline, whose submissions and oral argument focused solely on the first, objective prong of the sham exception, made the necessary showing that there were no trialworthy issues with respect to the second, subjective prong.

2. Walker Process Exception

The Supreme Court in Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172 (1965), held that "the enforcement of a patent procured by fraud on the Patent Office may be violative of § 2 of the Sherman Act." Id. at 174. In so holding, the Supreme Court emphasized the strong public interests in the proper possession and enforcement of patent rights:

A patent by its very nature is affected with a public interest. . . . [It] is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.

382 U.S. at 177 (alterations in original) (quoting Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co., 324 U.S. 806 (1945)). The Federal Circuit has interpreted Walker Process to provide an "alternative" legal theory, which may strip a patentee of immunity independently of or in addition to the sham litigation exception: "[E]ither or both may be applicable to a particular party's conduct" Nobelpharma, 141 F.3d at 1071.

For Walker Process to apply, an antitrust plaintiff must establish, by clear and convincing evidence, (1) a misrepresentation or omission, (2) made with intent to deceive the Patent Office, (3) on which the Patent Office justifiably relied, and (4) but for which the patent would not have issued. C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1364 (Fed. Cir. 1998); Nobelpharma, 141 F.3d at 1070-71, 1073. "Simply put Walker Process fraud is a more serious offense than

inequitable conduct" and "requires higher threshold showings of both intent and materiality." Nobelpharma, 141 F.3d at 1070. In addition, the antitrust plaintiff must demonstrate that the party asserting the patent was aware of the fraud when it brought suit. Id. at 1069.

Here, SmithKline challenged the plaintiffs' showings of awareness and materiality, arguing that appropriate scrutiny of these elements ought to "dispose of plaintiffs' claims." Defs.' Noerr-Pennington Mem. at 28-30. The Court considers the elements below, mindful as before that "[c]redibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge." Anderson, 477 U.S. at 255.

a. Awareness

As to awareness, SmithKline contended that the only evidence in the record -- the deposition testimony of David Roberts ("Roberts"), SmithKline's Senior Vice President for Intellectual Property -- indicated that the company initiated suit believing that its prosecution of the '639 patent was not misleading. Defs.' Noerr-Pennington Mem. at 36. Roberts testified to SmithKline's "change in view" regarding the significance of Chatterjea & Prasad publication. Defs.' Stmt. of Noerr-Pennington Facts [Doc. No. 172] ¶ 36 (quoting Roberts Dep. at 186:25-187:3). He maintained that SmithKline's understanding of Chatterjea & Prasad had progressed from an initial belief that the publication described nabumetone to the "deeper" realization that it was "flawed." Id. (quoting Roberts Dep. 187:25-188:13).

Yet contrary to SmithKline's assertions, Roberts's testimony on these issues did not "stand[] alone and uncontroverted." Defs.' Noerr-Pennington Mem. at 37. Rather, the plaintiffs submitted numerous internal documents suggesting that even after what Roberts described as SmithKline's "change in view," the company continued to consider the Chatterjea & Prasad publication an anticipating reference. Perhaps most tellingly, shortly after the Patent Office allowed SmithKline's application, M. J. Stott ("Stott"), the SmithKline attorney directing the prosecution, wrote:

The Examiner's decision is completely unexpected. . . . It would appear that this is the first time a patent has been allowed

in the U.S.A. for a compound that is described in the prior art under these circumstances.

Direct Purchaser Pls.' Noerr-Pennington Facts, Tab 17; see In re '639 Patent Litig., 154 F. Supp. 2d at 194 (interpreting Stott's memorandum as an "acknowledgment by Beecham that it had 'put one over on' the PTO"). On the basis of this and other internal documents, Judge Lindsay expressly rejected the argument advanced by Roberts, concluding that "Beecham's internal understanding that the Chatterjea & Prasad publication disclosed nabumetone appears to have remained unchanged throughout the prosecution of the . . . '639 patent." Id.

A reasonable jury, presented with the same evidence, could also conclude that SmithKline was aware that it had "put one over" on the Patent Office when it prosecuted the '639 patent, and by extension, when it later enforced it. See Kobak, supra, at 198 (suggesting that knowledge of fraud before the Patent Office "might be imputed when the plaintiff was the same party that had prosecuted the patent"). SmithKline's awareness, then, remained a genuinely disputed issue.

b. Materiality

SmithKline also maintained that its statements regarding the Chatterjea & Prasad publication were not material. Defs.' Noerr-Pennington Mem. at 30-35. Its argument proceeded in three steps, each focused on SmithKline's claim to nabumetone in solid form. First, the Board of Patent Appeals reversed the rejection of this claim for anticipation without "any consideration" of SmithKline's declarations. Decision of the Board of Patent Appeals at 2 (noting, without reference to SmithKline's declarations, that the Chatterjea & Prasad publication lacked a written disclosure of nabumetone in "solid form"); Defs.' Noerr-Pennington Mem. at 31. Second, although the Board of Patent Appeals affirmed the rejection for obviousness, SmithKline later challenged the holding with an affidavit sworn by Dr. Chatterjea, which affidavit Plaintiffs had not challenged as incomplete or inaccurate. Defs.' Noerr-Pennington Mem. at 32-34. Third, because SmithKline's solid-form claim was independently patentable over the Chatterjea & Prasad publication (as demonstrated by the first and second steps above), the plaintiffs could not

establish that the '639 patent would not have issued "but for" the alleged misrepresentations. Id. at 34-35.

