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:** Teva Defendants C.A. No. 00-CV-4168 (FSH) C.A. No. 00-CV-4589 (FSH) IVAX Defendants C.A. No. 00-CV-6073 (FSH) C.A. No. 01-CV-0193 (FSH) C.A. No. 01-CV-1537 (FSH) Eon Defendants C.A. No. 01-CV-2194 (FSH) **OPINION** Date: August 27, 2009

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HOCHBERG, District Judge

This matter comes before the Court upon Plaintiff Warner-Lambert's Motion to Strike Certain Affirmative Defenses of the Teva, IVAX, and Eon Defendants (Docket # 430), pursuant to Fed. R. Civ. P. 12(f).[1] The Court has considered the briefs of the parties, and oral argument held on April 22, 2009.[2]

I. Background

Plaintiffs are the drug manufacturers and patent holders for gabapentin, a drug that is used to prevent and limit epileptic seizures. Gabapentin has been marketed under the tradename Neurontin since 1994.[3] Defendants are generic drug manufacturers seeking to market their own

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[1] This proceeding involves several interrelated Plaintiffs. Pfizer Inc. is a Delaware corporation. Warner-Lambert Company LLC, formerly Warner-Lambert Company, is a Delaware limited liability company, which became a wholly-owned subsidiary of Pfizer Inc. on or about June 19, 2000. Plaintiff Gödecke GmbH, formerly Gödecke Aktiengesellschaft, is a German corporation and an indirect wholly-owned subsidiary of Pfizer Inc. Pfizer Pharmaceuticals LLC is a Delaware limited liability company and also an indirect wholly-owned subsidiary of Pfizer Inc. Unless greater specification is required, Plaintiffs will be referenced collectively herein as "Warner-Lambert."

[2] Plaintiffs filed a separate, though similar, motion against the Purepac Defendants (Docket # 431). To the extent the motions raise identical arguments concerning affirmative defenses raised by all Defendants, those arguments will be primarily addressed herein. The Purepac Defendants have, however, asserted a distinct set of additional antitrust and unfair competition counterclaims, which Plaintiffs have moved to dismiss. The Court will address the unique portions of that motion separately, in a corresponding Opinion also handed down today (the "Purepac Opinion"). The Court recommends that this Opinion be read in conjunction with the Purepac Opinion, as well as the Opinion issued today in a related matter, *In re Neurontin Antitrust Litig.* (No. 02-1390, MDL No. 1479).

[3] Gödecke GmbH is the assignee of the patents for Neurontin, and Pfizer Pharmaceuticals LLC is the exclusive licensee of those patents. Pfizer Pharmaceuticals manufactures pharmaceutical compositions of the drug gabapentin, which it supplies to Warner-Lambert Company LLC. Warner-Lambert Company LLC, through its Parke-Davis Division, has sold and continues to sell those compositions under the Neurontin tradename, and is the exclusive distributor of Neurontin in the United States.

generic versions of Neurontin.[4] Plaintiffs brought suit against Defendants, alleging infringement of U.S. Patent No. 6,054,482, entitled "Lactam-Free Amino Acids" (the "'482 Patent").[5] The facts and allegations underlying this action have been discussed comprehensively, both in this Court's earlier opinions and in other actions involving the same parties and patents. However, for purposes of this motion and the others decided by the Court today, the following background is relevant and bears repeating.

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[4] The Teva Defendants ("Teva") are Teva Pharmaceuticals USA Inc. ("Teva USA"), a Delaware corporation, and Teva Pharmaceuticals Industries, Ltd. ("Teva Ltd."), an Israeli corporation. Teva USA is a wholly-owned subsidiary of Teva Ltd.

The IVAX Defendants ("IVAX") are: (1) IVAX Pharmaceuticals NV, Inc., which was formerly known as Zenith Laboratories, Inc., a Florida corporation; (2) IVAX Pharmaceuticals, Inc., formerly known as Zenith Goldline Pharmaceuticals, Inc., a Florida corporation; and (3) IVAX Corporation, also a Florida corporation. Zenith Laboratories was a wholly-owned subsidiary of Zenith Goldline, and Zenith Goldline was a wholly-owned subsidiary of IVAX Corporation. IVAX Pharmaceuticals NV, Inc. is a wholly-owned subsidiary of IVAX Pharmaceuticals, Inc., which is a wholly-owned subsidiary of IVAX Corporation. The parties refer interchangeably to the Zenith Defendants and the IVAX Defendants; these companies are herein referred to collectively as the IVAX Defendants.

The Eon Defendants ("Eon") are Eon Labs Manufacturing, Inc., known as Eon Labs, Inc., a Delaware corporation. Plaintiffs allege that Eon has changed its name to Sandoz, Inc., which is a Colorado corporation. The Eon Defendants deny such allegations in their Answer and refer to Eon Labs and Sandoz, Inc., seemingly as separate entities. Nonetheless, they will be referred to collectively herein as the Eon Defendants.

[5] Warner-Lambert filed separate patent infringement actions against multiple generic drug manufacturers. The Judicial Panel on Multidistrict Litigation directed that all such actions be consolidated before this Court for coordinated pretrial proceedings. The proceeding was originally assigned to Hon. John C. Lifland, U.S.D.J., and was reassigned to this Court on March 9, 2007.

The instant motion pertains to a number of the remaining "first-wave" defendants. Additional "second-wave" and "third-wave" defendants were sued by Warner-Lambert after the close of discovery for first-wave defendants. Plaintiffs ultimately settled with many of the second- and third- wave defendants.

