FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE GABAPENTIN PATENT LITIGATION	MDL Docket No. 1384 Master Civil Action No. 00-2931 **This Filing Applies To:** Purepac Defendants C.A. No. 00-CV-2931 (FSH) C.A. No. 00-CV-3522 (FSH) **OPINION** Date: August 27, 2009

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HOCHBERG, District Judge

This matter comes before the Court upon Plaintiffs' (collectively, "Warner-Lambert") Motion to Strike Certain Affirmative Defenses and to Dismiss Certain Counterclaims of Purepac Defendants (Docket # 431), pursuant to Fed. R. Civ. P. 12(b) and 12(f).[1] The Court has considered the briefs of the parties, and oral argument held on April 22, 2009.

I. Background And Procedural Posture

A detailed account of the factual and procedural backdrop to this case is set forth in the Opinion issued by this Court today, deciding Plaintiffs' separate, though similar, Motion to Strike Certain Affirmative Defenses of the Teva, IVAX and Eon Defendants (the "Teva Opinion"). Background information concerning Warner-Lambert's gabapentin patents, Neurontin products and related Orange Book listings need not be reiterated in full for purposes of the instant motion, and is incorporated herein by reference.[2] To the extent that there are facts unique to Purepac and specifically relevant to the resolution of the present motion, they are set forth below.

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[1] The Purepac Defendants ("Purepac") are Purepac Pharmaceutical Co., a Delaware corporation; Faulding Inc., a Delaware corporation; and Actavis Elizabeth LLC, a Delaware limited liability company. Purepac was a wholly-owned subsidiary of Faulding, and was the initial holder of the ANDAs at issue in this proceeding. Actavis is the successor to Purepac Pharmaceutical Co. and is the current holder of the relevant ANDAs.

[2] The Court recommends that this Opinion be read in conjunction with the Teva Opinion as well as the Opinion handed down today deciding Warner-Lambert's Motion to Dismiss the Direct Purchaser Plaintiffs' Claims in a related matter, *In re Neurontin Antitrust Litig.* (No. 02-1390, MDL No. 1479) (the "Neurontin Antitrust Opinion"). The Court presumes familiarity with the facts and arguments set forth in such Opinions, as well as with the abbreviations and acronyms used therein.

Purepac was the first generic drug manufacturer to file ANDAs seeking FDA approval to market generic gabapentin products after the expiration of the '544 Patent (and its pediatric extension). Purepac filed two ANDAs: No. 75-370 for gabapentin capsules on March 30, 1998 and No. 75-694 for gabapentin tablets on September 3, 1999. When Purepac initially filed ANDAs, it submitted a Paragraph IV Certification concerning the '476 Patent and a section viii statement concerning the '479 Patent.

Relying on the Paragraph IV Certifications in these ANDAs, Warner-Lambert sued Purepac for infringement of the '476 and '479 Patents.[3] Purepac filed counterclaims alleging, in pertinent part, violation of the antitrust laws and unfair competition.[4] In a motion similar to that now pending before this Court, Warner-Lambert moved to dismiss Purepac's antitrust counterclaims. Warner-Lambert argued that Purepac lacked standing to bring a claim for antitrust injury and that its infringement actions were protected by the *Noerr-Pennington* doctrine and were therefore immune from antitrust liability. Judge Lifland denied Warner-Lambert's

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[3] Warner-Lambert filed two separate lawsuits against Purepac, one based on the ANDA for generic gabapentin capsules and the other based on the ANDA for generic gabapentin tablets. The "Capsule Lawsuit" was initiated in June 1998 (No. 98-2749) and the "Tablet Lawsuit" was initiated in December 1999 (No. 99-5948). In each lawsuit, Warner-Lambert asserted actual infringement of the '476 Patent and induced infringement of the '479 Patent. The lawsuits were consolidated for trial purposes in April 2001 in front of Hon. John C. Lifland, U.S.D.J.

[4] Purepac alleges in its counterclaims that Warner-Lambert fraudulently included the '476 and '479 Patents in its NDA for approval of gabapentin anhydrous, which led to the listing of those patents in the Orange Book. According to Purepac, Warner-Lambert listed the '476 Patent even though the gabapentin monohydrate covered by that patent was not used at any point during the production of Neurontin, and listed the '479 Patent even though the labeling authorization for Neurontin permits treatment only for illnesses related to epilepsy. Purepac alleged that Warner-Lambert's fraudulent listing of the '476 and '479 Patents prevented Purepac from competing in the gabapentin market. Purepac further alleged that Warner-Lambert used the Orange Book listings of these patents as a basis to initiate patent infringement litigation solely to forestall Purepac's entrance into that market.

motion on December 22, 2000. *Warner-Lambert Co. v. Purepac Pharm. Co.*, Nos. 98-2749, 99-5948, 00-2053, 2000 WL 34213890 (D.N.J. Dec. 22, 2000) (the "December 22 Opinion").[5]

Judge Lifland ultimately granted summary judgment in Purepac's favor in May 2003. *Warner-Lambert Co. v. Purepac Pharm. Co., et al.*, Nos. 98-2749, 99-5948, 2003 WL 21698310 (D.N.J. May 22, 2003) (the "May 22 Opinion").[6] As discussed in greater detail below, Purepac

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[5] Judge Lifland held that Purepac had standing to bring antitrust counterclaims, because Purepac had sufficiently alleged a causal connection between Warner-Lambert's actions and its injuries. Judge Lifland also held that the fact that Warner-Lambert's infringement actions had survived motions for summary judgment did not, on its own, preclude Purepac's antitrust claims, which were based on allegations that those infringement actions constituted "sham litigation" instituted for the sole purpose of precluding competition. Finally, with respect to the allegations of fraudulent Orange Book listings, Judge Lifland held that Purepac had adequately alleged "that Warner-Lambert knowingly made misrepresentations to the FDA with the specific intent to prevent competition," such that discovery might develop proof that Warner-Lambert engaged in actionable anticompetitive conduct. *Id.* at *6.

[6] Purepac moved for summary judgment of noninfringement, arguing that its gabapentin product did not infringe the '476 Patent because it did not contain the monohydrate form of gabapentin claimed in that patent, and did not infringe the '479 Patent because the generic product would not be labeled for treating the neurodegenerative diseases covered by that patent. Warner-Lambert responded that Purepac's gabapentin compounds may "pass through" the patented monohydrate form during the production process, thereby infringing the '476 Patent. Furthermore, Purepac's products would be prescribed and dispensed for off-label uses, thereby infringing the '479 Patent.

Judge Lifland granted summary judgment of noninfringement of the '476 Patent in light of evidence that Purepac's gabapentin anhydrous was produced outside of the United States. Because United States patent laws are territorially limited, a U.S. patent cannot be infringed by acts entirely committed in a foreign country. *See Pellegrini v. Analog Devices, Inc.*, 375 F.3d 1113, 1117 (Fed. Cir. 2004) ("[As] the U.S. Supreme Court explained nearly 150 years ago in *Brown v. Duchesne*, 60 U.S. (19 How.) 183, 15 L. Ed. 595 (1857), ... the U.S. patent laws 'do not, and were not intended to, operate beyond the limits of the United States.'"); *Rotec Indus., Inc. v. Mitsubishi Corp.*, 215 F.3d 1246, 1251 (Fed. Cir. 2000) ("'[T]he right conferred by a patent under our law is confined to the United States and its territories, and infringement of this right cannot be predicated [on] acts wholly done in a foreign country.'" (quoting *Dowagiac Mfg. Co. v. Minnesota Moline Plow Co.*, 235 U.S. 641, 650 (1915)). Warner-Lambert conceded this point, and did not oppose the motion for summary judgment with respect to the '476 Patent.

Judge Lifland granted summary judgment of noninfringement of the '479 Patent on the basis of the summary judgment decision issued in *Warner-Lambert Co. v. Apotex Corp.*, 316

now alleges that the Tablet and Capsule Lawsuits were sham litigation pursued by Warner-Lambert purely for anticompetitive purposes.[7]

Once the '482 Patent was issued and listed in the Orange Book, Purepac amended its ANDAs to include Paragraph IV Certifications concerning that patent. This second certification forms the basis for the current patent infringement litigation. Like the Teva, IVAX and Eon Defendants, Purepac launched its gabapentin capsules and tablets despite the pending litigation, first offering its gabapentin capsules for sale in October 2004, and its gabapentin tablets in December 2004.

F.3d 1348 (Fed. Cir. 2003). In that decision, based on facts that precisely mirrored those before Judge Lifland, the Federal Circuit held that Warner-Lambert had no cause of action for infringement of the '479 Patent because Congress intended to limit infringement actions for method-of-use patents to "'controlling use patents,' or patents that claim an approved use of a drug." *Id*. at 1362. Because Apotex had not submitted an application to sell a drug to treat neurodegenerative diseases, the only approved use covered by the '479 Patent, Warner-Lambert could not claim infringement of that patent, and Apotex was entitled to summary judgment of noninfringement. Judge Lifland held that the *Apotex* decision was binding precedent and that Purepac was entitled to summary judgment on the same grounds.

[7] The Capsule and Tablet Lawsuits also triggered a collateral proceeding between Purepac and the FDA concerning the section viii statement Purepac initially filed with respect to the '479 Patent. Purepac submitted a section viii statement, rather than a Paragraph IV Certification, because the '479 Patent covered a use other than the labeled use for which Purepac sought generic approval. Section viii statements do not require notice to the patent-holder and do not allow the patent-holder to automatically initiate infringement litigation. The FDA, however, demanded that Purepac change its certification to one under either Paragraph III or Paragraph IV, arguing that a section viii statement was only appropriate when a label has more than one indication and the generic applicant seeks approval for only one of the many approved uses. Believing the demands made by the FDA, which would result in formal notice to Warner-Lambert, and likely result in another infringement action, 30-month stay and the loss of generic exclusivity, to be untenable, Purepac successfully sued the FDA to compel acceptance of the section viii statement. *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002), *aff'd Purepac Pharm. Co. v. Thompson*, 354 F.3d 877 (D.C. Cir. 2004). Purepac argues that this collateral litigation should also be considered to be an anticompetitive injury stemming from Warner-Lambert's allegedly improper listing of the '479 Patent.

Purepac filed an Answer to Plaintiffs' Amended Complaint on April 21, 2008. In addition to the affirmative defenses and counterclaims raised by its co-Defendants, Purepac has also requested declarations of unenforceability of the '482 Patent on grounds of patent misuse and unclean hands, and has raised counterclaims asserting (1) monopolization and attempted monopolization in violation of Section 2 of the Sherman Act and (2) common-law unfair competition.[8] Purepac bases these counterclaims on allegations that Warner-Lambert engaged in an "overall scheme to forestall, preclude, and delay generic competition" for Neurontin. Amended Answer and Amended and Supplemental Counterclaims ¶ 104, *In re Gabapentin Patent Litig.*, No. 00-2931 (D.N.J. Apr. 21, 2008) ("Purepac Answer").