The end payor plaintiffs challenged SmithKline's argument as eliding a material omission. See End Payor Pls.' Noerr- Pennington Opp'n at 20 n.9. Specifically, neither the Board of Patent Appeals nor the examiner reviewing Dr. Chatterjea's affidavit was informed that "nabumetone when made is in an oil form and always solidifies at room temperature." SmithKline Beecham, 45 Fed. Appx. at 917. Rather, Dr. Rose declared before the Board of Patent Appeals that he had "diverged from the described processes" to obtain solid nabumetone. See Decision of the Board of Patent Appeals at 5 (quoting Rose Decl. ¶ 5). On the basis of this and other alleged misrepresentations, the Board of Patent Appeals (mistakenly) concluded that Chatterjea & Prasad's "thick pale yellow oil" solidified only upon purification. See id. at 5-6 (quoting SmithKline's statements that an alternative preparation yielded "a clear oil" which solidified "after purification," and that the compound produced by Chatterjea & Prasad "was an oil," unlike the compound produced by SmithKline, which was "a solid when pharmaceutically pure").

Yet when provided with complete information, Judge Lindsay found, and the Federal Circuit affirmed, that the solid form was an inherent property of nabumetone.⁹ See In re '639 Patent Litigation, 154 F. Supp. 2d at 187; SmithKline Beecham, 45 Fed. Appx. at 917. The cited portions of Dr. Chatterjea's affidavit thus appeared largely beside the point. Simply stated, Dr. Chatterjea's statements regarding motive to purify were irrelevant because there was no need to purify. That Dr. Chatterjea's affidavit might be undisputed or confirmed by the plaintiffs' experts, but see, e.g., End Payor Pls.' Stmt. of Noerr-Pennington Facts [Doc. No. 186] ¶¶ 25-26, did not alter the Court's analysis.

FN9. As described above, the Court gave preclusive effect to Judge Lindsay's finding that "the Chatterjea & Prasad publication anticipates claim 2 [reciting nabumetone in solid form] as well as claim 4 [reciting nabumetone per se] of the '639 patent." In re Relafen Antitrust Litigation, 286 F. Supp. 2d at 68 (quoting In re '639 Patent Litigation, 154 F. Supp. 2d at 187) (internal

quotation marks omitted).

Ultimately, the "best evidence" that SmithKline's statements were material might be that the Patent Office issued the '639 patent. See Unitherm Food Sys., Inc. v. Swift Eckrich, Inc., Nos. 03-1472, 03-1473, 2004 WL 1543286, at *18 (Fed. Cir. July 12, 2004). The Federal Circuit has explained that given "[t]he statutory pronouncement that 'a patent shall be presumed valid,' 35 U.S.C. § 282 implies that patent examiners are presumed to issue only valid patents." Id. (citing Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed. Cir. 1984)). Thus, had the Patent Office not relied on SmithKline's alleged misrepresentations, it presumably "would have reached the same conclusion as did the district court and [the Federal Circuit]," id. -- here, that the Chatterjea & Prasad publication anticipates SmithKline's claims to nabumetone per se and to nabumetone in solid form, as the solid form is an inherent property of the compound.

In sum, the Court concluded that genuine disputes remained regarding both awareness and materiality. As such, the Court deemed it inappropriate to grant summary judgment as to application of the Walker Process exception.

C. The Federal Claims Asserted by the Drugstore Plaintiffs

SmithKline also argued that the drugstore plaintiffs' federal claims were barred under Illinois Brick v. Illinois, 431 U.S. 720 (1977). In Illinois Brick, the Supreme Court considered an antitrust action brought by governmental entities that had purchased concrete blocks indirectly from the manufacturer defendants. Id. at 720, 726 (explaining that the concrete blocks pass from the manufacturer to masonry contractors and to general contractors before reaching the governmental entities). In rejecting the action for lack of standing, the Supreme Court interpreted federal antitrust law to prevent indirect purchasers from seeking antitrust damages except in certain limited circumstances. See Illinois Brick, 431 U.S. at 728-29.

The rationales for this interpretation were several. First, permitting indirect purchasers to recover damages "would create a serious risk of multiple liability for defendants." Id. at 720, 730.

The seriousness of this risk arose from the Supreme Court's decision in Hanover Shoe v. United Shoe Mach. Corp., 392 U.S. 481 (1968), which held that a direct purchaser is not subject to a "passing-on defense" -- that is, he is "equally entitled to damages if he raises the price for his own product" (a practice known as "passing on" the overcharge). Id. at 489, 494. Because, under Hanover Shoe, a direct purchaser is allowed full recovery of the overcharge, recovery by an indirect purchaser often would be duplicative. Illinois Brick, 431 U.S. at 730-31. Second, the claims of indirect purchasers "would add whole new dimensions of complexity to treble-damages suits," as courts struggled to "apportion the recovery among all potential plaintiffs." Id. at 737. Finally, the increased costs and diffused benefits of treble-damages actions "could seriously impair this important weapon of antitrust enforcement." Id. at 745.

Here, the drugstore plaintiffs were not direct purchasers of Relafen. Rather, as is typical of pharmaceutical distribution, the drugstore plaintiffs purchased Relafen from wholesalers, who purchased Relafen from SmithKline. See Drugstore Pls.' Illinois Brick Opp'n [Doc. No. 200] at 2-3. Accordingly, in the "ordinary antitrust case," id., the drugstore plaintiffs' claims would be barred by the indirect purchaser rule of Illinois Brick. See Loeb Indus. v. Sumitomo Corp., 306 F.3d 469, 482 (7th Cir. 2002) (describing the paradigmatic claim barred by Illinois Brick: "Party A, the antitrust violator, sells to Party B, and then Party C, a down-stream purchaser from B, seeks to recover the implicit overcharges that B passed on to C"). But the drugstore plaintiffs contended that this was no "ordinary case." Most significantly, the drugstore plaintiffs had been expressly assigned the rights of several national wholesalers, undisputed direct purchasers that had opted out of the direct purchaser plaintiffs' class.¹⁰ See Drugstore Pls.' Illinois Brick App., Exs. A-K.