A. Warner-Lambert's Gabapentin Patents

Warner-Lambert scientists discovered gabapentin in the 1970s, and learned that gabapentin was useful in preventing and limiting epileptic seizures. Warner-Lambert has since obtained various patents covering the drug and its uses. In 1977, Warner-Lambert obtained U.S. Patent No. 4,024,175 (the "'175 Patent"), which claimed the chemical molecule gabapentin anhydrous. The '175 Patent expired in 1994. In 1979, Warner-Lambert obtained U.S. Patent No. 4,087,544 (the "'544 Patent") covering the use of gabapentin to treat epilepsy. The '544 Patent would have expired on May 2, 1995, but its term was extended under 35 U.S.C. § 156 until January 16, 2000 (and subsequently until July 16, 2000 pursuant to the FDA's pediatric exclusivity regulations).

In the late 1980s, Warner-Lambert chemists discovered a new form of the gabapentin compound in which each gabapentin molecule is associated with one molecule of water.[6] This monohydrate is very crystalline and can be purified to a high degree. After purification, the monohydrate can be readily converted back to the anhydrous form, containing no water. On January 16, 1990, Warner-Lambert obtained U.S. Patent No. 4,894,476 (the "'476 Patent") claiming the new monohydrate. The '476 Patent expired on May 2, 2008.

At about the same time, Warner-Lambert also discovered that gabapentin could be useful in slowing or preventing neurodegeneration. On January 28, 1992, Warner-Lambert received U.S. Patent No. 5,084,479 (the "'479 Patent"), claiming the use of gabapentin anhydrous to treat

[6] Before this point, gabapentin was known to exist in two principal forms: (1) an anhydrous form where no water is associated with the gabapentin molecules; and (2) a hydrated form where some water is associated with the gabapentin molecules. Only two hydrated forms were known: (1) two gabapentin molecules associated with each molecule of water; and (2) four gabapentin molecules associated with each molecule of water.

neurodegenerative diseases. This patent expires on January 2, 2010. The '479 Patent's dependent claims describe a method wherein the neurodegenerative disease is stroke, Alzheimer's disease, Huntington's disease, Amyotrophic Lateral Sclerosis (A.L.S.), and Parkinson's disease. Warner-Lambert has neither sought nor received FDA approval to promote Neurontin for the treatment of neurodegenerative diseases.

Despite holding the initial patent for gabapentin since 1979, the creation of a commercially viable gabapentin product was complicated by the fact that under certain conditions during the manufacturing process, gabapentin has a tendency to form a lactam, which makes the drug unstable and unsafe. Warner-Lambert scientists ultimately determined that all gabapentin products had to be essentially free from mineral acid impurities, and that certain adjuvants that promote the conversion of gabapentin to gabapentin lactam must be avoided. In an effort to minimize the formation of lactam during the manufacturing process, Warner Lambert developed a new process, for which the company sought an additional patent in August 1990 when it filed U.S. Patent Application No. 07/570,500 ("the '500 Application"). As described below, the parties dispute the details of the resulting patent prosecution. The low-lactam gabapentin patent ultimately issued as the '482 Patent on April 25, 2000 and it expires on April 25, 2017. The '482 Patent is the subject of Warner-Lambert's current infringement actions.[7]

[7] The '482 Patent covers the manufacturing process for a substantially lactam-free form of gabapentin. This process incorporates two key limitations that help achieve a stable formation of gabapentin. First, the '482 Patent discloses that gabapentin must be highly purified before being formulated into the pharmaceutical preparation. In preparing purified gabapentin, the hydrochloride admixture, or other mineral acid, remaining from the manufacturing process must not exceed twenty parts per million ("20 ppm"). Second, Warner-Lambert determined that certain adjuvants that reduce the stability of gabapentin must be avoided in the preparation process. *See In re Gabapentin Patent Litig.*, 503 F.3d 1254, 1257 (Fed. Cir. 2007).

B. Neurontin And The Neurontin Market

Warner-Lambert developed its Neurontin products on the basis of these patents. Following clinical trials, Warner-Lambert submitted New Drug Applications ("NDAs") to the FDA for the use of gabapentin to treat epilepsy. The FDA approved NDA No. 20-235, for Neurontin capsules, on December 30, 1993 and NDA No. 20-882, for Neurontin tablets, on October 9, 1998.

Warner-Lambert filed several Orange Book listings in connection with the development and sale of Neurontin. In January 1992, Warner-Lambert certified that the '175 Patent and the '544 Patent covered the formulation, composition and/or method of use of the drug product that was the subject of NDA No. 20-235. Both the '175 Patent and the '544 Patent were then listed in the Orange Book. Once NDA No. 20-235 was approved, Warner-Lambert amended its patent notification statement to include the '476 and '479 Patents, certifying that they also covered the formulation, composition and/or method of use of the drug product that was the subject of that NDA. They were listed in the Orange Book in May 1994 and January 1996, respectively. In April 2000, Warner-Lambert certified that the '482 Patent also covered the drug product at issue in both NDA No. 20-235 and NDA No. 20-882, resulting in an Orange Book listing for the '482 Patent as well.

Warner-Lambert first began selling Neurontin capsules in early 1994. According to the FDA's required labeling, gabapentin is useful for "adjunctive therapy in the treatment of partial

seizures with and without secondary generalization in adults with epilepsy."[8] This was the only use approved by the FDA at the time.[9]

Once Warner-Lambert began marketing Neurontin, however, doctors also began to use Neurontin to treat neurodegenerative conditions such as Parkinson's disease, A.L.S. and neuropathic pain, even though it had not been approved by the FDA for such uses.[10] Increased awareness of these off-label uses of Neurontin led to significant sales for non-epilepsy uses. By 2000, more than 78% of Neurontin prescriptions were written for off-label uses, including the treatment of neuropathic pain and neurodegenerative diseases.

C. Generic Manufacturers And Their Gabapentin Products

Beginning in 1998, several generic drug manufacturers filed Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to market generic gabapentin products after the expiration of the '544 Patent (and its pediatric extension).[11]

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[8] Pursuant to this approval, Neurontin was only designed to be a second-line defense for patients who were already taking other anti-epilepsy drugs.

