NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE NEURONTIN ANTITRUST LITIGATION	Hon. Faith S. Hochberg, U.S.D.J. MDL No. 1479 Master Docket No. 02-1390 (FSH) **OPINION** Date: August 8, 2013

HOCHBERG, District Judge:

This matter comes before the Court upon Defendants'[1] Motion for Summary Judgment [Docket No. 515], and Plaintiffs'[2] Motion for Partial Summary Judgment [Docket Nos. 514, 517] and Motion to Strike [Docket No. 545].

I. BACKGROUND[3]

Plaintiffs allege that Pfizer engaged in an anticompetitive scheme to acquire and maintain monopoly power in the market for gabapentin products in violation of Section 2 of the Sherman

[1] "Defendants" are Pfizer Inc. and Warner-Lambert Co. (collectively "Pfizer" or Defendants).

[2] "Plaintiffs" are the certified direct purchaser class ("Class Plaintiffs"), opt-outs CVS Pharmacy, Inc., Rite Aid Corp. and Rite Aid HDQ TRS. Corp. ("CVS/Rite Aid") and opt-outs Walgreen Co., The Kroger Co., Safeway Inc., American Sales Co., Inc., Supervalu Inc. and HEB Grocery Co. LP ("Walgreen").

[3] The background of the instant litigation was set forth in detail in the Court's Opinions dated August 27, 2009, deciding Pfizer's motion to dismiss, dated January 25, 2011, granting Plaintiffs' motion for class certification, and dated August 10, 2011, granting in part and denying in part Class Plaintiffs' initial crime-fraud motion. The Court presumes familiarity with the facts and arguments summarized in those Opinions as well as the abbreviations and acronyms used therein.

Act, 15 U.S.C. § 2. As the Court explained upon deciding the motion to dismiss in this case, 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. . . . The possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive conduct." *In re Neurontin Antitrust Litigation*, MDL No. 1479, 2009 WL 2751029, at *8 (D.N.J. Aug. 28, 2009) (citations omitted). A claim for attempted monopolization has three elements: (1) predatory or anticompetitive 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. *Id.*

Antitrust plaintiffs must also 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." *Id.* at 10. To this end, a plaintiff must show both harm of the type antitrust laws were intended to prevent, and an injury to the plaintiff that flows from what makes the defendant's actions unlawful. *Id.*

Defendants move for summary judgment on all claims while Plaintiffs seek partial summary judgment requesting the Court to find as a matter of law Defendants' possession of monopoly power and key elements of its alleged anticompetitive scheme to maintain that power. Plaintiffs have also moved to strike Defendants' references to its settlement agreements in patent infringement litigations, which Defendants use to defend against Plaintiffs' sham litigation allegations.

II. STANDARD

Pursuant to Fed. R. Civ. P. 56(c), a motion for summary judgment will be granted if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). In other words, "[s]ummary judgment may be granted only if there exists no genuine issue of material fact that would permit a reasonable jury to find for the nonmoving party." *Miller v. Indiana Hosp.*, 843 F.2d 139, 143 (3d Cir. 1988). All facts and inferences must be construed in the light most favorable to the non-moving party. *Peters v. Delaware River Port Auth.*, 16 F.3d 1346, 1349 (3d Cir. 1994). The judge's function is not to weigh the evidence and determine the truth of the matter, but to determine whether there is a genuine issue for trial. *See Anderson*, 477 U.S. at 249. "Consequently, the court must ask whether, on the summary judgment record, reasonable jurors could find facts that demonstrated, by a preponderance of the evidence, that the nonmoving party is entitled to a verdict." *In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829, 860 (3d Cir. 1990).

The party seeking summary judgment always bears the initial burden of production. *Celotex Corp.*, 477 U.S. at 323. This burden requires the moving party to establish either that there is no genuine issue of material fact and that the moving party must prevail as a matter of law, or to demonstrate that the nonmoving party has not shown the requisite facts relating to an essential element of an issue on which it bears the burden. *Id.* at 322-23. Once the party seeking summary judgment has carried this initial burden, the burden shifts to the nonmoving party.