FN10. In addition to their claims as assignees, the drugstore plaintiffs asserted claims as "but for" direct purchasers of generic nabumetone. See Drugstore Pls.' Illinois Brick Opp'n at 5. As conceded by the drugstore plaintiffs, these additional claims -- and SmithKline's vigorous

opposition to them -- were "rendered largely moot" by the Court's decision regarding the assigned claims. Id. at 4.

SmithKline responded that the claims of the national wholesalers were themselves limited. Defs.' Illinois Brick Mem. at 5 n.3. As the Court explained in a previous memorandum, experts have observed that "while manufacturers of branded drugs 'typically sell the majority of their products through pharmaceutical wholesalers,' the manufacturers of generic drugs often [bypass such wholesalers and] 'sell directly to retail stores, HMOs, hospitals, and other customers.'" In re Relafen Antitrust Litig., 218 F.R.D. at 344 (D. Mass. 2003) (quoting Greenhalgh Decl. at 8, 15). Wholesalers that would otherwise lose sales to bypass may thus benefit from conduct that delays generic entry. See Valley Drug Co. v. Geneva Pharm., Inc., 350 F.3d 1181, 1191 (11th Cir. 2003). SmithKline argues that any damages recoverable by the national wholesalers -- and, in turn, their assignees -- must be reduced accordingly.¹¹ See Defs.' Illinois Brick Mem. at 5 n.3; In re Cardizem CD Antitrust Litig., 200 F.R.D. 297, 317 (D. Mich. 2001) (requiring a class of pharmaceutical wholesalers to account for the "by-pass phenomenon" by considering class members' typically "reduced quantity of generic substitutions").

FN11. SmithKline suggested that the "wholesalers themselves have acknowledged that their alleged damages will have to be reduced." Defs.' Illinois Brick Mem. at 5 n.3. The acknowledgments cited, however, were those of experts retained by the direct purchaser class. See id., Exs. 3-4. As stated above, the national wholesalers opted out of this class and thus were in no way bound by the views of class experts. Moreover, at least one expert stated that he adjusted his damages estimate to be "consistent with the [c]ourt's opinion In re Cardizem CD Antitrust Litigation, [200 F.R.D. 297, 317 (E.D. Mich. 2001)]." Id., Ex. 3, at 62-63. Respectfully, this Court did not consider Cardizem conclusive.

SmithKline's argument, however, appeared inconsistent with Hanover Shoe. Hanover Shoe precludes not only the "passing on" defense, but also the subtle variation asserted here, which might be termed the "otherwise benefitting" defense. See Sports Racing Servs., Inc. v. Sports Car Club of Am., Inc., 131 F.3d 874, 884-85 (10th Cir. 1997). The Tenth Circuit has accordingly rejected the argument that a direct purchaser does not suffer cognizable antitrust injury if the "defendants' monopoly power . . . actually redounded to [the direct purchaser's] benefit as it similarly protected [the direct purchaser] from competition." Id. at 884. Moreover, as Illinois Brick makes clear, Hanover Shoe permits a direct purchaser to recover the "full amount of the overcharge," Illinois Brick, 431 U.S. at 730, 731, 745-46, even if he is otherwise benefitted, Sports Racing Servs., 131 F.3d at 885. See Hanover Shoe, 392 U.S. at 489 ("As long as the seller continues to charge the illegal price, he takes from the buyer more than the law allows."); Herbert Hovenkamp, The Indirect-Purchaser Rule and Cost-Plus Sales, 103 Harv. L. Rev. 1717, 1718 (1990) (acknowledging that the rules of Hanover Shoe and Illinois Brick "potentially award[] the direct purchaser more than three times the damages 'by him sustained'" (quoting 15 U.S.C. § 15)). Notwithstanding the unique "channel of distribution" alleged here, Drugstore Pls.' Illinois Brick Opp'n at 1, the Court declined to create an exception to Hanover Shoe. See Valley Drug, 350 F.3d at 1193 (suggesting that even "direct purchasers who potentially experienced a net benefit from the defendants' conduct" may "nevertheless bring[] suit against the defendants to recover their damages in the form of an overcharge"); cf. Kansas v. UtiliCorp United, Inc., 497 U.S. 199, 217 (1990) ("[E]ven assuming that any economic assumptions underlying the Illinois Brick rule might be disproved in a specific case, we think it an unwarranted and counterproductive exercise to litigate a series of exceptions.").

What was more, the unstated consequence of SmithKline's argument was that "no one [could] recover the illegal overcharges that GSK in fact collected on these bypassed units." Drugstore Pls.' Illinois Brick Opp'n at 3. Following SmithKline's reasoning, wholesalers could not recover the bypass overcharges, because wholesalers would not have purchased the generic drug in the "but for" world. See Defs.'

Illinois Brick Mem. at 5 n.3. Nor could retailers recover the bypass overcharges, because retailers were not direct purchasers of the branded drug in the actual world. See id. at 10-11. As a result, a substantial portion of the harm attributed to SmithKline's conduct would go completely unredressed. See Direct Purchaser Pls.' Illinois Brick App., Ex. L (Leffler Report) at 30 n.67, Ex. N (Baumann Report) at 5 (estimating that approximately 50 percent of sales bypassed wholesalers after generic entry). Contrary to SmithKline's assertions, this outcome "is not supported by Illinois Brick -- or economics or fairness for that matter." Loeb Indus., Inc. v. Sumitomo Corp., 306 F.3d 469, 484 (7th Cir. 2002). As the Seventh Circuit has explained:

[T]he antitrust laws create a system that, to the extent possible, permits recovery in rough proportion to the actual harm a defendant's unlawful conduct causes in the market without complex damage apportionment. This scheme at times favors plaintiffs (Hanover Shoe) and at times defendants (Illinois Brick), but it never operates entirely to preclude market recovery for an injury.