According to Purepac, Warner-Lambert perpetrated this scheme by: (1) intentionally withholding material prior art from the Patent Office during prosecution of the '482 Patent, resulting in a delayed issuance of the patent and ultimately allowing Warner-Lambert to obtain a successive 30-month stay of FDA approval for Purepac's products; (2) abusing FDA regulations by certifying that the '476 and '479 Patents covered the approved compounds in and uses of Neurontin, while knowing that such certifications were false; and (3) filing objectively baseless patent-infringement lawsuits asserting the '476 and '479 Patents against Purepac. Purepac alleges that Warner-Lambert's objective was to obtain more market exclusivity for Neurontin than the patent laws and regulatory system allow.

[8] Purepac asserts that its counterclaims arise under both Section 2 of the Sherman Act and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a), 26. These antitrust counterclaims, discussed in greater detail below, are substantially similar to the claims raised in *In re Neurontin Antitrust Litig.* and examined in the Neurontin Antitrust Opinion. Where appropriate, the Court will refer herein to arguments made or conclusions reached in connection with that Opinion.

On June 16, 2008, Warner-Lambert moved to strike Purepac's unclean hands and patent misuse defenses and moved to dismiss Purepac's counterclaims for declaratory relief, monopolization, attempted monopolization and unfair competition, claiming that they are not viable as a matter of law.

II. Standard of Review

Warner-Lambert moves to strike certain of Purepac's affirmative defenses pursuant to Fed. R. Civ. P. 12(f) and moves to dismiss certain of Purepac's counterclaims pursuant to Fed. R. Civ. P. 12(b)(6). As discussed in the Teva Opinion, Fed. R. Civ. P. 12(f), which allows the Court to "strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter," offers the primary opportunity for plaintiffs to object to affirmative defenses. An affirmative defense is insufficient as a matter of law if it cannot succeed under any circumstances. *Eisai Co., Ltd. v. Teva Pharm. USA, Inc.*, 557 F. Supp. 2d 490, 493 (D.N.J. 2008) (citing *In re Sunrise Sec. Litig.*, 818 F. Supp. 830, 840 (E.D. Pa. 1993)).

As also discussed in the Teva Opinion, striking an affirmative defense "is a drastic remedy, to be resorted to only when required for the purposes of justice." *North Penn Transfer, Inc. v. Victaulic Co. of America*, 859 F. Supp. 154, 158 (E.D. Pa. 1994). Courts have, however, "recognized that such motions may serve to hasten resolution of cases by eliminating the need for discovery which in turn saves time and litigation expenses." *Resolution Trust Corp. v. Moskowitz*, No. 93-2080, 1994 WL 229812, at *13 (D.N.J. May 24, 1994). Motions to strike will, therefore, be granted "when a defense is legally insufficient under any set of facts which may be inferred from the allegations of the pleading." *Glenside West Corp. v. Exxon Co. U.S.A.*, 761 F. Supp. 1100, 1115 (D.N.J. 1991).

To survive a motion to dismiss filed under Rule 12(b)(6), "[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true," even if doubtful in fact. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 545 (2007) ("*Twombly*"). According to the Third Circuit, "stating ... a claim requires a complaint with enough factual matter (taken as true) to suggest the required element. This does not impose a probability requirement at the pleading stage, but instead simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element." *Phillips v. County of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (internal quotations omitted) (citing *Twombly*, 550 U.S. at 555-56). The same standards are applied to a court's analysis of the sufficiency of counterclaims. *See e.g.*, *Organon Inc. v. Mylan Pharm.*, 293 F. Supp. 2d 453, 456-57 (D.N.J. 2003) ("*Organon*").

Although a court does not need to credit "bald assertions" or "legal conclusions," it must view all of the allegations in the counterclaim as well as all reasonable inferences that can be drawn therefrom in the light most favorable to the counterclaimant. *Morse v. Lower Merion Sch. Dist*., 132 F.3d 902, 906 (3d Cir. 1997) (citing *Rocks v. City of Philadelphia*, 868 F.2d 644, 645 (3d Cir. 1989)); *see also In re Burlington Coat Factory Sec. Litig*., 114 F.3d 1410, 1429-30 (3d Cir. 1997).[9] The Supreme Court recently held that "once a claim has been stated adequately, it

[9] Because a Rule 12(f) motion also challenges the legal sufficiency of the pleading, it is governed by the same standards as a motion to dismiss filed pursuant to Fed. R. Civ. P. 12(b)(6). *Eisai Co.,* 557 F. Supp. 2d at 493 (citing *Mars Inc. v. JCM American Corp.*, No. 05-3165, 2006 WL 1704469, at *4 (D.N.J. June 14, 2006)). Accordingly, to determine whether Defendants' affirmative defenses are sufficient, the Court applies the same legal framework, accepting all factual allegations in Purepac's Answer as true, construing the Answer in the light most favorable to Purepac, and determining whether, under any reasonable reading of the pleadings, Purepac may be entitled to relief. *Phillips*, 515 F.3d at 233.

may be supported by showing any set of facts consistent with the allegations in the complaint." *Twombly*, 550 U.S. at 546.[10]

Antitrust complaints, in particular, are to be liberally construed at this stage of the proceeding. *See In re Hypodermic Prods. Antitrust Litig.*, MDL No. 1730, 2007 WL 1959224, at *5 (D.N.J. June 29, 2007) (citing *Commonwealth of Pa. ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 179 (3d Cir. 1988)). "[I]n antitrust cases, where 'the proof is largely in the hands of the alleged conspirators,' dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly." *Hosp. Bldg. Co. v. Trustees of Rex Hosp.*, 425 U.S. 738, 746 (1976) (quoting *Poller v. Colombia Broad.*, 368 U.S. 464, 473 (1962)). "The liberal approach to the consideration of antitrust complaints is important because inherent in such an action is the fact that all details and specific facts relied upon cannot properly be set forth as part of the pleadings." *Lucas Indus., Inc. v. Kendiesel, Inc.*, No. 93-4480, 1995 WL 350050, at *3 (D.N.J. June 9, 1995). Nevertheless, courts have determined that "the heavy costs of modern federal litigation, especially antitrust litigation, and the mounting caseload pressure on the federal courts, militate in favor of requiring some reasonable particularity in pleading violations of the federal antitrust laws." *Garshman v. Universal Res. Holding, Inc.*, 641 F. Supp. 1359, 1367 (D.N.J. 1986) (internal quotations and citations omitted).

[10] In evaluating a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), the Court may consider only the allegations pled in the counterclaim, exhibits attached to the counterclaim, matters of public record, and undisputedly authentic documents if the counterclaims are based on those documents. *Pension Ben. Guar. Corp. v. White Consol. Indus*., 998 F.2d 1192, 1196 (3d Cir. 1992).

III. Discussion

The instant motion raises issues of both patent and antitrust law. For the sake of clarity, the Court will address the patent issues first and then turn to the antitrust issues separately.

A. Purepac's Unclean Hands And Patent Misuse Affirmative Defenses

Purepac has asserted affirmative defenses of unclean hands and patent misuse on the same facts relied upon by its co-Defendants. Warner-Lambert has, as a result, raised arguments in support of its motion to strike those defenses that are virtually identical to those asserted against Teva, IVAX and Eon. Warner-Lambert again argues that there is no connection between its alleged off-label marketing misconduct and its current efforts to enforce the '482 Patent, and again stresses that Purepac has asserted nothing more than a shift in the 17-year patent term, which does not constitute an actionable temporal expansion of the patent. For the reasons set forth by this Court in the Teva Opinion, Warner-Lambert's motion to strike Purepac's affirmative defense of unclean hands is granted and its motion to strike Purepac's affirmative defense of patent misuse is denied.

B. Purepac's Counterclaims For Declaratory Judgment Of Unenforceability

Purepac, unlike its co-Defendants, has also requested affirmative relief on the basis of unclean hands and patent misuse, by seeking a declaration that the '482 Patent is unenforceable on either, or both, of those grounds. Warner-Lambert has moved to dismiss these counterclaims, arguing that neither allegations of unclean hands nor allegations of patent misuse can form the basis for affirmative relief. This motion will be granted in part and denied in part.

First, the Court notes that because Purepac's affirmative defense of unclean hands has been stricken, Purepac's claim for declaratory relief on the basis of unclean hands necessarily

fails as well. *See Reid-Ashman Mfg, Inc. v. Swanson Semiconductor Serv., L.L.C.*, No. 06-4693, 2007 WL 1394427, at *8 (N.D. Cal. May 10, 2007) (dismissing a declaratory relief counterclaim "to the extent that the affirmative defenses on which it is based fail," because "if any affirmative defense is stricken, then the counterclaim cannot state a claim based on that defense.") (citing *Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, No. 96-0942, 1996 WL 467273, at *6 (N.D. Cal. July 24, 1996)); *Precimed S.A. v. Orthogenesis, Inc.*, No. 04-1842, 2005 WL 991277, at *2 (E.D. Pa. Apr. 25, 2005) (dismissing a counterclaim because defendant incorporated all affirmative defenses, which were then stricken, into such counterclaim and provided no other factual allegations upon which the counterclaim might be based). Counsel for Purepac conceded as much during oral argument before this Court on April 22, 2009. Transcript of Motion Hearing at 74-75, *In re Gabapentin Patent Litig.*, No. 00-2931 (FSH) (Apr. 22, 2009) ("April 22 Transcript").

Moreover, Warner-Lambert has correctly argued that, as a matter of law, unclean hands cannot form the basis for a declaration of unenforceability of a patent. *Aptix Corp. v. Quickturn Design Sys., Inc.*, a case upon which Plaintiffs rely, establishes that a patent cannot be invalidated by the patentee's unclean hands. 269 F.3d 1369, 1378 (Fed. Cir. 2001) ("Nor does the doctrine of unclean hands provide a suitable basis for the trial court's judgment, as this equitable doctrine is not a source of power to punish. In declaring the '069 patent unenforceable based solely on misconduct during litigation, the trial court clearly exceeded the bounds of *Keystone I* and the doctrine of unclean hands.").