[9] In May 2002, Neurontin was also approved by the FDA for the treatment of post-therapeutic neuralgia, a chronic debilitating pain frequently accompanying shingles. Such use is not directly at issue in this proceeding.

[10] Under the Federal Food, Drug and Cosmetics Act ("FDCA"), pharmaceutical manufacturers may not market or promote a drug for a use that has not been approved by the FDA unless certain "stringent requirements" are met and the manufacturer resubmits the drug to the FDA testing and approval process. *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 44 (D. Mass. 2001). Once a drug is approved for a particular use, however, the FDA does not prevent doctors from prescribing the drug for uses that are different than those approved by the FDA. Allowing physicians to prescribe drugs for such "off-label" usage is a widely-accepted practice that corresponds with the FDA's fundamental mission of regulating pharmaceuticals without interfering directly with the practice of medicine.

[11] In an ANDA, a generic manufacturer must make one of four certifications concerning each patent that is listed in the Orange Book in conjunction with the approved pioneer drug:

The Teva Defendants filed two ANDAs: No. 75-435 for gabapentin capsules on or before September 24, 1998; and No. 75-827 for gabapentin tablets on or before June 5, 2000. The IVAX Defendants also filed two ANDAs: No. 75-477 for gabapentin capsules on or before November 2, 2000; and No. 76-017 for gabapentin tablets on or before December 21, 2000. The Eon Defendants filed one ANDA, No. 75-539 for gabapentin capsules on or before February 5, 2001. Each applicant filed Paragraph III Certifications with respect to the '544 Patent and Paragraph IV Certifications with respect to the '482 Patent.[12] Warner-Lambert initiated this litigation in June 2000 on the basis of Defendants' Paragraph IV Certifications concerning the '482 Patent.

Despite these lawsuits, Defendants began selling their generic gabapentin products "at risk" before a court ruling on infringement liability had issued. The Teva Defendants launched their gabapentin capsules in October 2004 and their tablets in December 2004. The IVAX

I. That no patent for the pioneer drug has been filed with the FDA (Paragraph I Certification);
II. That the patent for the pioneer drug has expired (Paragraph II Certification);
III. That the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (Paragraph III Certification); or
IV. That the patent for the pioneer drug is invalid or will not be infringed by the generic company's proposed product (Paragraph IV Certification).

21 U.S.C. § 355(j)(2)(A)(vii). Alternatively, an ANDA may assert that a patent is inapplicable to the indication for which the drug product will be marketed (a "section viii statement").

[12] If a generic manufacturer files a Paragraph III Certification, the FDA will not approve the ANDA until the patent at issue expires. If a generic manufacturer chooses to file a Paragraph IV Certification, the manufacturer must promptly disclose its Certification to both the NDA-owner and the patent-owner. Upon receipt of a Paragraph IV Certification, the patent-owner may initiate an action for patent infringement within 45 days, and if no such action is brought, the FDA may approve the generic manufacturer's ANDA. If an infringement action is brought within 45 days, FDA approval of the ANDA is automatically postponed for 30 months.

Defendants launched their gabapentin tablets in August 2004 and their capsules in March 2005. And the Eon Defendants launched their gabapentin capsules in or about April 2005.

II. Procedural History

In June 2000, Warner-Lambert sued Defendants for infringement of the '482 Patent on the basis of the Paragraph IV Certifications directed at that patent. After an initial period of discovery, Defendants filed various summary judgment motions between 2001 and 2003, including motions for summary judgment of noninfringement and patent invalidity. During the pendency of those motions, Warner-Lambert unsuccessfully sought a preliminary injunction to enjoin IVAX, Purepac and Teva from launching their products.

On August 25, 2005, Judge Lifland issued several rulings based upon his claim construction of the '482 Patent.[13] Judge Lifland also granted the motion for summary judgment of noninfringement, finding that Warner-Lambert had not adduced sufficient evidence to establish that the allegedly infringing generic products met the limitation imposed by the '482 Patent that anions of a mineral acid could not exceed 20 ppm, and, therefore, did not satisfy its burden of proof on the issue of infringement.

Plaintiffs appealed the claim construction of "anion of a mineral acid" and "adjuvant," which appear in Claim 7 of the '482 Patent, as well as the finding of noninfringement. On September 21, 2007, the Federal Circuit upheld Judge Lifland's construction of those patent

[13] Specifically, Judge Lifland, relying on intrinsic evidence, construed "anion of a mineral acid" as "anion derived from a mineral acid." Judge Lifland also construed "adjuvants" as a "subset of [eight particular] inactive ingredients that is intimately mixed with gabapentin to form the drug mixture, and thus [does not] refer to the ingredients of capsule shells or tablet coatings." Further issues of claim construction have not been raised in connection with any of the pending motions.

terms but concluded that the district court had "erred in determining that there was no genuine issue of material fact concerning whether Warner Lambert failed to meet its burden of proof that the accused products infringe the asserted claims of the '482 Patent." *In re Gabapentin Patent Litig.*, 503 F.3d at 1256.[14] The Federal Circuit remanded the case for further proceedings. *Id*. at 1266.

On April 1, 2008, Plaintiffs filed Amended Complaints against the Teva, IVAX, Eon and Purepac Defendants. Each of the Amended Complaints sets out the same two claims. Count 1 asserts patent infringement under 35 U.S.C. § 271(e)(2)(A) based on Defendants' submission of ANDAs seeking approval to market their own gabapentin capsules and/or tablets. Count 2 asserts actual infringement of the '482 Patent under 35 U.S.C. § 271(a) based upon Defendants' launch and subsequent sales of their gabapentin products.[15] Plaintiffs argue that Defendants have infringed their patent "by making, using, offering to sell, selling and/or importing" the gabapentin products referenced in the ANDAs. Plaintiffs seek judgment that Defendants have infringed the '482 Patent under both statutory provisions; an order directing the FDA to revoke or withdraw approval of the ANDAs until the expiration of the '482 Patent; a permanent injunction restraining Defendants from manufacturing, selling or importing any gabapentin product covered by the '482 Patent; and awards of damages, interest, costs and attorneys' fees.