To avoid summary judgment, the nonmoving party must then demonstrate facts supporting each element for which it bears the burden, and it must establish the existence of a

"genuine issue of material fact" justifying trial. *Miller*, 843 F.2d at 143; *accord Celotex Corp.*, 477 U.S. at 324. The nonmoving party "must do more than simply show that there is some metaphysical doubt as to material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). "Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no 'genuine issue for trial.'" *Id*. at 587 (quoting *First National Bank of Arizona v. Cities Serv. Co.*, 391 U.S. 253, 289 (1968)). Further, summary judgment may be granted if the nonmoving party's "evidence is merely colorable or is not significantly probative." *Anderson*, 477 U.S. at 249-50.

III. DISCUSSION

A. Monopoly Power

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). The parties agree that a plaintiff can establish monopoly power in two ways: through direct evidence of monopoly power, or through indirect evidence of the structure and composition of the relevant market by defining a market and establishing a dominant market share. (Pl. MSJ Br., ECF No. 583, at 17-18; Def. MSJ Br., ECF No. 595, at 12.) *Harrison Aire, Inc. v. Aerostar Intern., Inc.*, 423 F.3d 374, 381 (3d Cir. 2004); *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007). However, "because 'direct proof is only rarely available, courts more typically examine market structure in search of circumstantial evidence of monopoly power.'" *Harrison Aire*, 423 F.3d at 381 (quoting *United States v. Microsoft*, 253 F.3d 34, 51 (D.C. Cir. 2001)). The parties dispute what is required to establish monopoly power under both methods; whether Plaintiffs are able to show monopoly through either method; and thus whether summary judgment is appropriate for this element of Plaintiffs' monopolization claims.

i. Direct Evidence Method

The parties dispute whether a plaintiff attempting to establish monopoly power through the direct evidence method must define the relevant market. They also dispute whether such a plaintiff must show both supracompetitive pricing and restricted output to establish monopoly power.

a. Relevant Market

While the indirect evidence method of proving monopoly power clearly requires definition of the relevant market, it is disputed whether the direct evidence method similarly requires such definition. In *Broadcom Corp. v. Qualcomm Inc.*, the Third Circuit Court of Appeals compared the direct and indirect evidence methods of proving monopoly power and wrote in a footnote that "[b]ecause market share and barriers to entry are merely surrogates for determining the existence of monopoly power, . . . direct proof of monopoly power does not require a definition of the relevant market." 501 F.3d 297, 307 n.3. However, in that case, direct proof was not a contested issue, and cases following *Broadcom* have held that *Broadcom* did not remove the requirement of establishing the relevant market under the direct evidence method, but that a plaintiff must still define or refer to the relevant market, or at least the rough contours of one. *See, e.g., Carpenter Tech. Corp. v. Allegheny Tech. Inc*., No. 08-2907, 2011 WL 4528303, *11 (E.D. Pa. Sept. 30, 2011) (finding Section 2 antitrust claim lacking for plaintiff's failure to proffer sufficient evidence in support of its relevant market definition); *In re Comp. of Managerial, Prof. and Technical Employees Antitrust Litig.*, No. 02-2924, 2008 WL 3887619, at *8 (D.N.J. Aug. 20, 2008) ("The Third Circuit [in *Broadcom*] did not state that the direct evidence could be completely untethered or unmoored from a roughly identified relevant market . . . . Although Plaintiffs may not need to define the relevant market with the same level of

precision that is required under the traditional method of demonstrating market power, Plaintiffs are required to prove, at least roughly, the parameters of the relevant [] markets.") (internal citation omitted); *Republic Tobacco Co. v. North Atlantic Trading Co., Inc.*, 381 F.3d 717, 737 (7th Cir. 2004) ("Economic analysis is virtually meaningless if it is entirely unmoored from at least a rough definition of a product and geographic market.").