Id. at 483.

The Court was not persuaded that the above concerns were mitigated by the end payor plaintiffs' potential for recovery. See Defs.' Illinois Brick Mem. at 4-5. The claims of the end payors plaintiffs arise solely under state law. In re Relafen Antitrust Litig., 221 F.R.D. at 275. The remedies available under state law, however, "cannot and do not purport to affect remedies available under federal law." California v. ARC America Corp., 490 U.S. 93, 103 (1989). Thus, the Court considered the claims of the drugstore plaintiffs under principles of federal law, independently of claims asserted by different plaintiffs under different bodies of law.

To SmithKline's complaint that multiple claims threaten it with "unfairness," Defs.' Illinois Brick Mem. at 5, the Court offered two responses. First, the perceived "unfairness" arises from Congress's choice "to supplement, not displace, state antitrust remedies." ARC America, 490 U.S. at 102; accord Loeb Indus., 306 F.3d at 492 (reasoning that "different bodies in our federal system seeking to remedy separate harms" pose "no risk of duplicate recovery for the same

injury under the same law"). Second, the risk of multiple liability was substantially reduced because the claims of the several plaintiffs had been consolidated before a single court, and both this Court and the laws of the relevant states acknowledged the seriousness of SmithKline's concerns. See, e.g., 740 Ill. Comp. Stat. 10/7 ("Provided, however, that in any case in which claims are asserted against a defendant by both direct and indirect purchasers, the court shall take all steps necessary to avoid duplicate liability for the same injury including transfer and consolidation of all actions.").

For these reasons, the Court tentatively concluded that the national wholesalers could seek to recover the "full amount of the overcharge" -- that is, the overcharges paid on all purchases of Relafen, including bypassed units. As assignees of the national wholesalers, the drugstore plaintiffs could do the same.

III. CONCLUSION

Because a reasonable jury could conclude that SmithKline's Noerr-Pennington immunity ought be stripped under either or both of the recognized exceptions, SmithKline's Motion for Summary Judgment on All Claims [Doc. No. 169] was DENIED. In addition, because the drugstore plaintiffs' assigned claims were not clearly barred by federal law, SmithKline's Motion for Partial Summary Judgment on the Drugstore Plaintiffs' Claims [Doc. No. 197] was also DENIED.

In re Relafen Antitrust Litig., 346 F. Supp. 2d. 349, 358-70 (D. Mass. 2004).

It is worth a moment to reflect on the bearing that this reasoning has on the matters presently before the Court. The first legal issue addressed refutes SmithKline's argument that all of the claims of all of the plaintiffs are barred by the Noerr-Pennington doctrine. In re Relafen Antitrust Litig., 346 F. Supp. 2d. at 358-59 (emphasis added). Specifically, the Court discussed the "Sham" and "Walker Process" exceptions to that

doctrine. Id. at 359-64, 364-67. The Court's resolution of these issues is of critical importance to the End Payors' class claims.⁴ Indeed, had this Court granted a favorable ruling to SmithKline, the End Payors' claims would have been at an end and the case would already have gone to judgment with SmithKline the winner. Conversely, the Court's actual ruling sustained the viability of those claims and sets the stage for the proposed settlement presently under discussion.

SmithKline moved for partial summary judgment of the End Payors' unjust enrichment claims based on Illinois Brick v. Illinois 431 U.S. 720 (1977). SmithKline's Mot. for Partial Summ. J. [Doc. No. 202]; SmithKline's Mem. in Support of Mot. for Partial Summ. J. [Doc. No. 203] at 5-7. The Court's December 19, 2003 order denied SmithKline's motion in part and allowed it in part. Order of 12/19/03 at 2-3.

The December 19, 2003 order briefly explained that the motion was allowed to the extent that the End Payors' claims were asserted under the laws of states in which such claims would constitute an end-run around those states' adherence to Illinois

⁴ The End Payors submitted a detailed memorandum arguing against SmithKline's defense based on the Noerr-Pennington doctrine. End Payors' Opp'n [Doc. No. 184]. These arguments were specifically addressed in the Court's discussion. In re Relafen Antitrust Litig., 346 F. Supp. 2d. at 359 n.3, 362-64, 366-67. Thus, the Court's Noerr-Pennington discussion relates directly both to the viability of the End Payors' claims as well as to the merits of their particular arguments.

Brick. Id. The Court provided no discussion of the Illinois Brick doctrine itself. See id. In the Court's November 29, 2004 Memorandum, the Court discussed Illinois Brick in greater detail, In re Relafen Antitrust Litig., 346 F. Supp. 2d. at 367-370, as it related to SmithKline's Motion for Partial Summary Judgment of the Drug Store Plaintiffs' federal claims [Doc. No. 197], parties no longer participating in this case. The importance of the Court's reasoning, however, was not limited to the Drugstore Plaintiffs' claims.