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[14] Whereas Judge Lifland had not credited certain expert reports and pH tests offered by Warner-Lambert, the Federal Circuit found them sufficiently credible. As such, they provided sufficient evidence to create a genuine issue of material fact regarding whether the tested samples met the 20 ppm claim limitation. The Federal Circuit also concluded that comparative pH testing is a valid technique in this proceeding for determining whether a generic sample falls within the acid limitations of the '482 Patent.

[15] Plaintiffs also include additional allegations against the Teva Defendants of inducing infringement, in violation of 35 U.S.C. § 271(b) and (c).

Answers to Plaintiffs' Amended Complaints were filed on April 14, 2008 and raise a number of affirmative defenses and counterclaims. On June 16, 2008, Warner-Lambert moved to strike the unclean hands defense raised by the Eon, IVAX and Teva Defendants and the patent misuse defense raised by the IVAX and Teva Defendants, claiming that they are not viable as a matter of law.[16]

III. Standard of Review

Plaintiffs submit this motion pursuant to 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." Such a motion offers the primary opportunity for a plaintiff to object to affirmative defenses. "The purpose of a motion to strike is to clean up the pleadings, streamline litigation, and avoid unnecessary forays into immaterial matters." *McInerney v. Moyer Lumber & Hardware, Inc.*, 244 F. Supp. 2d 393, 402 (E.D. Pa. 2002).

Because a motion of this sort 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., Ltd. v. Teva Pharm. USA, Inc.*, 557 F. Supp. 2d 490, 493 (D.N.J. 2008) (citing *Mars Inc. v. JCM American Corp.*, No. 05-3165, 2006 WL 1704469, at *4 (D.N.J. June 14, 2006)). An affirmative defense is insufficient as a matter of law if it cannot succeed under any circumstances. *Id*. (citing *In re Sunrise Sec. Litig*., 818 F. Supp. 830, 840 (E.D. Pa. 1993)). Accordingly, to determine whether Defendants' affirmative defenses are insufficient, the Court

[16] In addition to those addressed specifically in this motion, Defendants raise the following defenses in their Amended Answers: (1) noninfringement; (2) invalidity; (3) failure to state a claim for willful infringement; and (4) failure to state a claim upon which relief may be granted.

must accept all factual allegations in the Answers as true, construe the Answers in the light most favorable to Defendants, and determine whether, under any reasonable reading of the pleadings, Defendants may be entitled to relief. *Phillips v. County of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008).

The Court recognizes that applying Rule 12(f) to strike 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); *see also Garlanger v. Verbeke*, 223 F. Supp. 2d 596, 609 (D.N.J. 2002) ("Because of the drastic nature of the remedy, however, motions to strike are usually 'viewed with disfavor' and will generally 'be denied unless the allegations have no possible relation to the controversy and may cause prejudice to one of the parties, or if the allegations confuse the issues.'") (citing *Tonka Corp. v. Rose Art Indus., Inc.*, 836 F. Supp. 200, 217 (D.N.J. 1993)). Nevertheless, "courts have 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 are granted, therefore, "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.*, 761 F. Supp. 1100, 1115 (D.N.J. 1991).

IV. Discussion

Plaintiffs argue that Defendants' unclean hands and patent misuse defenses are not viable as a matter of law. In support, they claim that these defenses "have absolutely nothing to do with the infringement issue or the enforcement of the '482 Patent." Plaintiffs' Opening Brief in

Support of Their Motion to Strike Certain Affirmative Defenses of Teva, IVAX, and Eon Defendants at 1, *In re Gabapentin Patent Litig.*, No. 00-2931 (D.N.J. June 16, 2008) ("Plaintiffs' Opening Brief"). In response, Defendants argue that neither defense should be so narrowly-construed or mechanically-applied. They emphasize that patent misuse and unclean hands are both equitable defenses and that the Court has broad discretion to grant relief on a case-by-case basis. Because they have made specific allegations of bad-faith and anticompetitive conduct, Defendants urge the Court to exercise its discretion in their favor, so long as they can prove that Plaintiffs' conduct was sufficiently egregious.

A. Unclean Hands

Defendants have asserted an unclean hands defense on the basis of allegations and admitted facts concerning Warner-Lambert's efforts to promote Neurontin for off-label uses.[17] Shortly after Warner-Lambert launched Neurontin, the company estimated that its potential lifetime sales would likely amount to less than $500 million, partly because Neurontin was

[17] Defendants in this proceeding are not the first to challenge Warner-Lambert's marketing of Neurontin. The Department of Justice investigated Warner-Lambert's marketing conduct over a seven-year period, filing felony criminal charges in the District of Massachusetts on May 13, 2004. Warner-Lambert was charged with the criminal distribution of an unapproved new drug and distribution of a misbranded drug. Warner-Lambert ultimately admitted that its marketing of Neurontin was criminal, pled guilty to the charges on June 7, 2004, and agreed to pay more than $430 million in sanctions, along with restitution to federally-funded Medicaid programs.