Plaintiffs contend that defining the relevant market is unnecessary under *Broadcom*, but regardless, they have defined the rough contours of the relevant market "because the violation at issue was directed at delaying generic entry and necessarily suggests a market consisting of branded Neurontin and its generic equivalents." (Pl. MSJ Br., ECF No. 583 at 25.) Plaintiffs further assert that their expert Dr. Keith Leffler discusses the direct evidence approach in terms of market power and the supply of gabapentin, and has confirmed even through a full market analysis that the relevant market is Neurontin and its AB-rated generics.

The Court concludes that Plaintiffs must define, at least with a degree of approximation, the relevant market in their analysis under the direct evidence method. However, Plaintiffs have defined the approximate contours of the relevant market, at least roughly, and there are disputed issues of fact as to the boundaries of that market. (*See, e.g.*, DS[4] ¶¶ 1-3, 6, 9-13; PS ¶¶ 74-79.) Because market definition is a question of fact, *Weiss v. York Hosp.*, 745 F.2d 786, 825 (3d Cir. 1984), summary judgment is denied on this issue.

b. Supracompetitive Pricing and Restricted Output

The direct evidence method allows a plaintiff to establish monopoly power through direct proof of injury to competition that a competitor with market power may inflict. The parties

[4] DS refers to Defendants Statement of Undisputed Facts and Plaintiffs' corresponding responses, ECF No. 593; PS refers to Plaintiffs' Revised Statement of Undisputed Material Facts and Defendants' corresponding responses, ECF No. 570; JS refers to the Joint Statement of Undisputed Material Facts, ECF No. 592.

dispute what constitutes direct evidence of monopoly power. Plaintiffs claim that Dr. Leffler has thoroughly analyzed and established direct evidence of monopoly power, ultimately showing that before generic entry, *inter alia*, Pfizer earned a large margin on Neurontin with prices 13 times the cost of production and almost 8 times its total average cost; such high prices had nothing to do with high costs of production or sunk R&D costs; Neurontin sales declined after generic entry; Pfizer lost 66% of its branded Neurontin sales to lower-priced generic alternatives within 6 months of generic entry; and after generic entry Pfizer started selling generic gabapentin capsules and tablets that were virtually identical to Neurontin but lower priced. (PS ¶¶ 4, 5; JS ¶¶ 245-47, 252-53.)

Defendants argue that the evidence Plaintiffs use to show monopoly power is similar to the evidence that was rejected in *In re Remeron Direct Purchaser Antitrust Litigation*, a Section 2 antitrust case where summary judgment with respect to establishing monopoly power through the direct evidence approach was granted for defendants. 367 F. Supp. 2d 675, 679-80 (D.N.J. 2005). The direct evidence plaintiffs proffered there was that once generic producers of a drug were able to enter the market, "they did so with prices that were substantially lower than the price of their bioequivalent brand name competitor, Remeron. As more generic producers entered the market, the price of [the generic] continued to decline." [5] *Id.* at 680-81. Plaintiffs

[5] This Court summarized and rejected plaintiffs' additional direct evidence of market power as follows:

> Plaintiffs also offer the following as direct evidence of market power: (1) testimony of Plaintiffs' economic expert, Dr. Jeffrey Leitzinger that for a 3-year period prior to generic entry Remeron's price had increased from approximately $1.86 per tablet to approximately $2.29 per tablet, (2) Organon's internal documentation showing that Organon lost a significant percentage of its sales following generic entry, and (3) testimony of a Defense economic expert, Dr. Januz Ordover, that Organon had the ability to charge prices above short-run marginal cost prior to generic competition. Plaintiffs devote only a few sentences discussing these facts and offer no analysis about how these facts suffice to permit a reasonable juror to find monopoly power. As will be discussed,

argued that because the brand name price was much greater than the subsequent generic price, the defendant necessarily had monopoly power prior to generic entry. *Id.*