The Court's memorandum explained why under Illinois Brick indirect purchasers ordinarily cannot recover antitrust damages. In re Relafen Antitrust Litig., 346 F. Supp. 2d. at 367-68. Both the End Payor Class Plaintiffs and the Drugstore Plaintiffs are indirect purchasers. Thus, the Court's reasoning applies with equal force to the End Payors' claims. In other words, the Court's general discussion of Illinois Brick elucidated its ruling as to the End Payors' claims affected by that doctrine i.e. because the End Payors are indirect purchasers, certain of their antitrust claims must fail. While the Court's more particularized discussion of Illinois Brick related to the Drugstore Plaintiff's unique status as assignees of direct purchasers, id. at 368, SmithKline argued that concerns raised by granting summary judgment of the Drugstore Plaintiffs' claims would be mitigated by the End Payors' potential for recovery.

Id. at 370. In addressing this argument, the Court necessarily distinguished the claims of the Drugstore Plaintiffs from those of the End Payors. Id. Lest there be any doubt, the Court here re-states and expressly adopts the reasoning of In re Relafen Antitrust Litig., 346 F. Supp. 2d. 349 (D. Mass. 2004), and applies the Illinois Brick discussion to the End Payors. Illinois Brick has, and will continue to have, an affect on the Court's evaluation of how the differing subclasses should be treated, in order to ensure a fair, reasonable and adequate settlement. Indeed the consequences of Illinois Brick not only relate to the presently pending settlement issues, they suffuse them. It is precisely due to Illinois Brick and state repealers of Illinois Brick that it has been necessary to treat claimants from different states in different ways. See transcripts of hearings on 9/14/04 [Doc. No. 342], 10/5/04 [Doc. No. 368], 11/10/04 [Doc. No. 372].⁵

⁵Indeed, it is perhaps the central theme of the proposed settlement that claimants and their insurers from states that have enacted Illinois Brick repealers are treated far better than claimants and insurers from states that have not. This Court accordingly has had to consider motions to intervene from the States of Arkansas [Doc. No. 324], Idaho [Doc. No. 322], Illinois [Doc. No. 320], Maryland [Doc. No. 318], Oregon [Doc. No. 316], and Washington [Doc. No. 314], all of which raise Illinois Brick issues. 430 U.S. 720 (1977). The entire matter is one of important and recurrent litigation. See e.g. James Matthews, The Conundrum of Ciardi v. Hoffman-La Roche, Ltd.: Judicial Decision Making when the Plain Meaning of a Statute Collides Irrationally with Established Jurisprudence, 89 Mass. L. Rev. 35 (2004).

V. WHAT NOW?

A. Procedural Steps That Remain

This Court has, to date, taken only preliminary actions under Rule 23(e), see Order of 11/24/04 [Doc. No. 373], including the granting of preliminary approval of the settlement, cf. Fed. R. Civ. P. 23(e)(1)(A) ("The court must approve any settlement, voluntary dismissal, or compromise of the claims, issues, or defenses of a certified class."), and directing notice to the class of the proposed settlement. Fed. R. Civ. P. 23(e)(1)(B) ("The court must direct notice in a reasonable manner to all class members who would be bound by a proposed settlement, voluntary dismissal, or compromise.").

This Court has yet to fulfill several requirements of Rule 23(e) prior to approving the final settlement and the termination of this matter. See Order of 11/24/04 [Doc. No. 373]. These requirements include:

(1) providing full opportunity for, and accepting, any written notice of exclusion from members of the End-Payor Class, Fed. R. Civ. P. 23(e)(3) ("In an action previously certified as a class action under Rule 23(b)(3), the court may refuse to approve a settlement unless it affords a new opportunity to request exclusion to individual class members who had an earlier opportunity to request exclusion but did

not do so.") and Fed. R. Civ. P. 23(e)(4)(A) ("Any class member may object to a proposed settlement, voluntary dismissal, or compromise that requires court approval under Rule 23(e)(1)(A));

(2) conducting a fairness hearing, Fed. R. Civ. P. 23(e)(1)(C) ("The court may approve a settlement, voluntary dismissal, or compromise that would bind class members only after a hearing and on finding that the settlement, voluntary dismissal, or compromise is fair, reasonable, and adequate."); and

(3) granting final approval of the proposed settlement plan of allocation and distribution, Fed. R. Civ. P. 23(e)(1)(A) ("The court must approve any settlement, voluntary dismissal, or compromise of the claims, issues or defenses of a certified class.").

B. Legal Requirements the Court Must Meet in Discharging Its Judicial Responsibilities

Both the United States Supreme Court and the Courts of Appeals have repeatedly emphasized the important duties and responsibilities that devolve upon a district court pursuant to Rule 23(e) prior to final adjudication and settlement of a class action suit. See Devlin v. Scardelletti, 536 U.S. 1, 8-9 (2002) (explaining that, prior to the termination of a matter, a court must approve and give notice of a settlement and that unnamed

parties must have an opportunity to object, "as nonnamed parties have been consistently allowed to do"); Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 617, 623 (1997) (noting that Rule 23(e) prohibits settlement of a class action without the court's approval and that Rule 23(e) protects unnamed class members from "unjust or unfair settlements" agreed to by "fainthearted" or self-interested class representatives"); id. at 617 (citing the notes of the Advisory Committee, Adv. Comm. Notes, 28 U.S.C. App. at 699, and indicating that "[t]he Advisory Committee's sole comment . . . restates the Rule's instruction without elaboration: 'Subdivision (e) requires approval of the court, after notice, for the dismissal or compromise of any class action.'"); Evans v. Jeff D., 475 U.S. 717, 726 (1986) ("Rule 23(e) wisely requires court approval of the terms of any settlement of a class action . . . "); Marek v. Chesney, 473 U.S. 1, 33 n.49 (1985) (indicating that "Rule 23(e) requires the court's approval before a class action is compromised; the Rule protects class members from unjust or unfair settlements affecting their rights by representatives who lose interest or are able to secure satisfaction of their individual claims by compromise.") (internal quotations and citation omitted); Deposit Guar. Nat'l Bank v. Roper, 445 U.S. 326, 332 n.5 (1980) ("We note that Rule 23(e) prescribes certain responsibilities of a district court in a case brought as a class action: once a class is certified, a class action may not be dismissed or compromised