Consumer purchasers and third-party payors also brought suit against Warner-Lambert for violations of the Racketeer Influenced and Corrupt Organizations Act (RICO) and the New Jersey Consumer Fraud Act (NJCFA), alleging that Warner-Lambert engaged in a fraudulent scheme to promote and sell the drug Neurontin for "off-label" conditions. That proceeding is currently pending before Hon. Patti B. Saris, U.S.D.J., in the District of Massachusetts. *In re: Neurontin Marketing, Sales Practices and Products Liability Litig*. No. 04-10981; *see also In re Neurontin Marketing, Sales Practices and Products Liability Litig.*, 618 F. Supp. 2d 96 (2009) (outlining history of and claims asserted in the civil multi-district litigation).

approved only for limited use as an adjunct therapy for adult epilepsy and because the resulting market for that approved indication was small. *In re Neurontin Mktg. and Sales Practices Litig.*, 244 F.R.D. 89, 92 (D.Mass. 2007). Defendants allege that, in response, Warner-Lambert decided to aggressively and illegally promote Neurontin for a variety of unapproved uses, without seeking FDA approval, in order to inflate market share and profits.[18]

Warner-Lambert's off-label marketing of Neurontin was highly successful. By 2004, shortly before the launch of generic equivalents, an estimated 90% of Neurontin sales were for off-label uses, down slightly from a peak of 94% in 2002. According to Defendants, Warner-Lambert continues to benefit from these activities because it still exploits the market share it acquired illegally. Indeed, Defendants characterize the pending patent infringement actions as simply another attempt to preserve an ill-gotten profit stream by using patents to prevent competition and maintain market-exclusivity for Neurontin. According to Defendants, Plaintiffs have, therefore, approached this litigation with unclean hands which should preclude the injunctive and other equitable relief sought in their Amended Complaints.

Plaintiffs move to strike this defense on the grounds that the Teva, IVAX, and Eon Defendants have failed to tie Warner-Lambert's marketing misconduct to any issue pending before the Court.[19] Plaintiffs repeatedly emphasize that, even though Defendants have included

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[18] Warner-Lambert's improper marketing activities included, among other efforts: (1) publishing misleading articles in order to induce prescription of Neurontin for unapproved uses; (2) withholding studies showing that Neurontin was not effective for certain off-label uses while publishing contrary "positive" results concerning such uses; (3) encouraging salespeople to use biased "medical liaisons" in sales pitches to physicians; and (4) paying physicians to allow such sales representatives to accompany them on patient visits.

[19] Plaintiffs address most of their arguments on this point to the defenses pled by Teva and IVAX, which contain identical allegations. They challenge Eon's unclean hands defense

details of Warner-Lambert's marketing activities in their pleadings, the instant action concerns only the alleged infringement and enforcement of the '482 Patent. Any marketing misconduct on Warner-Lambert's part, Plaintiffs contend, is neither directly related nor closely connected to the issues and objectives of the litigation. This Court agrees.

The maxim of unclean hands mandates that "he who comes into equity must come with clean hands." *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945). Pursuant to this doctrine, a court may refuse to "grant relief to one who is a wrongdoer with respect to the subject matter of the suit." *DirecTV, Inc. v. Weikel*, No. 03-5300, 2005 WL 1243378, at *4 (D.N.J. May 25, 2005) (citing *Borough of Princeton v. Bd. of Chosen Freeholders of the County of Mercer*, 169 N.J. 135, 158 (2001)). In assessing whether to allow a defendant to pursue an unclean hands defense, courts are not "bound by formula or restrained by any limitation that tends to trammel the free and just exercise of discretion." *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245-46 (1933). However, in exercising such discretion, "the primary principle guiding application of the unclean hands doctrine is that the alleged inequitable conduct must be connected, *i.e.*, have a relationship, to the matters before the court for resolution." *In Re New Valley Corp.*, 181 F.3d 517, 525 (3d Cir. 1999) (quoting *Keystone Driller*, 290 U.S. at 245).

For purposes of this motion, the Court takes the allegations of Warner-Lambert's criminal misconduct as true. Despite doing so, it is clear that Defendants have not, however, alleged that

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separately, primarily to emphasize that Eon's Answer contains even fewer factual allegations concerning Warner-Lambert's misconduct and no specific reference to the '482 Patent. Plaintiffs contend that if the Court finds that Teva and IVAX have failed to present a viable defense, then Eon's unclean hands defense must necessarily fail as well.

such misconduct gave rise to or affected the patent rights or cause of action now pursued by Warner-Lambert. In the absence of such a connection, an unclean hands defense is not viable, as "courts in this Circuit have generally been clear that the connection between the misconduct and the claim must be close." *In Re New Valley Corp.*, 181 F.3d at 525. As the *New Valley* Court explained, a court should "not refuse relief to a party merely because it has engaged in misconduct which is unrelated to its claims before the court. Only when 'some unconscionable act of one coming for relief has immediate and necessary relation to the equity that' the party seeks, will the doctrine bar recovery." *Id*. (citing *Keystone Driller*, 290 U.S. at 245); *see also Ciba-Geigy Corp. v. Bolar Pharm. Co., Inc.*, 747 F.2d 844 (3d Cir. 1984) (upholding the district court's rejection of an unclean hands defense because the plaintiff's alleged wrongdoings did not relate to the subject matter of the plaintiff's trademark infringement claims and did not, therefore, merit the preclusion of an injunction).

In the context of patent litigation, assertions of unclean hands have typically succeeded only in situations in which the misconduct related in some way to the procurement of the particular patent in question. *See MedPointe Healthcare, Inc. v. Hi-Tech Pharmacal Co., Inc.*, 380 F. Supp. 2d 457, 465-66 (D.N.J. 2005); *see also Monsanto Co. v. Rohm & Haas Co.*, 456 F.2d 592, 594 n.3 (3d Cir. 1972) (observing that "a patentee guilty of obtaining a patent by fraudulent conduct could be denied equitable relief when bringing an infringement action, thus rendering the patent unenforceable against a defendant who could prove unclean hands."); *Republic Molding Corp. v. BW Photo Utilities*, 319 F.2d 347, 351 (9th Cir. 1963) (holding that "where unclean hands has been asserted to bar a claim of infringement it has usually been because the patent was fraudulently obtained or there had been a concealment of evidence

amounting to a fraud on the court or, perhaps more remotely, the patent was being misused, as, for example, in violation of the Sherman Act."). Furthermore, when the alleged misconduct does not directly relate to the particular patent that is the subject of the litigation, even if it involves other patents, courts have rejected claims of unclean hands. *See MedPointe Healthcare, Inc.*, 380 F. Supp. 2d at 465-66 (rejecting an assertion of unclean hands that at best involved plaintiff's failure to disclose a prior ruling on a different, though related, patent, which was not the patent involved in the litigation).