When granting summary judgment for defendants in *Remeron*, this Court held that "[i]f the direct evidence approach can ever supplant the market definition approach in the §2 context, it can only do so where a reasonable juror could find the evidence conclusive as to **why** Defendants' prices were higher." *Id.* at 683 (emphasis added). It further noted that "without evidence that sheds light on material factors such as [the alleged monopolist's] price relative to its total costs (marginal and fixed) and whether output was restricted, monopoly power cannot be found as a matter of law." *Id.* at 681 n.10. Plaintiffs did not meet their burden because they had "provided no evidence of excessive price-cost margins or restricted output but merely [relied] on the fact that later generic manufacturers could enter the market more cheaply than Remeron's price in order to establish monopoly power." *Id.* at 682.

Pfizer argues that Dr. Leffler failed to consider fixed costs as *Remeron* requires. Pfizer further contends that Plaintiffs have no evidence of restricted output, which is necessary because without it, there is no information from which a jury can determine why the defendant was able to charge a supracompetitive price. Plaintiffs initially argue that they need not offer independent proof of restricted output and that the sounder rule as a matter of economics is to recognize that

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> without evidence that sheds light on material factors such as Organon's price relative to its total costs (marginal *and* fixed) and whether output was restricted, monopoly power cannot be found as a matter of law. *See, e.g.*, PHILLIP E. AREEDA AND HERBERT HOVENKAMP, ANTITRUST LAW, AN ANALYSIS OF ANTITRUST PRINCIPLES AND THEIR APPLICATION, p. 516 (2d ed. 2002) ("No matter how accurately measured, of course, a substantial excess of price over marginal cost does not necessarily bring excess returns on investment. A firm generates excess profit only if price exceeds its average *total* cost, including its cost of capital.") (emphasis added); William M. Landes and Richard A. Posner, *Market Power in Antitrust Cases*, 94 HARV. L. REV. 937, 939 (1981) ("When the deviation of price from marginal cost ... simply reflects certain fixed costs, there is no occasion for antitrust concern.").

367 F. Supp. 2d at 681 n.10.

supracompetitive pricing and reduced output are alternative ways of proving the same anticompetitive effect.

While there may be other ways to prove monopoly power, proof of supracompetitive pricing cannot stand alone here. *Harrison Aire, Inc. v. Aerostar Intern., Inc.*, 423 F.3d 374 (3d Cir. 2005) (holding that supracompetitive price by itself did not support a reasonable inference of monopoly power); *Broadcom*, 501 F.3d at 307 (stating that direct evidence of supracompetitive prices **and** restricted output can show monopoly power) (emphasis added). Plaintiffs alternatively contend that even if evidence of restricted output is required, they have offered such evidence through Defendants' damages expert in the patent litigation, Dr. Phillip Beutel, who, according to Plaintiffs, testified that he expected gabapentin sales to be lower as a result of higher prices such as those before generic entry. (PS ¶ 61.)

While Defendants argue that Plaintiffs' evidence here is the same as that rejected in *Remeron*, Plaintiffs have proffered more evidence than the plaintiffs in *Remeron* to explain why there was a supracompetitive price, to wit, that it was not because of a higher quality product or because of R&D costs but was because Defendants had monopoly power. To this end, Plaintiffs have proffered evidence of, *inter alia*, Defendants' costs, Defendants' lost sales after generic entry, and Defendants' sale after generic entry of their own low-priced generic that was nearly identical to Neurontin. As evidenced by the voluminous record, the parties dispute material issues of fact as to Plaintiffs' indirect evidence of monopoly. Summary judgment is denied on this issue and thus on Plaintiffs' direct evidence approach as a whole. (*See*, *e.g.*, PS ¶¶ 4, 5, 59-61, 78; DS ¶ 8; JS ¶¶ 51, 245, 246-47, 250-53.)