without the approval of the court, and notice of the proposed dismissal or compromise shall be given to all members of the class in such manner as the court directs.”) (internal quotations and citation omitted); Duhaime v. John Hancock Mut. Life Ins. Co., 183 F.3d 1, 2 (1st Cir. 1999) (indicating the court approval and notice required prior to final settlement of a class action and noting that Rule 23(e) “scrutiny entails a detailed inquiry into whether the proposed class action settlement is fair, reasonable, and adequate” (citing In re Gen. Motors Corp. Pick-Up Truck Fuel Tank Prods. Litig., 55 F.3d 768, 804-19 (3d Cir. 1995))); Navarro-Ayala v. Hernandez-Colon, 951 F.2d 1325, 1336 (1st Cir. 1991) (“The language of Rule 23(e) . . . directs that notice be given to all members of the class before dismissal or compromise of a class action.”) (emphasis added) (internal quotations and footnote omitted); Reynolds v. Beneficial Nat’l Bank, 288 F.3d 277, 279-80 (7th Cir. 2002) (Posner, J.) (“We and other courts have gone so far as to term the district judge in the settlement phase of a class action suit a fiduciary of the class, who is subject therefore to the high duty of care that the law requires of fiduciaries.”); id. (explaining, in the words of Judge Posnor, that “district judges [are] to exercise the highest degree of vigilance in scrutinizing proposed settlements of class actions” prior to final settlement). See also Fed. R. Civ. P. 23 advisory committee notes (2003 Amendments, Subdivision (e))

("Subdivision (e) is amended to strengthen the process of reviewing proposed class-action settlements. Settlement may be a desirable means of resolving a class action. But court review and approval are essential to assure adequate representation of class members who have not participated in shaping the settlement."); id. ("Subdivision (e)(1)(C) confirms and mandates the already common practice of holding hearings as part of the process of approving settlement, voluntary dismissal, or compromise that would bind members of a class."); id. ("Subdivision (e)(1)(C) states the standard for approving a proposed settlement that would bind class members. The settlement must be fair, reasonable, and adequate. . . . Subdivision (e)(3) authorizes the court to refuse to approve a settlement unless the settlement affords class members a new opportunity to request exclusion from a class certified under Rule 23(b)(3) after settlement terms are known."); Fed. R. Civ. P. 23 advisory committee notes (1966 Amendments) ("[T]he original rule did not squarely address itself to the question of the measures that might be taken during the course of the action to assure procedural fairness, particularly giving notice to members of the class . . .") (citations omitted); id. ("Subdivision (e) requires approval of the court, after notice, for the dismissal or compromise of any class action."); Manual for Complex Litigation, Fourth, § 13.14 at 172 (noting that while most cases

do not require court approval for voluntary dismissal and settlement, the "Federal Rules require court approval of settlements in class actions" (footnote omitted); id. at 172-173 ("[T]he judge is required to scrutinize the proposed settlement to ensure that it is fair to the persons whose interests the court is to protect. Those affected may be entitled to notice and an opportunity to be heard. This usually involves a two-stage procedure. First, the judge reviews the proposal preliminarily to determine whether it is sufficient to warrant public notice and a hearing. If so, the final decision on approval is made after the hearing.") (footnotes and citations omitted); id. § 21.61 at 309 ("The judicial role in reviewing a proposed settlement is critical Even after notice of a proposed settlement is sent, a judge's statement of concerns about the settlement during the fairness hearing might stimulate the parties to renegotiate in order to avoid possible rejection by the judge. If the fairness hearing leads to substantial changes adversely affecting some members of the class, additional notice, followed by an opportunity to be heard, might be necessary.") (footnote and citations omitted); id. at 309-310 ("To determine whether a proposed settlement is fair, reasonable, and adequate, the court must examine whether the interests of the class are better served by the settlement than by further litigation. Judicial review must be exacting and thorough. The task is demanding because the adversariness of litigation is

often lost after the agreement to settle. The settling parties frequently make a joint presentation of the benefits of the settlement without significant information about any drawbacks. If objectors do not emerge, there may be no lawyers or litigants criticizing the settlement or seeking to expose flaws or abuses. Even if objectors are present, they might simply seek to be treated differently than the class as a whole, rather than advocating for class-wide interests. The lack of significant opposition may mean that the settlement meets the requirements of fairness, reasonableness, and adequacy. On the other hand, it might signify no more than inertia by class members or it may indicate success on counsel's part in obtaining, from likely opponents and critics, agreements not to object. Whether or not there are objectors or opponents to the proposed settlement, the court must make an independent analysis of the settlement terms."); 7B Charles Alan Wright, et al., Federal Practice & Procedure § 1797 (2d ed. 2004) (emphasizing the necessity of court approval prior to final settlement of a class action suit: "In light of its special prophylactic function, Rule 23(e) is specifically excepted from the general provision in Rule 41(a)(1) allowing voluntary dismissals without court approval.") (footnotes omitted); id. at § 1797.1 (indicating "a variety of different factors have been considered by the courts . . . as relevant to approving a dismissal or compromise," including likelihood of class success, the law underlying the settlement, a

comparison of the amount of recovery proposed in settlement as compared with the projected amount of recovery, distribution plan, process used to provide notice, waiver of other claims, recommendations of attorneys for the class, and opposition to the proposed settlement).