The *Aptix* Court found substantial evidence of litigation misconduct, which supported the district court's finding of unclean hands and thereby barred the plaintiff patentee from suing to

enforce the patent in question. However, the court also held that "[t]he doctrine of unclean hands does not reach out to extinguish a property right based on misconduct during litigation to enforce the right." *Id.* at 1375. While misconduct will prevent a litigant from suing in a particular instance, "[t]he property right itself remains independent of the conduct of the litigant." *Id.* The *Aptix* Court concluded, therefore, that the patent should not be declared completely invalid or unenforceable due to the patentee's unclean hands.[11]

Purepac's counterclaim for declaratory relief on the basis of patent misuse, however, survives. As noted in the Teva Opinion, successfully pleading a patent misuse defense at this stage of the litigation requires only allegations of conduct that had the effect of impermissibly extending the limited protection from competition afforded by the '482 Patent. Purepac, like its co-Defendants, has made such allegations. Furthermore, courts have found patent misuse, unlike unclean hands, to be a proper basis for declaratory relief. *See Glitsch, Inc. v. Koch Eng'g Co.*, 216 F.3d 1382, 1386 (Fed. Cir. 2000) (noting that the Supreme Court has made "clear that a party that did not raise the issue of patent misuse in one action may raise that issue in another action based on a separate assertion of infringement, whether as a defense against the claim of infringement or in a request for declaratory relief."); *Linzer Products Corp. v. Sekar*, 499 F. Supp. 2d 540, 552-53 (S.D.N.Y. 2007) (observing that "*Braun* did not proscribe claims seeking a

[11] The Court notes, however, that even though Purepac's unclean hands defense is not viable as a matter of law, evidence of Warner-Lambert's admitted marketing misconduct may be considered as a factor affecting Warner-Lambert's ability to obtain a permanent injunction as relief in this proceeding. As noted in the Teva Opinion, any arguments that Warner-Lambert should not be allowed to rely on illegally acquired market share as a basis for injunctive relief or that it would be inequitable and against public interest to use a permanent injunction to protect Warner-Lambert's ill-gotten gains are, though not determinative at this stage of the litigation, both relevant and compelling. Such arguments, and the evidence required to support them, may be considered by the Court at a later stage.

declaratory judgment of patent misuse. Indeed, in later actions, the Federal Circuit has allowed such claims without comment."); *see also Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1362 (Fed. Cir. 2001); *Competitive Techs., Inc. v. Fujitsu Ltd.*, 374 F.3d 1098, 1101 (Fed. Cir. 2004); *Marchon Eyewear, Inc. v. Tura LP*, No. 98-1932, 2002 WL 31253199, at *9 (E.D.N.Y. Sept. 30, 2002).

Indeed, the *Aptix* Court indicated this conclusion, noting that "[i]nequitable conduct in the process of procuring a patent taints the property right itself. ... Upon a showing of inequitable conduct during acquisition of the patent, courts declare the patent unenforceable because the property right is tainted *ab initio*." *Aptix Corp.*, 269 F.3d at 1376. Because Purepac's allegations of patent misuse rest on Warner-Lambert's allegedly inequitable conduct during the prosecution and procurement of the '482 Patent, if Purepac ultimately proves that Warner-Lambert engaged in the conduct alleged, this Court would have full discretion to declare the '482 Patent unenforceable.

C. Antitrust Counterclaims

Purepac alleges that Warner-Lambert perpetrated an "overall scheme to forestall, preclude, and delay generic competition" for Neurontin by manipulating the prosecution of the '482 Patent to delay its issuance, improperly listing the '476 and '479 Patents in the Orange Book to obtain additional stays of approval for generic applicants, and filing objectively baseless patent infringement actions concerning the '476 and '479 Patent. Purepac Answer ¶ 104. Warner-Lambert argues that these antitrust counterclaims should be dismissed for two primary reasons. First, Warner-Lambert asserts that Purepac has not suffered an antitrust injury and thus has no standing to bring antitrust claims. Second, Warner-Lambert argues that Purepac has failed

to state an antitrust claim as a matter of law because the allegedly anticompetitive conduct cited by Purepac is either immune from antitrust liability or proper under then-controlling Hatch-Waxman regulations. According to Warner-Lambert, Purepac cannot combine these otherwise lawful acts into an actionable "overall monopolization scheme," because none of the underlying actions individually or independently violated antitrust laws.[12] In response, Purepac argues that Warner-Lambert is simply attempting to rehash arguments previously rejected by the Court while mischaracterizing and misinterpreting both the monopolization claims and the anticompetitive effects alleged in Purepac's Answer.

1. Antitrust Claims Within The Context Of Patent Litigation

The purpose of the Sherman Act is "to protect the public from the failure of the market." 15 U.S.C.A. § 2 n.5 (quoting *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447 (1993)). Purepac

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[12] Warner-Lambert has also moved to dismiss Purepac's unfair competition counterclaims, arguing that the allegations in Purepac's Answer fail to satisfy the standards set by the U.S. Supreme Court in *Twombly*. Warner-Lambert further argues that even assuming Purepac has survived the pleading requirements, the *Noerr-Pennington* doctrine immunizes petitioning activity not only from federal antitrust laws but also from related state law claims of unfair competition. *See VIM, Inc. v. Somerset Hotel Ass'n*, 19 F. Supp. 2d 422, 430 (W.D. Pa. 1998), *aff'd without op.*, 187 F.3d 627 (3d Cir. 1999); *Suburban Restoration Co. v. ACMAT Corp.*, 700 F.2d 98, 101 (2d Cir. 1983).

Purepac argues in response that the factual allegations presented in support of its federal claims also support its common law claims. Purepac claims that, accordingly, its unfair competition counterclaims survive this motion for the same reasons that its federal antitrust counterclaims do.

Purepac is correct. In reviewing motions to dismiss both federal and New Jersey antitrust or unfair competition claims, when an antitrust plaintiff sufficiently alleges federal antitrust violations in the pleadings, "it is fair to say that the conduct states a claim under the much broader common law tort of unfair competition." *Biovail Corp. Int'l v. Hoechst AG*, 49 F. Supp. 2d 750, 777 (D.N.J. 1999); December 22 Opinion, 2000 WL 34213890, at *10; *see also* Restatement (Third) of Unfair Competition § 1 cmt. g (1995) (engaging in "an unlawful restraint of trade" constitutes unfair competition). Purepac's state law counterclaims will, therefore, be dismissed or survive to the same extent, and for the same reasons, as its federal antitrust counterclaims.

has asserted counterclaims of monopolization and attempted monopolization under Section 2 of the Sherman Act, which provides in pertinent part that "[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony." 15 U.S.C. § 2. Section 16 of the Clayton Act allows a person "threatened [with] loss or damage by a violation of the antitrust laws" to seek injunctive relief. The Clayton Act includes the Sherman Act as one of the applicable "antitrust laws."

A claim for monopolization has two elements: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).[13] A monopolization claim does not require proof of the specific intent to monopolize, demanding only proof of "a general intent to do the act, for no monopolist monopolizes unconscious of what he is doing." *Times-Picayune Publ'g Co. v. United States*, 345 U.S. 594, 626 (1953) (internal quotations and citations omitted). Nevertheless, "the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive conduct." *Verizon Commc'ns v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004). This requirement is particularly important in the patent context, because patents inherently grant certain rights to exclude competition. Actions that are permissible under the patent laws, such as the mere maintenance of the statutory patent monopoly, cannot therefore give rise to antitrust liability.

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[13] Monopoly power is defined as "the power to control prices or to exclude competition." *Barr Labs., Inc. v. Abbott Labs.*, 978 F.2d 98, 111-12 (3d Cir. 1992).

See, e.g., *Hoffman-La Roche Inc. v. Genpharm Inc.*, 50 F. Supp. 2d 367, 378 (D.N.J. 1999); *Sheet Metal Duct, Inc. v. Lindab, Inc.*, No. 99-6299, 2000 WL 987865, at *2-3 (E.D. Pa. July 18, 2000).[14]

A claim for attempted monopolization has three elements: (1) predatory or exclusionary conduct; (2) the possession of the specific intent to monopolize; and (3) a dangerous probability of achieving monopoly power or succeeding in the attempt to monopolize. *Ideal Dairy Farms, Inc. v. John Labatt, Ltd.*, 90 F.3d 737, 750 (3d Cir. 1996) (citing *Spectrum Sports,* 506 U.S. at 454-58). "Whether a party violates § 2 of the Sherman Act by attempting to monopolize is a question of proximity and degree." *Id*. (citations omitted). To determine whether there is a "dangerous probability of monopolization," courts will consider "the relevant market and the

[14] As one court observed, "[t]he presence of a patent informs our entire analysis here, because patent laws and antitrust laws exist in tension, as the patent laws protect monopoly power while antitrust laws seek to restrain it. ... Thus, any allegation of antitrust resulting from a patent must extend beyond the rights granted in the patent, and conduct permissible under the patent laws cannot trigger antitrust liability." *Sheet Metal Duct, Inc.*, 2000 WL 987865, at *2 (internal quotations and citations omitted).

Patent holders can, however, violate antitrust laws if they seek to expand the limited monopoly granted by their patents. *See, e.g.*, *DiscoVision Assoc. v. Disc Mfg., Inc.*, Nos. 95-21 & 95-345, 1997 WL 309499, at *8 (D. Del. Apr. 3, 1997) (citing *United States v. Westinghouse Elec. Corp.*, 648 F.2d 642, 647 (9th Cir. 1981)). Furthermore, "antitrust liability under section 2 of the Sherman Act may arise when a patent has been procured by knowing and willful fraud, the patentee has market power in the relevant market, and has used its fraudulently obtained patent to restrain competition." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1367 (Fed. Cir. 1998), *cert. denied*, 526 U.S. 1130 (1999). In addition, a claim may be stated for violation of Section 2 if the patentee brings an infringement suit as "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961) ("*Noerr*"). Antitrust claims are, moreover, frequently based on allegations of manipulation of the Hatch-Waxman regulatory framework. *See, e.g.*, *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006) ("*Teva Pharmaceuticals*"); *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522 (D.N.J. 2004) ("*Remeron*").

defendant's ability to lessen or destroy competition in that market." *Spectrum Sports*, 506 U.S. at 456.[15]

2. Allegations Concerning Warner-Lambert's Anticompetitive Conduct

Purepac contends that Warner-Lambert undertook an overarching scheme to delay and preclude generic competition for Neurontin by: (1) intentionally withholding material prior art from the Patent Office during prosecution of the '482 Patent in order to delay the issuance of that patent and obtain successive 30-month stays of FDA approval for Purepac's products; (2) abusing FDA regulations by certifying that the '476 and '479 Patents covered the approved compounds in and uses of Neurontin, while knowing that such certifications were false; and (3) filing objectively baseless patent-infringement lawsuits asserting the '476 and '479 Patents against Purepac. Purepac alleges that Warner-Lambert's objective was to obtain more market exclusivity for Neurontin than the patent laws and regulatory system allow.

a. Allegations Of Patent Prosecution Misconduct

Purepac alleges that Warner-Lambert intentionally withheld material prior art from the Patent Office during the prosecution of the '482 Patent, so that the patent would issue at a more optimal time. Beyond the allegations presented in support of its patent misuse affirmative defense, which also apply here, Purepac alleges that Warner-Lambert breached its duty of candor during the prosecution process by failing to cite all known, relevant prior art in its initial patent

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[15] "[A]lthough the size of a defendant's market share is a significant determinant of whether a defendant has a dangerous probability of successfully monopolizing the relevant market, it is not exclusive." *Barr Labs.,* 978 F.2d at 112. "Other factors to be considered include the strength of the competition, probable development of the industry, the barriers to entry, the nature of the anticompetitive conduct, and the elasticity of consumer demand." *Id.*; *see also Crossroads Cogeneration Corp. v. Orange & Rockland Util., Inc.*, 159 F.3d 129, 141 (3d Cir. 1998).

applications. Purepac claims that Warner-Lambert purposefully relied on regulations requiring confidentiality for pending patent applications to conceal its allegedly inequitable conduct until the '482 Patent finally issued.