ii. Indirect Evidence Method

To prove monopoly power under the indirect evidence method, a plaintiff must show that monopoly power can be inferred from the structure and composition of the relevant market. To support such an inference, a plaintiff must typically prove that the defendant has a dominant share in the relevant market, and that significant entry barriers protect that market. The scope of the market is a question of fact as to which the plaintiff bears the burden of proof. Proof of a relevant market requires an economic analysis of reasonable interchangeability of use and cross-elasticity of demand between a product and its substitutes. *Queen City Pizza, Inc. v. Domino's Pizza, Inc*., 124 F.3d 430, 436-37 (3d Cir. 1997); *Broadcom*, 501 F.3d at 307.

Plaintiffs utilize the indirect evidence method as an alternative way to show monopoly power, and attempt to do so through their expert Dr. Leffler who used principles of cross-elasticity of demand to define the relevant market as gabapentin. To examine cross-elasticity, Dr. Leffler considered 15 therapeutic alternatives that Pfizer identified during discovery as products that competed with Neurontin and gabapentin products, and analyzed their IMS sales data between 2004 and 2005 when the price of gabapentin fell by about 70% following generic entry. Dr. Leffler explained that if the 15 products were close economic substitutes for gabapentin, then their sales would have substantially decreased, but this did not occur. Therefore, Dr. Leffler did not include therapeutic alternatives in his definition of the relevant market. Furthermore, Dr. Leffler observed that when Pfizer's own subsidiary, Greenstone LLC, started selling Pfizer's authorized generic gabapentin, it based its price solely on Neurontin's price without considering the prices of other branded drugs. If other branded products were close economic substitutes for Neurontin, Dr. Leffler explained that Greenstone would be expected to have considered the prices of those products in pricing its generic gabapentin.

Pfizer argues that Dr. Leffler did not perform a proper market definition analysis because his analysis is based on observations of generic gabapentin entering the market as opposed to observations of Neurontin and its competitors, and because he did not consider all of Neurontin's primary competitors during the period of Pfizer's purported monopoly power (2002-2004). These issues will be tested by cross examination when this case goes to trial. The Court cannot find that monopoly power has or has not been established by the indirect method as a matter of law; there are disputed issues of material fact as to the confines of the relevant market, as supported by the parties' experts. (*See, e.g.*, PS ¶¶ 71, 73-78; DS ¶¶ 1-3, 6.) Therefore, summary judgment on the indirect evidence method is denied.

B. Anticompetitive Conduct

In deciding the motion to dismiss in this case, this Court held that "[i]f an antitrust 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 may trigger antitrust liability as an overall scheme." *In re Neurontin Antitrust Litigation*, 2009 WL 2751029, at *15. The parties dispute whether Plaintiffs have established Pfizer's anticompetitive conduct as a matter of law.

Plaintiffs attempt to show Pfizer's anticompetitive conduct through an overall scheme to delay generic entry through, *inter alia*, Pfizer's prosecution of its '482 patent and related infringement suit, which Plaintiffs claim were needlessly delayed and baseless; Pfizer's '476 and '479 Orange Book listings, which Plaintiffs claim were baseless; Pfizer's '476 and '479 patent infringement suits, which Plaintiffs contend were sham litigations; and Pfizer's statements upon pleading guilty to off-label marketing in 2004. Defendants respond that their patent

prosecutions, infringement suits, and Orange Book listings were reasonable and that the infringement suits are entitled to *Noerr-Pennington* immunity.

Because this element of Plaintiffs' claims is the source of Plaintiffs' request for collateral estoppel and their corollary motion to strike, both will be addressed in turn.

i. Collateral Estoppel

Plaintiffs request that the Court find Pfizer collaterally estopped from denying and relitigating certain key facts that have been determined against it in previous cases, including its 2004 guilty plea to illegal off-label marketing of Neurontin; findings of fact in the District of Massachusetts case before Judge Saris in 2010; and facts established in patent cases against potential generic entrants.