In *Ciba-Geigy Corp. v. Bolar Pharmaceutical Co.*, a case upon which Plaintiffs rely heavily, the patent-holder of a drug that was sold in three forms with different trade dress sued a generic manufacturer for trademark and trade dress infringement. The defendant alleged unclean hands on the basis of the plaintiffs' improper marketing activities concerning the drug, but the district court rejected the defense. On appeal, the Third Circuit upheld the decision because "the alleged wrongdoings do not relate to the subject matter of Bolar's claim." *Ciba-Geigy Corp.*, 747 F.2d at 855. The connection between improper marketing activities and alleged trademark and trade dress infringement was too attenuated to sustain assertions of unclean hands. A sufficient nexus between Warner-Lambert's patent infringement claims and the company's marketing misconduct is similarly absent here.

Despite the Court's concern whenever a litigant has a criminal record, the Court must ask how Warner-Lambert's off-label marketing tactics relate to the patent rights that the company is now seeking to enforce. In response, Defendants emphasize the "equitable factors governing injunctions." However, the argument that Defendants need only show that the alleged misconduct is related to the *equitable relief* sought in this action is not supported by existing case

law. Equitable relief is a question for the Court to consider if Plaintiffs ultimately prevail on the merits of their cause of action. At such time, the Court may choose to reconsider Warner-Lambert's admittedly criminal off-label marketing conduct, and whether it is equitable to award Plaintiffs an injunction that will preserve their admittedly ill-gotten market share and profits. Regardless of its relevance to the possible award of a permanent injunction, such conduct does not form a basis for an unclean hands defense to Warner-Lambert's patent infringement allegations.

Defendants are correct that the doctrine of unclean hands should not be as narrowly-construed or mechanically-applied as Plaintiffs claim. To that end, the Court does not credit Plaintiffs' argument that the defense should be stricken simply because Defendants do not specifically mention the '482 Patent in their allegations of unclean hands. Nonetheless, an examination of the substance of Defendants' allegations reveals that there is only a tenuous connection, if any, between the inequitable off-label marketing activities and the patent infringement action now at issue. Accordingly, Warner-Lambert's motion to strike Defendants' affirmative defense of unclean hands is granted.[20]

[20] The Court notes, however, that even if Warner-Lambert's admitted marketing misconduct cannot serve as the basis for Defendants' assertions of unclean hands, evidence of such misconduct may be considered as a factor affecting Warner-Lambert's ability to obtain a permanent injunction as relief in this proceeding. Judge Lifland considered the marketing misconduct in his determination that Warner-Lambert was not entitled to a preliminary injunction. Defendants' arguments to this effect - that Warner-Lambert should not be allowed to rely on illegally acquired market share as a basis for injunctive relief and that it would be inequitable and against public interest to use a permanent injunction to protect Warner-Lambert's ill-gotten gains - are both relevant and compelling. Such arguments, and the evidence required to support them, are not determinative at this point of the proceeding but may be considered by the Court at a later stage.

B. Patent Misuse

"The doctrine of patent misuse is 'an extension of the equitable doctrine of unclean hands to the patent field." *Hoffman-La Roche, Inc. v. Genpharm Inc.*, 50 F. Supp. 2d 367 (D.N.J. 1999) (quoting *United States Gypsum Co. v. Nat'l Gypsum Co.*, 352 U.S. 457, 465 (1957)). As an affirmative defense, patent misuse "relates generally to the use of patent rights to obtain or coerce an unfair commercial advantage." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998). Under this doctrine, "if the patentee attempts to extend that monopoly beyond the scope of the patent, to use the patent as a tool to restrain trade in areas not claimed under the patent, the patentee may lose her right to seek redress through the judicial process to protect her lawful patent monopoly." *Hoffman-La Roche, Inc.*, 50 F. Supp. 2d at 378. The "policy of the patent misuse doctrine is to prevent a patentee from using the patent to obtain market benefit beyond that which inures in the statutory patent right." *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1339 (Fed. Cir. 2006) (internal quotations and citations omitted).

To successfully assert a defense of patent misuse, the alleged infringer must "show that the patentee has impermissibly broadened the 'physical or temporal scope' of the patent grant with anticompetitive effect."[21] *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 868 (Fed. Cir. 1997) (quoting *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001 (Fed. Cir. 1986)). Certain activities, such as tying, enforced package licensing, price restraints, or extended royalty

[21] Teva and IVAX have not alleged that Warner-Lambert improperly broadened the physical scope of the '482 Patent. Rather, they have alleged that Warner-Lambert broadened the temporal scope of the '482 Patent by manipulating and delaying the prosecution of that patent. Cases involving the temporal expansion of a patent typically involve situations where the patentee "negotiate[s] with the leverage of [the patent] monopoly," often in order to "project th[e] royalty payments beyond the life of the patent." *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 265 (1979) (quoting *Brulotte v. Thys Co.*, 379 U.S. 29, 33 (1964)).

terms have been recognized as "classic grounds of patent misuse," and are treated as per se patent misuse. *C.R. Bard*, 157 F.3d at 1378. In contrast, Congress has identified certain other practices that may not support a finding of patent misuse. 35 U.S.C. § 271(d); *see Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 202 (1980) (construing an earlier version of § 271(d)).