Furthermore, Purepac argues that Warner-Lambert sought to delay the issuance of the '482 Patent in order to obtain an additional, successive 30-month stay of generic approval that would not run consecutively with those already in place. If Warner-Lambert had not withdrawn the '270 Application and the '482 Patent had issued in 1995, Purepac would have been able to address all of Warner-Lambert's gabapentin patents in its initial ANDAs. Any 30-month stays triggered by the ANDAs would, therefore, have run concurrently. Purepac alleges that instead "Warner-Lambert's inequitable conduct and failure to prosecute expeditiously enabled it to trigger a first 30-month stay based on the earlier-issued ... '476 Patent, followed by a second 30-month stay based on the later-issued '482 Patent." Purepac Answer ¶ 122.

b. Allegations Of Improper Orange Book Listings

Purepac alleges that Warner-Lambert abused FDA regulations and the Orange Book listing process by improperly certifying that the '476 and '479 Patents covered Neurontin, with anticompetitive intent and effect.

First, Purepac alleges that the listing of these patents was tied to the withdrawal of the '270 Application. Warner-Lambert, according to Purepac, felt that it was commercially able to withdraw the '270 Application and delay the '482 Patent because these listings, and the subsequent 30-month stays and litigation they enabled, protected the company's control over the gabapentin market in the interim. Without the Orange Book listings, it would allegedly have

been in Warner-Lambert's better interests to prosecute the '482 Patent expeditiously in order to gain similar protections.

Purepac also alleges that Plaintiffs listed these patents despite knowing that the patents did not actually cover Neurontin. In order to have them listed, Plaintiffs certified that the '476 and '479 Patents "cover a crystal form and the use of Neurontin," respectively. Purepac Answer ¶ 125. Purepac alleges that such certifications were false because (a) the '476 Patent covers gabapentin monohydrate, not a "crystal form" of Neurontin, which is composed of gabapentin anhydrous; and (b) the '479 Patent claims the treatment of neurodegenerative diseases rather than Neurontin's sole approved use for the treatment of epilepsy.[16]

Purepac's allegations that Warner-Lambert knew these listings were improper rest in large part on internal Warner-Lambert projections of generic competition, which were tied to the expiration of the '544 Patent in 2000, rather than the expiration of the '476 and '479 Patents in 2008 and 2010. Other internal documents indicate that Warner-Lambert chose not to seek FDA

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[16] According to Purepac, "Gabapentin monohydrate is not a component in Warner-Lambert's Neurontin products. Warner-Lambert tested formulations containing gabapentin monohydrate as the active ingredient and found them unsuitable because the additional water caused problems. Thus, gabapentin monohydrate and gabapentin anhydrous result in formulations with dissimilar characteristics. The FDA never authorized Warner-Lambert to use gabapentin monohydrate as a component in any Neurontin products. Neurontin products employ gabapentin anhydrous as the active ingredient." Purepac Answer ¶ 130. Purepac cites to statements made by Warner-Lambert to the Patent Office during the prosecution of the '476 Patent which indicated that the claimed gabapentin monohydrate differed from the prior art of the '175 or '544 Patents.

With respect to the '479 Patent, Purepac emphasizes that Warner-Lambert certified that the '479 Patent covered "the use of Neurontin," even though the only approved use of Neurontin was as a secondary treatment for epilepsy. *Id.* ¶ 136. Purepac further alleges that "[w]hen Warner-Lambert submitted the '479 patent for listing in the Orange Book, Warner-Lambert knew that it could not truthfully declare that the '479 patent covers the formulation, composition and/or method of use of Neurontin®." *Id.* ¶ 138

approval for additional indications because there was not enough time to do so before the expiration of the patents that Warner-Lambert believed were protecting the market. According to Purepac, if Warner-Lambert had "expected these patents to provide real protection for its Neurontin monopoly, its contemporaneous documents would have projected patent protection out until 2008 or 2010," rather than 2000. *Id*. ¶ 147.

c. Allegations Of Sham Patent Litigation

Purepac's final category of alleged anticompetitive conduct concerns the "objectively baseless" patent-infringement lawsuits filed to enforce the '476 and '479 patents against Purepac. As discussed, Warner-Lambert sued Purepac, on the basis of its ANDAs, for infringing the '476 and '479 Patents. Purepac now alleges that these lawsuits were objectively baseless and initiated solely to prevent or delay the approval and launch of Purepac's generic products by imposing additional regulatory hurdles and extra costs.

Purepac rests these allegations on the following claims: (1) that Warner-Lambert filed its lawsuits before testing samples of Purepac's generic product, which do not contain the gabapentin monohydrate compound covered by the '476 Patent; (2) that Warner-Lambert initiated the Tablet Lawsuit notwithstanding discovery in the Capsule Lawsuit revealing that the gabapentin anhydrous used by Purepac was manufactured abroad, and, therefore, not actionable; (3) that Warner-Lambert initiated the Tablet Lawsuit notwithstanding discovery in the Capsule Lawsuit revealing that Purepac's supplier manufactured gabapentin anhydrous, not gabapentin monohydrate, as claimed in the '476 Patent; and (4) that Warner-Lambert withdrew its claims of infringement of the '476 Patent before even reaching trial because information developed in discovery undermined the contention that Purepac was infringing the '476 Patent.

According to Purepac, these lawsuits were simply a pretext for Warner-Lambert's attempts to injure, destroy, or prevent generic competition. Purepac alleges that, in particular, Warner-Lambert planned these lawsuits in order to use the '476 and '479 Patents as a "stop gap" to extend the term of the '544 Patent until the '482 Patent issued and Warner-Lambert could obtain another 30-month stay. Warner-Lambert allegedly had no procompetitive justification for its conduct and such conduct was the "direct, proximate, and reasonably foreseeable cause of Purepac's foreclosure from the relevant market." *Id.* ¶ 181. Finally, Purepac alleges that "[e]ven if Warner-Lambert's resort to the administrative and judicial processes as alleged herein were not without probable cause, its actions were part and parcel of an overall anticompetitive scheme to monopolize and restrain trade in the market for gabapentin anhydrous." *Id.* ¶ 187.

3. Antitrust Injury

Warner-Lambert argues that Purepac's antitrust counterclaims should be dismissed because Purepac has not suffered an antitrust injury from Warner-Lambert's allegedly anticompetitive conduct. Antitrust plaintiffs must establish standing to pursue their claims. A threshold requirement for antitrust standing is proof of "antitrust injury," which requires that the injury be "causally linked to an illegal presence in the market." *Brunswick v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977); s*ee also Barton & Pittinos, Inc. v. SmithKline Beecham Corp.*, 118 F.3d 178, 182 (3d Cir. 1997) ("Antitrust injury is a necessary ... condition of antitrust standing."). To establish antitrust injury a plaintiff must show both harm of the type the antitrust laws were intended to prevent; and an injury to the plaintiff which flows from that which makes the defendant's actions unlawful. *Gulfstream III Assocs., Inc. v. Gulfstream Aerospace Corp.*,

995 F.2d 425, 429 (3d Cir. 1993). Once an antitrust injury has been established, the plaintiff must further establish that he or she is a proper antitrust plaintiff.[17]

Purepac has alleged that Warner-Lambert manipulated the regulatory advantages afforded by its patents to prevent Purepac's entry into the Neurontin marketplace. According to Purepac, "Warner-Lambert's pattern of predatory pricing and anticompetitive conduct delayed and hindered entry of generic gabapentin anhydrous drugs capable of competing with Warner-Lambert's lucrative branded drug Neurontin®." Purepac Answer ¶ 46. Purepac further alleges that but for such anticompetitive conduct, Purepac would have launched its generic gabapentin products at least 18 months earlier than it did. *Id*. ¶ 49.

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[17] Antitrust standing requirements insure that litigants will use the antitrust laws to prevent anticompetitive actions and to deal only with economic problems whose solutions those laws were intended to effect. To this end, an antitrust plaintiff must allege more than constitutional standing (*i.e.*, allegations of a case or controversy) to establish standing to pursue antitrust violations. *See* 54 Am. Jur. 2d Monopolies and Restraints of Trade § 400. In reaching a determination on standing, courts must consider the following:

> (1) whether there is a causal connection between an antitrust violation and harm to the plaintiff and the defendants intended to cause that harm; (2) whether the nature of the plaintiff's alleged injury was of the type the antitrust laws were intended to forestall; (3) the directness or indirectness of the asserted injury; (4) whether the claim rests on some abstract or speculative measure of harm; and (5) the strong interest in keeping the scope of complex antitrust trials within judicially manageable limits, avoiding both duplicative recoveries and the complex apportionment of damages.

December 22 Opinion, 2000 WL 34213890, at *7-8; *see also Indium Corp. of America v. Semi-Alloys, Inc.*, 781 F.2d 879, 882 (Fed. Cir.1985) (quoting *Associated Gen. Contractors v. Cal. State Council of Carpenters*, 459 U.S. 519, 534-45 (1983)); *St. Clair v. Citizens Fin. Group*, No. 08-1257, 2008 WL 4911870, at *4 (D.N.J. 2008) (same).

Nevertheless, there is no black-letter rule for determining standing in every antitrust case. *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 922 (3d Cir. 1999) (observing that "[t]he [Supreme] Court has emphasized that lower courts should avoid applying bright-line rules and instead should analyze the circumstance of each case, focusing on certain key factors.").