VI. CONCLUSION

This Court's November 24, 2004 order preliminarily approving the settlement also outlines the remaining duties of this Court prior to final adjudication and conclusion of this case. The Court has provided members of the End Payor Class an opportunity to request exclusion, and such members have until April 15, 2005 to file written statements of exclusion. Fed. R. Civ. P. 23(e)(3). The requisite fairness hearing will take place on May 4, 2005, at which hearing the Court will consider the fairness, reasonableness and adequacy of the settlement, Fed. R. Civ. P. 23(e)(1)(C), certification of the End Payor class, Fed. R. Civ. P. 23(b)(3) and attorneys' fees, Weinberger v. Great N. Nekoosa Corp., 925 F.2d 518, 523 (1st Cir. 1991) ("We have previously acknowledged, and today reaffirm, that jurisdiction over the main cause of action carries with it equitable jurisdiction to award attorneys' fees in appropriate circumstances."). Thereafter, to conclude this case, this Court must specifically find that the settlement is "fair, reasonable, and adequate" under Rule 23(e)(1)(C) before approving the settlement.

This Court takes seriously its "fiduciary duty," Reynolds, 288 F.3d at 279-80, to scrutinize the further proceedings in these ongoing cases. Such "scrutiny [will] entail[] a detailed inquiry into whether the proposed class action settlement is fair, reasonable, and adequate." Duhaime, 183 F.3d at 2. Make no mistake, the legal reasoning set forth in this opinion has, and will continue to, guide the Court in making these determinations.

/s/ William G. Young

WILLIAM G. YOUNG
CHIEF JUDGE

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William G. Young, presiding
Date filed: 12/18/2001
Date terminated: 04/13/2004 Date of last filing: 02/22/2005

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representing

State of Idaho (Intervenor Plaintiff) State of Illinois (Intervenor Plaintiff) State of Maryland (Intervenor Plaintiff) State of Oregon (Intervenor Plaintiff) State of Washington (Intervenor Plaintiff) A.F. of L. - A.G.C. Building Trades Welfare Plan (Consolidated Plaintiff)

End-Payor Plaintiffs (Consolidated Plaintiff) Hy-Vee, Inc. (Consolidated Plaintiff) IBEW - NECA Local 505 Health & Welfare Plan (Consolidated Plaintiff) Sheet Metal Workers Local 441 Health & Welfare Plan

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representing

(Consolidated Plaintiff)
Direct Purchaser (Consolidated Plaintiff)

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representing

Elliot Franklin (Consolidated Plaintiff)
Glaxosmithkline PLC (Defendant)

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representing

Smithkline Beecham Corporation (Defendant)
Beecham Group PLC (Consolidated Defendant)
Teva Pharmaceutical Industries LTD (Consolidated Plaintiff)

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representing

Teva Pharmaceuticals USA, Inc. (Consolidated Plaintiff)
Teamsters Local No. 35 Heath Plans (Consolidated Plaintiff)

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representing

Elliot Franklin (Consolidated Plaintiff)
Patrick J. Lynch (Consolidated Plaintiff)
State of Washington (Intervenor Plaintiff)

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representing

Barbara Brown (Consolidated Plaintiff)

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representing

Meijer Distribution, Inc. (Plaintiff)

Kevin T. Kerns Dechert LLP 4000 Bell

representing

Meijer, Inc. (Plaintiff)
Glaxosmithkline PLC (Defendant)

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Smithkline Beecham Corporation
(Defendant)
Meijer Distribution, Inc. (Plaintiff)

Meijer, Inc. (Plaintiff)
Meijer Distribution, Inc. (Plaintiff)

Meijer, Inc. (Plaintiff)
Teva Pharmaceutical Industries
LTD (Consolidated Plaintiff)

Teva Pharmaceuticals USA, Inc.
(Consolidated Plaintiff)
A.F. of L. - A.G.C. Building Trades
Welfare Plan (Consolidated
Plaintiff)

End-Payor Plaintiffs (Consolidated
Plaintiff)
IBEW - NECA Local 505 Health &
Welfare Plan (Consolidated
Plaintiff)
Sheet Metal Workers Local 441
Health & Welfare Plan
(Consolidated Plaintiff)
Barbara Brown (Consolidated
Plaintiff)

Eon Labs, Inc. (Consolidated
Plaintiff)

Teva Pharmaceutical Industries
LTD (Consolidated Plaintiff)

Teva Pharmaceuticals USA, Inc.
(Consolidated Plaintiff)

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CVS Meridian, Inc. (Consolidated
Plaintiff)
Rite Aid Corp. (Consolidated
Plaintiff)
Teva Pharmaceutical Industries
LTD (Consolidated Plaintiff)

Teva Pharmaceuticals USA, Inc.
(Consolidated Plaintiff)
CVS Meridian, Inc. (Consolidated
Plaintiff)
Rite Aid Corp. (Consolidated
Plaintiff)
Insurer Group (Plaintiff)

End-Payor Plaintiffs (Consolidated
Plaintiff)
SAJ Distributors, Inc. (Interested
Party)

Stephen L. LaFrance Holdings, Inc.
(Interested Party)
State of Oregon (Intervenor
Plaintiff)

A.F. of L. - A.G.C. Building Trades
Welfare Plan (Consolidated
Plaintiff)

End-Payor Plaintiffs (Consolidated
Plaintiff)
Hy-Vee, Inc. (Consolidated
Plaintiff)
IBEW - NECA Local 505 Health &
Welfare Plan (Consolidated
Plaintiff)
Safeway, Inc. (Consolidated
Plaintiff)
Sheet Metal Workers Local 441
Health & Welfare Plan