"When a practice alleged to constitute patent misuse is neither per se patent misuse nor specifically excluded from a misuse analysis by § 271(d), a court must determine if that practice is reasonably within the patent grant, *i.e.*, that it relates to subject matter within the scope of the patent claims." *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., Inc.*, No. 97-1568, 2007 WL 979854, at *20 (D.N.J. Mar. 30, 2007) (internal citations omitted). If a practice that is not per se patent misuse extends the patent grant, and does so with anticompetitive effect, it will be analyzed in accordance with a "rule of reason." *Id*. Under a rule of reason, "the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." *Virginia Panel Corp.*, 133 F.3d at 869 (citing *State Oil Co. v. Kahn*, 522 U.S. 3, 10 (1997)).

Here, the IVAX and Teva Defendants allege that Warner-Lambert committed patent misuse by manipulating the prosecution of the '482 Patent in a way that expanded the temporal scope of the patent with anticompetitive effect. They argue that such conduct, which delayed the issuance and ultimate expiration of the '482 Patent in order to prolong patent protection for the Neurontin franchise as a whole, renders the '482 Patent unenforceable due to patent misuse.

Specifically, Defendants focus on certain of Warner-Lambert's actions while prosecuting the '482 Patent. Warner-Lambert initially filed the '500 Application in order to receive a patent for a low-lactam form of gabapentin in August 1990. Early in the prosecution of the '500 Application, Warner-Lambert submitted an Information Disclosure Statement ("IDS") which should have disclosed all material prior art known to the applicant.[22] U.S. Patent No. 4,152,326 (the "'326 Patent"), which is also directed to compounds related to gabapentin, assigned to Warner-Lambert and lists the same inventors, was not initially listed in the '500 Application even though it had been referenced in the co-pending '056 Application. When Warner-Lambert filed a subsequent IDS to cite an additional patent, Patent No. 4,228,179 (the "'179 Patent") which was also directed to compounds related to gabapentin, assigned to Warner-Lambert and listed the same inventors, Warner-Lambert again failed to list the '326 Patent. Defendants allege that Warner-Lambert intentionally omitted the '326 Patent from its IDS filings in bad faith.

Warner-Lambert ultimately abandoned the '500 Application and filed a continuation application. On February 18, 1993, Warner-Lambert filed another continuation application, No. 08/020,270 (the "'270 Application"), which was subsequently approved for issuance as U.S. Patent No. 5,395,852 (the "'852 Patent"). The '852 Patent was scheduled to issue on March 7, 1995. Yet Warner-Lambert abandoned the '270 Application about a month before the '852

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[22] According to the Manual of Patent Examination Procedure ("MPEP"), "[a]pplicants and other individuals substantively involved with the preparation and/or prosecution of a patent application have a duty to submit to the Office information which is material to patentability as defined in 37 C.F.R. § 1.56." MPEP § 609 (5th ed., 1994).

Warner-Lambert disclosed the '175 Patent, the '544 Patent and the '476 Patent, as well as a co-pending application, No. 07/399,056 (the "'056 Application"). Each of the cited patents is directed to gabapentin or related compounds, assigned to Warner-Lambert and lists Johannes Hartenstein and Gerhard Satzinger as inventors.

Patent would have issued and filed yet another continuation application. In order to withdraw the '270 Application at such a late point in the approval process, Warner-Lambert had to show that it had "good and sufficient reasons why withdrawal of the application is necessary." *See* 37 C.F.R. § 1.313.[23] Warner-Lambert's proffered reason was the need to disclose the '326 Patent to the examiner.[24] Warner-Lambert's continuation application was prosecuted over the next five years. The low-lactam gabapentin patent was ultimately issued as the '482 Patent on April 25, 2000 and it will expire on April 25, 2017. The '482 Patent has claims similar to those previously allowed under the '270 Application.

According to Warner-Lambert, Defendants' patent misuse defense fails because any delay in the issuance of the '482 Patent "resulted in nothing more than a shift in the beginning and end dates of the 17-year patent term" rather than an expansion of its temporal scope. Plaintiffs' Opening Brief at 15. Plaintiffs claim that no court has found patent misuse in such circumstances, emphasizing that the length and complex nature of the patent prosecution should not undermine its validity. Adopting a rather formalistic approach, they argue that even Defendants have acknowledged that the actual term of the '482 Patent is still 17 years and that

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[23] Warner-Lambert had already paid the issue fee for the '270 Application. The general rule is that after the issue fee is paid, issuance may only be delayed for up to one month, in the absence of extraordinary circumstances or requirement of the regulations which would dictate a longer period. *See* MPEP § 1306.01.

[24] Defendants allege that this explanation was a bad faith pretext for delay because Warner-Lambert knew or should have known about the '326 Patent, and its significance to the pending applications, far earlier in the patent approval process. Warner-Lambert's newfound reliance on the '326 Patent, Defendants argue, was simply to mislead the Patent Office, effect a delay in the issuance of the new patent until shortly before the existing patent protection for Neurontin expired, and maximize the period of time in which the company could maintain and exploit an exclusive market for Neurontin.

because all of Warner-Lambert's allegedly improper actions occurred before the '482 Patent was officially issued, Defendants cannot validly claim that any benefits from a delayed patent term were obtained improperly by "negotiat[ing] with the leverage of [the patent] monopoly." *Aronson*, 440 U.S. at 265. In effect, they argue that the patentee could not have obtained a "market benefit beyond that which inures in the statutory patent right" if the patent itself has not yet issued. *See Monsanto Co. v. McFarling*, 363 F.3d 1336, 1342 (Fed. Cir. 2004) (citing *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 704 (Fed. Cir.1992)).