Courts have regularly held that such conduct creates the type of anticompetitive effect that the antitrust laws were designed to prevent, and therefore constitutes antitrust injury. *See, e.g.*, *Abbott Labs. v. Mylan Pharm., Inc.*, No. 05-6561, 2007 WL 625496, at *4-5 (N.D. Ill. Feb. 23, 2007) (holding that Defendant Mylan established antitrust injury and standing by alleging that Plaintiff Abbott Labs used "the regulatory advantage afforded via a fraudulently-procured patent to prevent Mylan's entrance into the relevant market" and that Mylan had been ready to enter the market "but for Abbott's actions in fraudulently procuring the patents.") ("*Mylan*"); *Teva Pharmaceuticals*, 432 F. Supp. 2d at 431 (finding antitrust injury on the basis of allegations that Teva was excluded from a market while patent litigation, concerning a patent allegedly obtained by fraud, remained unresolved because "[s]uch exclusion from the market is 'precisely the type of injury that the antitrust laws were intended to prevent,' because it reflects an injury to competition.") (internal citations omitted).

Warner-Lambert argues, however, that Purepac has failed to establish that it has suffered an antitrust injury because none of Warner-Lambert's allegedly anticompetitive activities proximately caused the delayed launch of Purepac's generic gabapentin products. These arguments focus on the second element of the *Gulfstream* standard and are essentially causation arguments. Warner-Lambert claims, for example, that any roadblocks imposed by its own actions were removed well before Purepac actually launched its products, and that Purepac has failed to allege facts establishing that Purepac would have launched any earlier but for such roadblocks.

Warner-Lambert is correct that proving antitrust injury depends, at least in part, on establishing proximate cause. *See Brunswick*, 429 U.S. at 489. Warner-Lambert's arguments

that Purepac's failure to prove proximate cause at this stage of the proceeding requires the dismissal of all antitrust counterclaims are, nonetheless, incorrect.

First, the Court notes that "the existence of antitrust injury is not typically resolved through motions to dismiss." *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997) (citing *Brader v. Allegheny Gen. Hosp.*, 64 F.3d 869, 876 (3d Cir. 1995)); *see also In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003) (denying motion to dismiss antitrust claims on similar grounds because "Plaintiffs may be able to prove that the allegedly frivolous lawsuits 'materially caused' their alleged injuries.") ("*Wellbutrin*").

Second, in arguing that none of its alleged anticompetitive activities proximately caused the delay in Purepac's launch, Warner-Lambert inappropriately compartmentalizes or fragments Purepac's allegations concerning an overall monopolization scheme. Purepac need not allege proximate cause or antitrust injury separately for each component of the alleged scheme. The injuries inflicted by Warner-Lambert's allegedly anticompetitive activities should, instead, be viewed as a whole. *Biovail Corp.*, 49 F. Supp. 2d at 767 ("Again, this court will not evaluate whether each and every anticompetitive act upon which Biovail's antitrust claims are based directly caused Biovail injury. Instead, it will determine whether Biovail was injured by the anticompetitive conduct as a whole, an analysis the court will refrain from conducting until it is established that an antitrust violation has been pleaded."); *see also SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 702 (E.D. Pa. 2004) (same); *Teva Pharmaceuticals*, 432 F. Supp. 2d at 430-31.

Similarly, Purepac need not allege that Warner-Lambert's anticompetitive actions were the sole cause of its injury. *See Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 n.9 (1969) (noting that an antitrust plaintiff may establish antitrust injury with "proof of some damage flowing from the unlawful conspiracy; inquiry beyond this minimum point goes only to the amount and not the fact of damage. It is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury."); *Greater Rockford Energy & Tech. Corp. v. Shell Oil Co.*, 998 F.2d 391, 401 (7th Cir. 1993) ("An antitrust violation need not be the sole cause of the alleged injuries, but the plaintiff must establish, with a fair degree of certainty, that the violation was a material element of, and substantial factor in producing, the injury."). The Court recognizes that requiring otherwise "would effectively deny private remedies, because multiple causes always affect everyone." 2 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 338a at 317 (2d Ed. 2000).

Nor must Purepac completely discredit in its initial pleadings all possible intervening causes of its delayed launch, particularly Purepac's failure to obtain tentative generic approval from the FDA. Several courts have held that a finding of antitrust injury cannot be tied to the status of FDA approval of a generic applicant. *See Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 90 F. Supp. 2d 540, 544-46 (D.N.J. 2000) (accepting the counterclaimants' contention that they need not demonstrate FDA approval in order to invoke antitrust standing); *Mylan*, 2007 WL 625496, at *4 n.2 (observing that "the structure of these statutes means that, if antitrust injury were tied to the status of FDA approval relative to the required timing of the suit, antitrust injury would be 'wholly contingent on the vagaries of timing of agency action' and go against the purpose of the Hatch-Waxman Act. If the FDA approved the ANDA before the patentee filed its

motion to dismiss the antitrust counterclaim, then antitrust injury would exist; but if the FDA took too long to complete the approval process, the generic company would be unable to establish injury to support its antitrust counterclaim.") (internal citations omitted).

Finally, and perhaps more importantly, Judge Lifland has already determined that Purepac has sufficiently alleged antitrust injury and the requisite causal connection.[18] In his December 22 Opinion, Judge Lifland held that Warner-Lambert filed patent infringement actions against Purepac and, in doing so, delayed FDA approval of Purepac's ANDAs. December 22 Opinion, 2000 WL 34213890, at *8. Because the decision to initiate litigation was made by Warner-Lambert, rather than the FDA, Judge Lifland found the decision to be a purposeful exercise of power under Hatch-Waxman regulations "to temporarily foreclose Purepac's access to the market for gabapentin," as Purepac had alleged. *Id.* As a result, Judge Lifland held that Purepac

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[18] Warner-Lambert appears to overlook the "law of the case" doctrine, which "limits relitigation of an issue once it has been decided" in an earlier stage of the same litigation. *Hamilton v. Leavy*, 322 F.3d 776, 786-87 (3d Cir. 2003); *In re Cont'l Airlines, Inc.*, 279 F.3d 226, 233 (3d Cir. 2002) (the law of the case doctrine stands for the proposition that "when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages in the same case") (quoting *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816, (1988)). The doctrine is designed to "promote finality, consistency, and judicial economy." *Hamilton*, 322 F.3d at 787. As the Third Circuit has explained:

> The law of the case doctrine does not limit a federal court's power; rather, it directs its exercise of discretion. ... A court has the power to revisit prior decisions of its own or of a coordinate court in any circumstance, although as a rule courts should be loathe to do so in the absence of extraordinary circumstances such as where the initial decision was clearly erroneous and would work a manifest injustice. This Circuit has recognized several "extraordinary circumstances" that warrant a court's reconsideration of an issue decided earlier in the course of litigation. They include situations in which: (1) new evidence is available; (2) a supervening new law has been announced; or (3) the earlier decision was clearly erroneous and would create manifest injustice.

Pub. Interest Research Group of N.J., Inc. v. Magnesium Elektron, Inc., 123 F.3d 111, 116-17 (3d Cir. 1997) (internal citations omitted).

had sufficiently alleged a causal connection between Warner-Lambert's conduct and the injury imposed and could, therefore, pursue its antitrust counterclaims.

Warner-Lambert did not argue in the papers now before the Court that any of the exceptions to the law of the case doctrine should apply. Indeed, Warner-Lambert's briefs were written without any mention of the law of the case doctrine. When pressed by the Court at oral argument, counsel explained that Warner-Lambert seeks to revisit this issue primarily because Judge Lifland failed to consider the intervening causes that delayed Purepac's launch. *See* April 22 Transcript at 77-109. The arguments concerning intervening causes are, however, unpersuasive as a basis to depart from the law of the case here. Purepac need not "allege (or dispose of) all alternative theories of causation to survive a motion to dismiss." *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 535 (D.N.J. 2004). Purepac is "simply required to allege facts showing that [it] suffered the type of injury or harm the antitrust laws were intended to prevent, and that [its] injury flows from the [Warner-Lambert's] anti-competitive conduct." *Id*. Purepac had satisfied this standard in its original pleadings, and has done so again with its amended pleadings.[19]

Accordingly, on the basis of Judge Lifland's earlier analysis as well as the factual allegations in Purepac's Amended Answer, this Court finds that Purepac has sufficiently alleged that it suffered an antitrust injury and that such injury flowed from Warner-Lambert's allegedly unlawful conduct. When evaluated as a whole, the Court need not determine whether each

[19] While additional facts and evidence may have developed since Judge Lifland issued the December 22 Opinion, a review of Purepac's Amended Answer indicates that Purepac has provided additional allegations concerning the antitrust injuries it has suffered, and in support of its standing to pursue them, beyond those that Judge Lifland initially deemed sufficient.

element of the alleged scheme imposed its own antitrust injury. Warner-Lambert's motion to dismiss Plaintiffs' antitrust counterclaims is, therefore, denied.

4. Purepac's "Overall Scheme" Claim

Purepac contends that Warner-Lambert undertook an "overall scheme to forestall, preclude, and delay generic competition" for Neurontin. Purepac Answer ¶ 104. Although Warner-Lambert allegedly carried out this scheme through its misconduct during the prosecution of the '482 Patent, improper listing of the '476 and '479 Patents in the Orange Book, and pursuit of sham infringement litigation to enforce the '476 and '479 Patents, Purepac is not asserting antitrust violations on the basis of any of those activities independently. Rather, Purepac repeatedly emphasizes that it is targeting Warner-Lambert's overall pattern of alleged abuse of the regulatory process, and that "[t]he anticompetitive effects and legality of the alleged monopolization scheme must be evaluated as a whole." Defendants' Brief in Opposition to Plaintiffs' Motion to Dismiss or Strike Certain Affirmative Defenses and Counterclaims at 20, *In re Gabapentin Patent Litig.*, No. 00-2931 (D.N.J. Aug. 11, 2008) ("Purepac's Opposition Brief").

Warner-Lambert moves to dismiss Purepac's antitrust counterclaims because none of the three anticompetitive acts alleged by Purepac independently states an antitrust claim. Purepac cannot, according to Warner-Lambert, "lump together otherwise lawful conduct to state an antitrust claim." Plaintiffs' Reply Brief in Support of Their Motion to Strike Certain Affirmative Defenses and to Dismiss Certain Counterclaims of Purepac Defendants at 17, *In re Gabapentin Patent Litig.*, No. 00-2931 (D.N.J. Sept. 17, 2008) ("Plaintiffs' Reply Brief"). Warner-Lambert further emphasizes that not only are the categories of conduct at issue lawful, they are expressly

authorized, if not encouraged, by the legal or regulatory framework in which they occur. "Conduct expressly authorized by one law or governmental agency cannot be simultaneously subject to antitrust scrutiny," Warner-Lambert asserts, in part because "allowing a plaintiff to combine a defendant's lawful and unlawful activities effectively would eliminate the requirement that an antitrust plaintiff must show a 'casual connection between the [defendant's] antitrust violations and [plaintiff's] injury.'" *In re Indep. Serv. Org. Antitrust Litig.*, 989 F. Supp. 1131, 1142 (D. Kan. 1997) (quoting *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 700 (1962) ("*Continental Ore*")). Courts that have examined antitrust allegations as an "overall scheme" have only done so, Plaintiffs claim, because some of the targeted conduct was already recognized as an antitrust violation.[20] As counsel for Warner-Lambert asserted at oral argument, "[i]f each piece [of the alleged scheme] is lawful, or not unlawful, then you can't assert an overall scheme to monopolize." April 22 Transcript at 117.