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representing

(Consolidated Plaintiff) Barbara Brown (Consolidated Plaintiff) Jennifer Kravitz (Consolidated Plaintiff) Meijer Distribution, Inc. (Plaintiff)

Meijer, Inc. (Plaintiff) Teva Pharmaceutical Industries LTD (Consolidated Plaintiff)

Teva Pharmaceuticals USA, Inc. (Consolidated Plaintiff) Teva Pharmaceutical Industries LTD (Consolidated Plaintiff)

Teva Pharmaceuticals USA, Inc. (Consolidated Plaintiff) Teva Pharmaceutical Industries LTD (Consolidated Plaintiff)

Teva Pharmaceuticals USA, Inc. (Consolidated Plaintiff) Tyler Fox (Consolidated Plaintiff)

Teamsters Local No. 35 Health Plans (Consolidated Plaintiff)

Walgreen Company (Consolidated Plaintiff) Elliot Franklin (Consolidated Plaintiff) Patrick J. Lynch (Consolidated Plaintiff)

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CVS Meridian, Inc. (Consolidated Plaintiff)
Direct Purchaser (Consolidated Plaintiff)
Meijer Distribution, Inc. (Plaintiff)

Albertson's, Inc. (Consolidated Plaintiff)

Eckerd Corporation (Consolidated Plaintiff)
Hy-Vee, Inc. (Consolidated Plaintiff)
Kroger Co., The (Consolidated Plaintiff)
Walgreen Company (Consolidated Plaintiff)
State of Arkansas (Intervenor Plaintiff)

Glaxosmithkline PLC (Defendant)

Smithkline Beecham Corporation (Defendant)
Carl J. Rose (Consolidated Defendant)
Richard K. Anderson (Consolidated Defendant)
State of Illinois (Intervenor Plaintiff)

State of Illinois (Consolidated Plaintiff)
CVS Meridian, Inc. (Consolidated

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Plaintiff)

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A.F. of L. - A.G.C. Building Trades Welfare Plan (Consolidated Plaintiff)

End-Payor Plaintiffs (Consolidated Plaintiff)
Hy-Vee, Inc. (Consolidated Plaintiff)
IBEW - NECA Local 505 Health & Welfare Plan (Consolidated Plaintiff)
Sheet Metal Workers Local 441 Health & Welfare Plan (Consolidated Plaintiff)
Teva Pharmaceutical Industries LTD (Consolidated Plaintiff)

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Teva Pharmaceuticals USA, Inc. (Consolidated Plaintiff)
Meijer Distribution, Inc. (Plaintiff)

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Direct Purchaser (Consolidated Plaintiff)

Direct Purchaser (Consolidated Plaintiff)

Teva Pharmaceutical Industries LTD (Consolidated Plaintiff)
Teva Pharmaceuticals USA, Inc. (Consolidated Plaintiff)
Eon Labs, Inc. (Consolidated Plaintiff)

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CVS Meridian, Inc. (Consolidated
Plaintiff)

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Direct Purchaser (Consolidated
Plaintiff)

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Meijer Distribution, Inc. (Plaintiff)

Meijer, Inc. (Plaintiff)
Direct Purchaser (Consolidated
Plaintiff)
Teamsters Local No. 35 Heath
Plans (Consolidated Plaintiff)
Elliot Franklin (Consolidated
Plaintiff)
Patrick J. Lynch (Consolidated
Plaintiff)
End-Payor Plaintiffs (Consolidated
Plaintiff)

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Glaxosmithkline PLC (Defendant)

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Smithkline Beecham Corporation
(Defendant)
Beecham Group PLC
(Consolidated Defendant)
Teamsters Local No. 35 Heath
Plans (Consolidated Plaintiff)

Elliot Franklin (Consolidated

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Plaintiff)
Patrick J. Lynch (Consolidated
Plaintiff)
A.F. of L. - A.G.C. Building Trades
Welfare Plan (Consolidated
Plaintiff)

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End-Payor Plaintiffs (Consolidated
Plaintiff)
Hy-Vee, Inc. (Consolidated
Plaintiff)
IBEW - NECA Local 505 Health &
Welfare Plan (Consolidated
Plaintiff)
Sheet Metal Workers Local 441
Health & Welfare Plan
(Consolidated Plaintiff)
A.F. of L. - A.G.C. Building Trades
Welfare Plan (Consolidated
Plaintiff)

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End-Payor Plaintiffs (Consolidated
Plaintiff)
Hy-Vee, Inc. (Consolidated
Plaintiff)
IBEW - NECA Local 505 Health &
Welfare Plan (Consolidated
Plaintiff)
Sheet Metal Workers Local 441
Health & Welfare Plan
(Consolidated Plaintiff)
Teva Pharmaceutical Industries
LTD (Consolidated Plaintiff)

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(Consolidated Plaintiff)
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LTD (Consolidated Plaintiff)

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Teva Pharmaceuticals USA, Inc.
(Consolidated Plaintiff)
Glaxosmithkline PLC (Defendant)

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Smithkline Beecham Corporation (Defendant)
State of Oregon (Intervenor Plaintiff)

Direct Purchaser (Consolidated Plaintiff)

Barbara Brown (Consolidated Plaintiff)

End-Payor Plaintiffs (Consolidated Plaintiff)

Teva Pharmaceutical Industries LTD (Consolidated Plaintiff)

Teva Pharmaceuticals USA, Inc. (Consolidated Plaintiff)
CVS Meridian, Inc. (Consolidated Plaintiff)
Rite Aid Corp. (Consolidated Plaintiff)