The Court is unconvinced by this limited reading of both Defendants' allegations and the patent misuse doctrine. Defendants contend that, as an equitable doctrine, presenting a defense of patent misuse requires only allegations of conduct which had the effect of impermissibly extending the limited protection from competition afforded by the '482 Patent. Warner-Lambert's alleged manipulation of the patent prosecution process, for the purpose of forestalling generic competition, is conduct that if proven could conceivably persuade a rational fact-finder applying a rule of reason that patent misuse has been established. *See e.g.*, *Bausch & Lomb, Inc. v. Allergan, Inc.*, 136 F. Supp. 2d 166, 171 (W.D.N.Y. 2001) (motion to strike denied where allegations, if proven, "conceivably could persuade a rational factfinder that patent misuse had been established.").

Under a rule of reason, patent misuse can be found where the patentee's conduct violates the public policies addressed by the patent laws. *See Morton Salt Co. v. G. S. Suppiger Co.*, 314 U.S. 488, 494 (1942); *see also Blonder-Tongue Labs. Inc. v. Univ. of Illinois Found.*, 402 U.S. 313, 343 (1971) (discussing the policy interests in keeping patent monopolies limited and equitable); *C.R. Bard,* 157 F.3d at 1372 ("[t]he concept of patent misuse arose to restrain

practices that did not in themselves violate any law, but that draw anticompetitive strength from the patent right, and thus were deemed contrary to public policy."). In this case, policy interests favor the prompt issuance and expiration of patents so that the public's free access to inventions, and, more specifically, to lower-priced generic pharmaceuticals, is not further delayed. Warner-Lambert's alleged efforts to delay the issuance of the '482 Patent in order to delay its expiration, thereby effectively broadening the temporal scope of the series of gabapentin patents held by Warner-Lambert and preserving an exclusive hold on the gabapentin market, may be found to contravene such policy.[25]

Plaintiffs' emphasis on their inability to unlawfully leverage a patent that had not yet issued ignores cases in which patent applicants were found to have committed patent misuse by

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[25] Defendants base their arguments here in part on an early Supreme Court decision, *Woodbridge v. United States*, which held that the deliberate and unlawful tolling of a patent's term by the applicant until competitors are close to entering the market is contrary to public policy. 263 U.S. 50, 56 (1923) ("Any practice by [the] applicant for a patent through which he deliberately and without excuse postpones beyond the date of the actual invention, the beginning of the term of his monopoly, and thus puts off the free public employment of the useful invention, is an evasion of the statute and defeats its benevolent aim.").

On reply, Plaintiffs argue that "[t]here is simply no authority for the proposition that prosecution delay can constitute patent misuse, and defendants cite none." Plaintiffs' Reply Brief in Support of Their Motion to Strike Certain Affirmative Defenses of Teva, IVAX, and Eon Defendants at 2, *In re Gabapentin Patent Litig.*, No. 00-2931 (D.N.J. Sept. 17, 2008) ("Plaintiffs' Reply Brief"). *Woodbridge*, they contend, is not about patent misuse but about prosecution laches, which Defendants have not asserted, cannot assert on the basis of a delay of only five years, and should not assert because prosecution laches is a disfavored doctrine. Prosecution laches is only to be used "sparingly" and "only in egregious cases of misuse of the statutory patent system." *Symbol Techs., Inc. v. Lemelson Med Educ. & Res. Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005).

Plaintiffs' arguments about the nature and application of prosecution laches are correct. However, Defendants are not advancing a prosecution laches defense, but are, instead, simply analogizing to the policy principles expressed by the Court in *Woodbridge*. *Woodbridge* is not controlling on the issues now before the Court, but can provide some guidance if incorporated into the flexible, equitable structure of the patent misuse doctrine as it is currently applied.

improperly leveraging pending patent applications. *See Aronson*, 440 U.S. at 265; *Boggild v. Kenner Prods.*, 776 F.2d 1315, 1320 (6th Cir. 1985). Their arguments that temporal misuse "primarily concerns" situations where the patentee leverages a patent to secure royalties after the patent expires ignores that the doctrine of patent misuse is not limited to per se violations. Any conduct that effectively extends the patentee's statutory rights with anticompetitive effect can qualify as misuse if the patentee sought to use the patent to secure more protection from competition than patent law intended to provide. *See Blonder-Tongue Labs.,* 402 U.S. at 344; *Virginia Panel Corp.*, 133 F.3d at 869; *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1046-47 (N.D. Ill. 2003).

Furthermore, preserving a patent misuse defense at this stage of the litigation requires only allegations of conduct which had the effect of impermissibly extending the limited protection from competition afforded by the '482 Patent. Defendants have made such allegations. If proven, these allegations could persuade a reasonable fact-finder that Warner-Lambert engaged in patent misuse. Whether Defendants are correct that intentionally postponing the term of a patent broadens the patent's temporal scope goes to the merits of the defense rather than its viability.[26] Accordingly, Warner-Lambert's Motion to Strike is denied as it relates to the Teva and IVAX Defendants' patent misuse defenses. Both the equitable nature of the defense and the rule of reason that must be applied to evaluate such a defense prevent the Court from reaching a conclusion, at this stage of the proceedings, that under no set of facts could these

[26] In this, the patent misuse defense differs from the unclean hands defense as they have been raised in Defendants' Answers. Even if accepted as true, none of the facts alleged in support of the unclean hands defense create an adequate connection with the patent infringement claims currently at issue.

defendants establish a claim of patent misuse. Discovery on such issues will proceed and the patent misuse affirmative defense will not be stricken.

V. Conclusion

For the reasons set forth in this Opinion, the Court grants Plaintiffs' Motion to Strike with respect to the affirmative defense of unclean hands asserted by the Teva, IVAX, and Eon Defendants, and denies the Motion to Strike with respect to the affirmative defense of patent misuse asserted by the Teva and IVAX Defendants. An appropriate Order will issue.

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