Warner-Lambert's arguments are not supported by the prevailing case law on this issue. When determining antitrust liability based on a collection of factual allegations, such as those made by Purepac, "courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation." *LePage's*, 324 F.3d at 162 (citing *Continental Ore*, 370 U.S. at 699 ("In cases such as this, plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean

[20] Warner-Lambert explains that *Remeron*, for example, involved the late listing of a patent in the Orange Book in violation of regulatory requirements, 335 F. Supp. 2d at 532; *LePage's Inc. v. 3M* involved exclusive dealing arrangements and bundled rebates which were both illegal exclusionary conduct, 324 F.3d 141, 154, 157 (3d Cir. 2003); *Continental Ore* involved an illegal group boycott, 370 U.S. at 698-99; and *Aspen Highland Skiing Corp. v. Aspen Skiing Co.* involved a refusal to deal. 738 F.2d 1509 (10th Cir. 1984), *aff'd*, 472 U.S. 585 (1985).

after scrutiny of each. ... The character and effect of a conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole.")); *see also City of Anaheim v. S. Cal. Edison Co.*, 955 F.2d 1373, 1376 (9th Cir. 1992) ("[I]t would not be proper to focus on specific individual acts of an accused monopolist while refusing to consider their overall combined effect. ... We are dealing with what has been called the 'synergistic effect' of the mixture of the elements."). If a plaintiff can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the antitrust laws, that series of actions, as an overall scheme, may trigger antitrust liability.

Indeed, courts have routinely upheld the validity of "overall monopolization scheme" claims in the patent context. *See, e.g.*, *Remeron*, 335 F. Supp. 2d 522. Moreover, courts have allowed antitrust plaintiffs to pursue such claims even in the absence of allegations that each of the scheme's predicate actions was independently violative of antitrust laws. As the court noted in *Teva Pharmaceuticals*, "[p]laintiffs are entitled to claim that individual acts are antitrust violations, as well as claiming that those acts as a group have an anticompetitive effect even if the acts taken separately do not." 432 F. Supp. 2d at 428.[21]

[21] *See also SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 702 (E.D. Pa. 2004) (denying motion to dismiss antitrust counterclaims based on a "larger scheme to maintain [a] monopoly," because of the court's obligation to "consider the anticompetitive effect of [plaintiff's] acts as a whole," even though certain elements of the scheme did not independently produce an antitrust injury); *Kobe, Inc. v. Dempsey Pump Co.*, 198 F.2d 416, 425 (10th Cir. 1952) ("The infringement action and the related activities, of course, in themselves were not unlawful, and standing alone would not be sufficient to sustain a claim for damages which they may have caused, but when considered with the entire monopolistic scheme which preceded them we think, as the trial court did, that they may be considered as having been done to give effect to the unlawful scheme."); *Biovail Corp.*, 49 F. Supp. 2d at 766.

Reviewing Purepac's allegations of anticompetitive conduct in their totality, it is clear that Purepac has adequately pled antitrust counterclaims. Purepac has alleged in detail how Warner-Lambert engaged in a comprehensive multifaceted scheme to monopolize the market for gabapentin anhydrous and how that scheme was designed to obtain more market exclusivity for Neurontin than the patent laws allow, thereby constituting the willful acquisition or maintenance of otherwise allowable monopoly power. The Court need not determine whether the three underlying elements of Purepac's alleged scheme are violations of the antitrust laws in their own right. As the Supreme Court stated in the context of evaluating a Section 2 claim:

> It is not the form of the combination or the particular means used but the result to be achieved that the statute condemns. It is not of importance whether the means used to accomplish the unlawful objective are in themselves lawful or unlawful. Acts done to give effect to the conspiracy may be in themselves wholly innocent acts. Yet, if they are part of the sum of the acts which are relied upon to effectuate the conspiracy which the statute forbids, they come within its prohibition.

Am. Tobacco Co. v. United States, 328 U.S. 781, 809 (1946). Accordingly, the Court finds that Purepac has adequately stated a claim for monopolization and attempted monopolization on the basis of allegations that Warner-Lambert has engaged in an overall scheme to monopolize the market for gabapentin anhydrous.[22]

5. *Noerr-Pennington* Immunity And The Proper Scope Of The "Overall Scheme" Claim

Warner-Lambert's arguments that certain of the anticompetitive acts alleged by Purepac are immune from antitrust liability under the *Noerr-Pennington* doctrine require further consideration. Conduct protected by *Noerr-Pennington* immunity cannot be properly included

[22] Purepac has, moreover, sufficiently alleged that some of the activities that make up the challenged monopolization scheme may constitute independent antitrust violations. *See* Sections III.C.5.b, c, below.

within the scope of the monopolization scheme at issue. *United Mine Workers v. Pennington*, 381 U.S. 657, 670 (1965) (holding that conduct that is protected from antitrust liability "is not illegal, either standing alone or as part of a broader scheme itself violative of the Sherman Act.") ("*Pennington*"). Warner-Lambert asserts that its efforts to enforce the '476 and '479 Patents against Purepac through infringement actions and its conduct in prosecuting the '482 Patent are both immune from antitrust liability and any allegations based upon those activities must be dismissed.[23]

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[23] Warner-Lambert does not move to dismiss Purepac's allegations of improper Orange Book listings on immunity grounds, arguing instead that Purepac's claims based on improper listing of the '476 and '479 Patents fail because both listings were proper as a matter of law. This approach is consistent with case law establishing that the listing of patents in the Orange Book is not government petitioning as defined by the *Noerr-Pennington* doctrine and therefore not eligible for *Noerr-Pennington* immunity. *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 372-73 (S.D.N.Y. 2002) ("[L]isting [patents in the Orange Book] is much more like the filing of a tariff than the kind of conduct through which private parties seek to influence governmental decision making and that has traditionally been immunized under the *Noerr-Pennington* doctrine. ... This conduct is therefore not immune from liability under the Sherman Act.") ("*Buspirone*"); *Mylan*, 293 F. Supp. 2d at 458-59 ("This Court finds that filing a patent for listing in the Orange Book is not 'petitioning activity' within the meaning of the *Noerr-Pennington* doctrine because the FDA's action in listing Organon's '099 patent in the Orange Book was not an independent governmental determination, but rather a purely ministerial function."). The Court need not address Warner-Lambert's challenges to Purepac's improper listing allegations because, as just discussed, the propriety or lawfulness of the predicate activities of a monopolization scheme do not determine whether the scheme itself is actionable or unlawful.

Nonetheless, the Court notes that Purepac has amply pled that Warner-Lambert listed the '476 and '479 Patents in the Orange Book with anticompetitive purpose and effect. Judge Lifland allowed Purepac to pursue improper listing claims on the basis of its original pleadings. December 22 Opinion, 2000 WL 34213890, at *6-7. The Court finds similarly sufficient allegations in its Amended Answer.

Viewing such allegations in the light most favorable to Purepac, discovery could demonstrate fraudulent, anticompetitive, or improper conduct by Warner-Lambert that proves that these listings were made in furtherance of an overall scheme to monopolize. Purepac is entitled to attempt to meet its burden of proof by developing facts that will show that the listings were improper because they did not cover the drugs or uses in the NDA and because a claim of patent infringement could not be reasonably asserted against the generic applicants. Warner-Lambert's arguments that such listings were proper as a matter of law address the merits of

a. The *Noerr-Pennington* Doctrine And Its Exceptions

The *Noerr-Pennington* doctrine protects activities by parties to influence government policy or legislation from antitrust claims. *See Noerr*, 365 U.S. 127; *Pennington*, 381 U.S. 657. The doctrine nominally began as a judicially-created limitation on the scope of the Sherman Act with respect to activities by parties to petition the government to take a certain course of action beneficial to them and harmful to their competitors. It has since been extended to protect those who petition for other forms of governmental action. *See, e.g.*, *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508 (1972) (administrative and judicial proceedings); *City of Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365 (1991) (municipal ordinances) ("*Omni*"). The doctrine has also been expanded to include litigation to protect rights such as patents. *See Professional Real Estate Investors v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993) ("*PRE*").

The *Noerr-Pennington* doctrine is not, however, without limit. The *Noerr* Court acknowledged that activity "ostensibly directed toward influencing governmental action" would not be immune from antitrust liability if it constituted "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *Noerr*, 365 U.S. at 144. Courts have held that activities in which the government entity merely plays a ministerial role, rather than making an independent determination, should

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Purepac's claims, rather than the sufficiency of the pleadings. Because Warner-Lambert's Orange Book listings for the '476 and '479 Patents are not eligible for *Noerr-Pennington* immunity and because Purepac has adequately alleged that such listings were a part of an overall pattern of abuse of the Hatch-Waxman regulatory process, these allegations are properly included within the scope of the alleged monopolization scheme at issue. Warner-Lambert's arguments would be better addressed at the summary judgment stage than upon a motion to dismiss.

not be afforded *Noerr-Pennington* immunity. *See Buspirone*, 185 F. Supp. 2d at 369-73; *Organon*, 293 F. Supp. 2d at 458-59. Litigation will not be protected when a court determines that it is "sham" litigation, i.e., instituted for the sole purpose of precluding competition. *PRE*, 508 U.S. at 60-61 (quoting *Noerr*, 365 U.S. at 144). And the "[f]raudulent procurement of a patent or the enforcement of a patent obtained by fraud may provide the basis for Sherman Act Section 2 liability if the other elements of a Sherman Act claim are present." *Remeron*, 335 F. Supp. 2d at 528 (citing *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp*., 382 U.S. 172, 177 (1965)).

b. Sham Infringement Actions

Purepac claims that Warner-Lambert initiated the Capsule and Tablet Lawsuits "without an objective basis" and "with an intent to delay, hamper, hinder, and impede Purepac from obtaining immediate or early FDA approval of its proposed gabapentin anhydrous" products. Purepac Answer ¶¶ 158, 164. Warner-Lambert asserts immunity for the Capsule and Tablet Lawsuits because "[l]itigation, including litigation to protect one's patent rights, is presumptively immune from antitrust scrutiny under *Noerr-Pennington*." Plaintiffs' Opening Brief in Support of Their Motion to Strike Certain Affirmative Defenses and to Dismiss Certain Counterclaims of Purepac Defendants at 38, *In re Gabapentin Patent Litig.*, No. 00-2931 (D.N.J. June 16, 2008) ("Plaintiffs' Opening Brief"). Warner-Lambert is entitled to such immunity unless Purepac can establish that the Capsule and Tablet Lawsuits were "sham litigation."