"Under the doctrine of collateral estoppel, 'once an issue is actually and necessarily determined by a court of competent jurisdiction, that determination is conclusive in subsequent suits based on a different cause of action involving a party to the prior litigation.'" *Anderson v. C.I.R.*, 698 F.3d 160, 164 (3d Cir. 2012) (quoting *Montana v. United States*, 440 U.S. 147, 153-54 (1979)). The doctrine only applies if: "1) the issue sought to be precluded [is] the same as that involved in the prior action; 2) that issue [was] actually litigated; 3) it [was] determined by a final and valid judgment; and 4) the determination [was] essential to the prior judgment." *Id.*, (citing *In re Graham*, 973 F.2d 1089, 1097 (3d Cir. 1992)); *Nat'l RR Passenger Corp. v. Pennsylvania Public Utility Com'n*, 342 F.3d 242 (3d Cir. 2003).

a. <u>2004 Guilty Plea</u>

In 2004, Pfizer pled guilty to distributing Neurontin as an "unapproved new drug" and as a "misbranded drug." In the instant action, Plaintiffs allege that Pfizer used off-label marketing as part of its overall scheme to preserve its gabapentin monopoly and that Pfizer's off-label

marketing increased the size of the market making its efforts to delay competition worthwhile while creating an opportunity to convert the market to Lyrica, a successor product.

Plaintiffs contend that some issues in this action are the same as in the 2004 criminal case where Pfizer pled guilty; that those issues were actually litigated in 2004 and determined by a final and valid criminal judgment; that the determination was essential to the prior judgment; and that statements in the criminal Information were essential to Pfizer's guilt, Pfizer acknowledged them, and Pfizer pled guilty with a complete recognition of their significance.

Collateral estoppel will apply here to those facts that formed the basis of the guilty plea as set forth in the plea allocution and the essential facts pertaining thereto. The parties mainly dispute to what Defendants pled guilty. Therefore, the parties are directed to meet and confer in person within 30 days regarding what these essential facts are and narrow their differences. The parties shall thereafter submit a joint report within 45 days to the Court regarding disputed facts in a dual column chart with a concise explanation of disputed positions as to each such fact. Genuine disputes will be referred to a Magistrate Judge or to a Special Master for a report and recommendation as to whether the facts were essential to the guilty plea. The parties are advised that cost shifting will occur if either side wastes the time of the Special Master or the Court on issues that were not encompassed within the guilty plea. The Court expects that the criminal guilty plea will speak for itself, and expects that the issues in dispute will be narrowly circumscribed.

b. District of Massachusetts Litigation

Plaintiffs contend that the findings of fact issued by Judge Saris following a civil trial in the District of Massachusetts regarding fraudulent marketing of Neurontin should be given preclusive effect in this case. *In re Neurontin Marketing and Sales Practices Litig.*, No. 04-cv-

10739, 2011 WL 3852254, *1 (D. Mass. Aug. 31, 2011). Defendants oppose Plaintiffs' request and argue that the issues in the two cases are not identical, and that the scope and duration of Pfizer's alleged off-label marketing were not essential to the final judgment in the *Marketing Practices Litigation.*[6]

While the ultimate issues in the two cases are not entirely congruent, the specific issue on which Plaintiffs seek preclusion was a major issue litigated in the *Marketing Practices Litigation*—namely whether Pfizer illegally marketed Neurontin for off-label uses—and was a basis for the judgment. Judge Saris made findings of fact regarding Pfizer's off-label marketing, specifically holding that the off-label marketing was national in scope and that it continued through December 2004, which was after Pfizer acquired Warner-Lambert. *Id.* at *7, *12, *13. Pfizer's fraudulent off-label marketing was the basis for its liability and was essential to the question of damages in the *Marketing Practices Litigation*. *Id.* at *30-34, *46.[7] Differences in

[6] Defendants also argued that Plaintiffs' request should not be granted because the case was on appeal, but the Court has since been notified that the First Circuit Court of Appeals affirmed the jury verdict following trial and Judge Saris's Findings of Fact and Conclusions of Law concerning Pfizer's off-label marketing of Neurontin. *In re Neurontin Marketing and Sales Practices Litig*., 712 F.3d 21 (1st Cir. 2013).