The Supreme Court has established the following test for sham litigation:

> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr*, and an antitrust claim premised on the sham exception must fail. Only if

> challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals "an attempt to interfere directly with the business relationships of a competitor."

PRE, 508 U.S. at 60-61 (quoting *Noerr*, 365 U.S. at 144). The outcome of this analysis is determined, in large part, by a court's finding that the antitrust defendant had probable cause to initiate the litigation being challenged as sham.[24]

Warner-Lambert encourages the Court to decide whether the Capsule and Tablet Lawsuits were sham, as a matter of law and at this relatively early stage of the current litigation, because "[w]here, as here, there is no dispute over the predicate facts of the underlying legal proceeding, a court may decide probable cause as a matter of law." *Id*. at 63. According to Warner-Lambert, a series of earlier rulings clearly establish that the infringement claims concerning the '476 and '479 Patents were not unreasonable, thereby also establishing the

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[24] As the Supreme Court further explained in *PRE*:

> The existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation. The notion of probable cause, as understood and applied in the common law tort of wrongful civil proceedings, requires the plaintiff to prove that the defendant lacked probable cause to institute an unsuccessful civil lawsuit and that the defendant pressed the action for an improper, malicious purpose. Probable cause to institute civil proceedings requires no more than a "reasonabl[e] belie[f] that there is a chance that [a] claim may be held valid upon adjudication." ... When a court has found that an antitrust defendant claiming *Noerr* immunity had probable cause to sue, that finding compels the conclusion that a reasonable litigant in the defendant's position could realistically expect success on the merits of the challenged lawsuit. Under our decision today, therefore, a proper probable cause determination irrefutably demonstrates that an antitrust plaintiff has not proved the objective prong of the sham exception and that the defendant is accordingly entitled to *Noerr* immunity.

Id. at 62 (internal citations omitted).

existence of probable cause and precluding a determination that such claims were objectively baseless.[25]

Purepac, however, does dispute the predicate facts of the Capsule and Tablet Lawsuits, as well as the results and implications of many of the decisions on which Warner-Lambert now relies. Purepac argues that it has adequately alleged the elements of the sham litigation exception to *Noerr-Pennington* immunity, that Warner-Lambert's entitlement to immunity rests upon determinations that flow from disputed factual allegations, and that full development of the record in this proceeding will ultimately prove that Warner-Lambert's earlier infringement actions were sham.

Although "the Court may take judicial notice of the opinions filed in the underlying actions ... the scope of that notice is subject to important limitations. The Court may take judicial notice only of the 'existence of the opinion, which is not subject to reasonable dispute over its

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[25] In support of this argument, Warner-Lambert cites a long list of prior rulings: (1) *Warner-Lambert Co. v. Purepac Pharm. Co.,* Nos. 98-2749, 98-5948, 2003 WL 21698310, at *1 (D.N.J. May 22, 2003) (stating on denial of a motion for attorneys' fees that "there is insufficient evidence to support a conclusion that Warner-Lambert's claim of infringement was unreasonable or that its listing in the Orange Book was improper."); (2) *Warner-Lambert Co. v. Apotex Corp.*, No. 98-4293, 2003 WL 21754948, at *4 (N.D. Ill. July 28, 2003) (rejecting a motion for fees and Rule 11 sanctions and observing that Warner-Lambert "had a reasonable basis to think that it would ultimately discover that Teva performed some step in the production process" that would support an infringement claim); (3) *Warner-Lambert Co. v. Apotex Corp.*, No. 98-4293, 2003 WL 22887861, at *4-5 (N.D. Ill. Dec. 4, 2003) (affirming the rejection of fees and sanctions, noting that "TorPharm has not demonstrated that Warner-Lambert initiated a frivolous suit with respect to this claim," and that Warner-Lambert "had the right to conduct a fair and reasonable investigation of its claims [in discovery]."); (4) *Warner-Lambert Co. v. Apotex Corp.*, No. 98-4293, 1999 WL 259946, at *3, *6 (N.D. Ill. Apr. 8, 1999) (denying a motion for summary judgment because Warner-Lambert was "perfectly entitled" to proceed under a theory of inducement and had submitted sufficient evidence to avoid summary judgment); and (5) *Warner-Lambert Co. v. Purepac Pharm. Co.*, No. 98-2749, slip. op. at 7-8 (D.N.J. Aug. 26, 1999) (denying summary judgment on the inducement claim because there were genuine issues of fact as to "whether Purepac will knowingly and actively induce infringement of the patent.").

authenticity.'" *Wellbutrin*, 2006 WL 616292, at *6 (quoting *S. Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Group Ltd.*, 181 F.3d 410, 426 (3d Cir. 1999)). The Court is not, however, permitted to "make factual findings in this case based on the facts recited in the opinions of other courts." *Id*.

Moreover, when the predicate facts of an allegedly sham lawsuit are disputed, sham litigation claims should not be decided by the court as a matter of law. *In re Relafen Antitrust Litig.*, 346 F. Supp. 2d 349, 361 (D. Mass. 2004) (finding that "'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.") (quoting *Nelson v. Miller*, 227 Kan. 271, 277 (1980)). At this stage of the litigation, the Court's probable cause analysis is based exclusively on the allegations in Purepac's Answer. *Jarrow Formulas, Inc. v. Int'l Nutrition Co.*, 175 F. Supp. 2d 296, 310-11 (D. Conn. 2001) ("Here, all that is required is that the complaint allege facts, which, if proven, show that the defendant is not entitled to *Noerr-Pennington* immunity under the sham litigation exception."); *Skinder-Strauss Assocs. v. Mass. Continuing Legal Educ., Inc.*, 870 F. Supp. 8, 10 (D. Mass. 1994) ("Because [the defendant's] counterclaims allege that the lawsuit filed by [the plaintiff] is objectively baseless and conceals an attempt to interfere directly with the business relationships of a competitor, the counterclaims adequately state a claim and should not be dismissed under Fed. R. Civ. P. 12(b)(6).").[26]

[26] *See also Abraxis Bioscience, Inc. v. Navinta LLC*, No. 07-1251, 2008 WL 2967034, at *7 (D.N.J. July 31, 2008) (holding that defendant had sufficiently alleged the elements necessary to plead sham litigation and that, as a result, plaintiff was not entitled to immunity at the "preliminary stage of the action," but explaining that "upon litigation of the patent infringement claims and upon discovery as to Defendant's Counterclaims, if Defendant does not bear its burden of proof as to a 'sham' litigation, Plaintiff may seek anew Noerr-Pennington immunity.").

Courts have rejected claims of *Noerr-Pennington* immunity made through motions to dismiss in situations similar to that now before this Court. In *Hoffman-LaRoche, Inc. v. Genpharm, Inc.*, for example, the court determined that:

> The resolution of the question whether plaintiffs' suit is objectively baseless as to Genpharm involves the determination of whether plaintiffs undertook a reasonable investigation before filing suit, whether plaintiffs knew or should have known that Genpharm had not infringed the Syntex process patents, and whether a reasonable litigant could have realistically expected success on the merits at the time the suit was filed. Reasonableness is a question of fact, and the Court cannot make such factual determinations on a factual controversy roiled by a motion to dismiss.

50 F. Supp. 2d 367, 380 (D.N.J. 1999). Purepac has raised similar questions about whether Warner-Lambert examined or tested Purepac's proposed generic products before initiating litigation, and whether Warner-Lambert knew, as a result of the Capsule Lawsuit, that Purepac had not infringed the patents at issue in the Tablet Lawsuit. Here, as in other cases, Warner-Lambert's knowledge and intent are "disputed factual issue[s] that the Court [i]s duty-bound to submit to the jury." *Relafen*, 346 F. Supp. 2d at 362. This Court cannot now look to the basis for lines included in other courts' rulings on matters such as sanctions and attorneys' fees to ascertain what analysis was done on the above-enumerated factors; what each court knew or did not know about the full panoply of the litigation; nor what claims were asserted in those cases about the objective reasonableness, or lack thereof, of the infringement actions brought by Warner-Lambert. As a result, the Court cannot make a determination about the existence or want of probable cause for the Capsule and Tablet Lawsuits upon the pending motions to dismiss but will rather reserve judgment on such issues until motions for summary judgment are made.

Additionally, in arguing that Purepac's allegations of sham litigation must be rejected, Warner-Lambert seeks to relitigate rulings already made by Judge Lifland, without addressing the

doctrine of law of the case or arguing that an exception to that doctrine applies. In its initial motion to dismiss, Warner-Lambert had argued that because the Capsule Lawsuit survived summary judgment, it could not be considered objectively baseless. Judge Lifland, however, determined that the denial of summary judgment did not, in and of itself, deem either that lawsuit or related lawsuits objectively reasonable, without specific examination of the basis for the denial. He further concluded that the denial of summary judgment in one proceeding "does not necessarily relate to the asserted basis for antitrust relief" in this proceeding, suggesting that the sham litigation and overall antitrust claims were premised on a broader range of facts and issues. December 22 Opinion, 2000 WL 34213890, at *5. He ultimately concluded that Purepac could pursue sham litigation claims. Warner-Lambert's briefs on the pending motion simply ignored the well-established principle of law of the case and thus offered neither compelling analysis nor reasons to disregard it.[27]

In sum, Purepac has adequately alleged facts, which, if proven, will show that Warner-Lambert's Capsule and Tablet Lawsuits are not entitled to *Noerr-Pennington* immunity under the sham litigation exception. Accordingly, such lawsuits will not be deemed immune from antitrust liability under *Noerr-Pennington* at this stage of the proceeding.[28] Purepac's allegations of sham

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[27] Warner-Lambert does, however, assert that "[m]uch has changed since 2000," and attempts to point the Court to the subsequent decisions denying Rule 11 motions and allegedly finding that Warner-Lambert's infringement claims were not objectively baseless. Plaintiffs' Reply Brief at 26. As noted above, these decisions are not dispositive where, as here, Purepac disputes some of the predicate facts underlying the actions in which those decisions were issued.