[7] Judge Saris's findings included: "[F]raudulent marketing activities took place during the following time periods for each indication: (1) bipolar disorder: July 1998 through December 2004; (2) neuropathic pain: November 1997 through December 2004; (3) migraine: April 1999 through December 2004; and (4) doses greater than 1800 mg/day: November 1997 through December 2004." (*id.* at *12); "Kaiser relied on defendants' fraudulent marketing activities during the following time periods for each indication: (1) bipolar disorder: June 1999 through December 2004; (2) neuropathic pain: September 1999 through December 2004; (3) migraine: September 1999 through December 2004; and (4) doses greater than 1800 mg/day: September 1999 through December 2004." (*id.* at *30); "[T]here is no reliable scientific evidence that Neurontin is effective for bipolar disorder, migraine, or at high doses. With respect to some kinds of neuropathic pain, there is some scientific evidence of efficacy. However, as the FDA found, there is no reliable scientific evidence to support a broad indication of neuropathic pain." (*id.* at *34); "[T]he jury returned a verdict for Kaiser . . . finding that defendants engaged in fraudulent business acts or practices with respect to all off-label indications except nociceptive pain. The jury also found that those fraudulent acts or practices caused Kaiser damages with respect to all off-label indications except nociceptive pain. The Court agrees with the jury's conclusion." (*id.*

application of the fact of illegal off-label promotion to the legal issue before Judge Saris and the legal issue before this Court do not change the facts themselves. Therefore, Defendants are precluded from denying those findings of fact in Judge Saris's opinion that govern the nature and scope of Pfizer's off-label marketing.

c. Unsuccessful Patent Cases

Pfizer has been involved in various patent cases with respect to Neurontin, and Plaintiffs argue that Pfizer should not be allowed to relitigate facts established in those cases. Plaintiffs request that the court estop Pfizer from denying:

1) The holding in *Warner-Lambert Co. v. Apotex Corp.* that Pfizer had no evidence that the generic defendants "took any steps to encourage doctors to write gabapentin prescriptions for neurodegenerative diseases" or that they "knew doctors were prescribing gabapentin for the neurodegenerative diseases covered by the '479 patent," and that the inference that steps were taken to promote neurodegenerative use would be inappropriate given the infrequency with which Neurontin is prescribed for neurodegenerative diseases. No. 98 C 4293, 2001 WL 1104618, *3, *4, n.12 (N.D. Ill. Sept. 14, 2001) (granting defendants' motion for summary judgment on claim for infringement).
2) The conclusions in the subsequent *Warner-Lambert Co. v. Apotex Corp.* appeal that Pfizer had "not produced any authority" that the '479 patent was "required to be filed under subsection (b) or (c)" of 21 U.S.C. § 355, and that given the small percentage of Neurontin prescriptions to treat neurodegenerative disease, "it defie[d] common

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at 46). Judge Saris's findings of fact relating to the nature and scope of the off-label marketing were necessary to the finding of Pfizer's liability in that case such that Pfizer is estopped from denying them in this case.

sense to expect that Apotex [would] actively promote the sale of its approved gabapentin in contravention of FDA regulations for a use that a) might infringe Warner-Lambert's patent and b) constitutes such a small fraction of total sales." 316 F.3d 1348, 1361, 1363-65 (Fed. Cir. 2003).