[28] The Court notes, however, that after litigation of Warner-Lambert's patent infringement claims and upon discovery as to Purepac's counterclaims, if Purepac is unable to meet its burden of proof as to the sham exception, Plaintiffs may renew their claims for *Noerr-Pennington* immunity.

litigation will not be dismissed and can properly be considered within the scope of Warner-Lambert's overall scheme to monopolize the gabapentin anhydrous market.

c. Patent Prosecution Misconduct

Purepac also alleges that, in their attempts to "gam[e] the regulatory and patent systems to secure more exclusivity than Warner-Lambert was lawfully entitled to receive," Plaintiffs purposefully manipulated the patent prosecution of the '482 Patent in order to expand and secure patent protection for the Neurontin franchise. Purepac Answer ¶ 104. Warner-Lambert's manipulations allegedly included "repeatedly making the same arguments to the patent examiner in response to claim rejections and repeatedly filing continuation applications," as well as withholding material, known, prior art in order to delay the ultimate issuance of the '482 Patent. *Id*. ¶¶ 105, 110-13. Warner-Lambert asserts immunity for its prosecution of the '482 Patent because its "actions constitute quintessential petitioning activity that are protected under the *Noerr-Pennington* doctrine." Plaintiffs' Opening Brief at 28. Plaintiffs claim that "[t]he only exception to immunity under *Noerr-Pennington* in prosecuting and later enforcing a patent is where the petitioning party is shown to have committed fraud on the Patent Office, under *Walker Process Equipment, Inc. v. Food Machinery and Chemical Corp*." *Id*. at 29.

Under the *Walker Process* doctrine, the "[f]raudulent procurement of a patent or the enforcement of a patent obtained by fraud," although an act or result of government petitioning, may provide the basis for antitrust liability. *Remeron*, 335 F. Supp. 2d at 528. To establish a *Walker Process* claim of fraud, an antitrust plaintiff must show: "(1) [a] false representation or deliberate omission of a fact material to patentability (2) made with the intent to deceive the patent examiner (3) on which the examiner justifiably relied in granting the patent, and (4) but

for which misrepresentation or deliberate omission the patent would not have been granted." *Id*. (quoting *C.R. Bard*, 157 F.3d at 1364).

Warner-Lambert argues that Purepac has failed to allege any of the elements of the *Walker Process* exception to *Noerr-Pennington* immunity. According to Plaintiffs, Purepac has alleged an initial failure to disclose the '326 Patent, but not a false representation or omission material to patentability. Furthermore, the '326 Patent was cited to the Patent Examiner before the '482 Patent issued, which arguably prevents Purepac from claiming that but for the misrepresentation or omission the '482 Patent would not have issued. Without pleading a *Walker Process* claim, Warner-Lambert concludes, "Purepac's antitrust claim based on any alleged misconduct with respect to the '482 Patent prosecution must be dismissed." Plaintiffs' Opening Brief at 30.

Warner-Lambert correctly asserts that Purepac has not pled a *Walker Process* claim. Warner-Lambert's argument that the prosecution of the '482 Patent is therefore necessarily immune from antitrust liability is, however, incorrect. Purepac is not asserting that the '482 Patent should not have issued because of fraud on the Patent Office. Indeed, Purepac has conceded that the '482 Patent was not procured by fraud, as contemplated by the *Walker Process* exception. Rather, Purepac is challenging "Warner-Lambert's abuse of Patent Office process to cause the '482 [Patent] to issue in 2000 instead of 1995 for the purpose of triggering a second 30-month stay of FDA approval and extending Warner-Lambert's monopoly." Purepac's Opposition Brief at 24. To that end, Purepac's allegations implicate not the *Walker Process* exception but rather a more generalized "sham" or "sham petitioning" exception to *Noerr-Pennington* immunity.

The *Noerr* Court did not immunize activities which are "ostensibly directed toward influencing governmental action" but which are, in fact, shown to be "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *Noerr*, 365 U.S. at 144. Sham petitioning "encompasses situations in which persons use the governmental *process* - as opposed to the *outcome* of that process - as an anticompetitive weapon. A classic example is the filing of frivolous objections to the license application of a competitor, with no expectation of achieving denial of the license but simply in order to impose expense and delay." *Omni*, 499 U.S. at 380 (citing *Cal. Motor Transp.*, 404 U.S. 508) (emphasis in original). Under this exception to *Noerr-Pennington* immunity, proof of "a pattern of baseless, repetitive claims" may lead "the factfinder to conclude that the administrative and judicial processes have been abused. ... actions of that kind cannot acquire immunity by seeking refuge under the umbrella of 'political expression.'" *Cal. Motor Transp.*, 404 U.S. at 513.

While not referencing "sham petitioning" in those words, Purepac's Answer does contain factual allegations which, if proven, are sufficient to warrant an exception to *Noerr-Pennington* immunity under this theory. Purepac has clearly alleged that Warner-Lambert manipulated the prosecution of the '482 Patent, not to promptly obtain government action in its favor, but rather to delay its issuance, forestall generic competition for Neurontin, and improperly preserve its patent monopoly. Purepac alleges that Warner-Lambert, acting with the specific intent to monopolize or maintain its monopoly in the gabapentin anhydrous market, withheld prior art, abandoned a patent application that had already been approved approximately one month before the patent was scheduled to issue, and filed unnecessary continuation applications. If such

allegations are proven, Warner-Lambert's patent prosecution misconduct could reasonably be considered "nothing more than an attempt to interfere directly with the business" of Warner-Lambert's generic competitors. As such, this Court cannot declare such conduct immune as a matter of law at this stage of the litigation.[29]

Courts have held that abuse of the patent prosecution process and inequitable conduct before the Patent Office similar to what is alleged here may form the basis for a viable antitrust claim. In *DiscoVision Associates v. Disc Manufacturing, Inc.*, the court denied a motion to dismiss Disc Manufacturing's monopolization claim based on, among other things, allegations that DiscoVision "committed fraud and misrepresentations in prosecuting its patents" and "committed these acts and filed continuation applications with the specific intent to monopolize or maintain its monopoly" in the relevant markets. *DiscoVision Assoc.,* 1997 WL 309499, at *8. Disc Manufacturing had also alleged that DiscoVision had "employ[ed] improper delaying tactics in the PTO," and had "purposefully withheld material prior art during the prosecution of applications that led to" some of the patents at issue in the lawsuit. *Id*. at *3. The court concluded that "[t]hese allegations, if true, are sufficient to support the inference that DiscoVision's continuation applications had an anticompetitive effect beyond the grant of the patent ... [and] may form a basis for antitrust liability." *Id*. at *8. Purepac has made comparable allegations concerning Warner-Lambert's misconduct during prosecution of the '482 Patent.

Similarly, in denying a motion to dismiss antitrust claims based on the "late listing" of patents in the Orange Book, this Court held that:

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[29] The Court notes again that if Purepac is unable to meet its burden of proof as to the sham exception, Plaintiffs may renew their claims for *Noerr-Pennington* immunity at a later stage of the proceeding.

> Within the maze of Hatch-Waxman, if a patent-holder's actions unlawfully maintain otherwise lawful monopoly power or use a lawful patent to manipulate the ANDA process, such actions could lead to anticompetitive effects in the relevant market. ... At this stage in the instant action, it cannot be said to a legal certainty that no relief could be granted under Section 2.

Remeron, 335 F. Supp. 2d at 532.[30]

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[30] The FTC has recently applied a similar analysis to claims of systematic abuse of the Hatch-Waxman regulatory framework, in evaluating a complaint that Bristol-Myers Squibb ("BMS") had engaged in a scheme to obstruct the launch of generic competitors to its BuSpar, Taxol, and Platinol drug products. Faced with imminent competition for these drugs, BMS allegedly undertook a course of conduct that included: paying potential competitors to abandon a challenge to a BMS patent and stay off the market until the patent expired; abusing FDA regulations to block generic entry; making false statements to the FDA in connection with listing patents in the Orange Book; engaging in inequitable conduct before the PTO to obtain patents; and filing baseless patent infringement suits. The FTC expressed concerns with such conduct, explaining that:

> the logic and policy underlying the Supreme Court's decision in *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972), which held a pattern of filings undertaken without regard to their merits to be outside the protections of Noerr, supports the application of a pattern exception for BMS's alleged pattern of conduct across its buspirone, paclitaxel, and cisplatin products, and thus provides a separate reason to reject Noerr immunity here. As is reflected in the complaint, the overall course of conduct challenged here constitutes a clear and systematic pattern of anticompetitive misuse of governmental processes, that is, abusive filings undertaken without regard to the merits, in order to use administrative and judicial processes - rather than the outcome of those processes - as a weapon to obstruct competition. Just as the repeated filing of lawsuits brought without regard to the merits, and for the purpose of using the judicial process (as opposed to the outcome of the process), warrants rejection of Noerr immunity, so too do the alleged repeated filing of patents on the Orange Book without regard to their validity, enforceability, or listability; repeated filing of recklessly or deliberately false statements with government agencies; and filing of lawsuits brought with or without regard to the merits, also cause the actions challenged here to fall outside the scope of Noerr's protection.

Analysis to Aid Public Comment, *In re Bristol-Myers Squibb Co.*, No. C-4076 (F.T.C. Mar. 7, 2003), *available at* http://www.ftc.gov/os/2003/03/bristolmyersanalysis.htm. The Court reaches a similar conclusion about Warner-Lambert's overall course of conduct before the Patent Office with respect to the '482 Patent.

The same principles should apply to the conduct at issue in this proceeding. The Hatch-Waxman regulatory scheme presents unique opportunities for gamesmanship, and offers substantial benefits, particularly the imposition of 30-month stays, to pioneer drug manufacturers who may manipulate the process and timing of patent prosecutions in order to expand the otherwise lawful monopoly granted by a patent or a series of patents. Fraudulently delaying the issuance of a patent could lead to anticompetitive effects in the relevant market, if such delays were intended to obtain control over or exclude competitors from such market. Such abuse of the Patent Office's administrative and regulatory process itself is not entitled to immunity.

In sum, Purepac has adequately alleged facts, which, if proven, will show that Warner-Lambert's prosecution of the '482 Patent was conducted in a manner that was "ostensibly directed toward influencing governmental action," but was really meant "to interfere directly with the business relationships of a competitor." *Noerr*, 365 U.S. at 144. Examined outside of the *Walker Process* framework, the conduct alleged may form the basis for antitrust liability if Purepac can establish the remaining requirements under Section 2. Purepac's allegations of patent prosecution misconduct will not, therefore, be dismissed and can properly be considered within the scope of Warner-Lambert's overall scheme to monopolize the gabapentin anhydrous market.

IV. Conclusion

For the reasons set forth in this Opinion, the Court grants Plaintiffs' Motion to Strike with respect to Purepac's affirmative defense of unclean hands and denies the Motion to Strike with respect to Purepac's affirmative defense of patent misuse. The Court grants Plaintiffs' Motion to Dismiss Purepac's counterclaim for declaratory judgment of unenforceability to the extent such

counterclaim relies on the concept of unclean hands, and denies the motion to the extent such counterclaim relies on the patent misuse doctrine. Finally, the Court denies Plaintiffs' Motion to Dismiss Purepac's federal antitrust and common-law unfair competition counterclaims as pled in Counts Four, Five, and Six of Purepac's Amended Answer. An appropriate Order will issue.

s/ Faith S. Hochberg
Hon. Faith S. Hochberg, U.S.D.J.