3) The court's holding in *In re Gabapentin Patent Litig.* that Apotex's formulation of generic gabapentin did not infringe Pfizer's '482 patent because it contained sodium croscarmelose, an adjuvant excluded by the "clear teaching of claim 7" of the patent. MDL No. 1384, 2005 WL 4066434, at *11-12 (D.N.J. Aug. 22, 2005).

Plaintiffs argue that all of the issues in these cases are the same as issues here; that those issues were actually litigated and determined by a final and valid judgment in the previous patent cases; and that the determinations were essential to the prior judgments in the previous patent cases. Defendants dispute the similarity of the issues and dispute that the findings in those cases were essential to the final judgments. Further, they note that later opinions in the patent infringement cases undercut Plaintiffs' sham litigation claims. For example, Defendants note that in an opinion denying a motion for attorney's fees, Judge Plunkett wrote that Pfizer's '479 infringement claim had a reasonable basis in law and fact. *Warner-Lambert v. Apotex Corp.*, No. 98 C 4293, 2003 WL 22887861, *7 (N.D. Ill. Dec. 4, 2003).

Both sides here seek to use portions of prior court rulings to support and defend against the sham litigation allegations. The Court holds that each side may use prior court rulings in a stipulation that does not contain any names of judges. It will conserve judicial time not to relitigate those predicate fact issues, where such issues and cases have already consumed an inordinate amount of judicial time. However, the legal question of whether such facts do or do

not meet the burdens of proof in this case as to sham litigation must still be litigated, as this is a different conclusion of law.

ii. Motion to Strike

In response to Plaintiffs' sham litigation allegations, Pfizer seeks to use evidence of settlements it reached with generic manufacturers in prior infringement cases to establish that its infringement lawsuits had merit. Plaintiffs request that Defendants be precluded from using those settlements as evidence in this litigation, and request that the Court strike all references to those settlements in Pfizer's Motion for Summary Judgment. Alternatively, Plaintiffs request full discovery as to Pfizer's settlement agreements, including their negotiation, drafting and execution.

Plaintiffs argue that evidence of settlement is barred by Federal Rule of Evidence 408, particularly where such evidence is used to show a lack of liability, and would also be more prejudicial than probative under Rule 403. The purpose of Rule 408, however, is to encourage settlement, and such a purpose is not jeopardized in situations where, as here, the settlement agreements at issue involve parties different from the case where the agreements are sought to be introduced. Further, courts have considered settlement agreements where there are allegations of sham litigation. *See, e.g., Rubloff Dev. Grp., Inc. v. Supervalu, Inc.*, No. 10 C 3917, 2012 WL 1032784, at *7 (N.D. Ill. Mar. 27, 2012) (holding that a settlement comprising of a $200,000 payment and significant concessions was "fatal to the sham litigation" allegation). Therefore, the Court will allow Defendants' use of settlement agreements to defend against Plaintiffs' allegations of sham litigation. However, the Court will refer the parties to Magistrate Judge Hammer for appropriately circumscribed discovery on those settlement agreements Defendants seek to use in order to determine the reasons that the defendants in those patent infringement

suits entered into the settlement agreements and agreed to the terms thereof. Such information will assist a fact finder in determining whether the patent infringement suits were indeed sham litigations.

Summary judgment is denied as to the anticompetitive conduct element of Plaintiffs' monopolization claims because there are numerous disputed issues of material fact. (*See, e.g.*, PS ¶¶ 7, 12, 15, 19, 20, 45-46; DS ¶¶ 34, 42.)

C. Causation

To prove damages, a plaintiff has the burden of showing that in a hypothetical but-for world without the alleged antitrust misconduct, their claimed injury would not have occurred.

Plaintiffs assert that in their but-for world, Apotex would have obtained a final court order of dismissal triggering Purepac's 180-day Hatch-Waxman exclusivity at least six months before December 2002, as a result of either: 1) Pfizer conceding that Apotex's product contained excluded adjuvants on or about March 7, 2001 when Aptoex filed its motion for summary judgment, thereby resulting in dismissal of the matter, or 2) an earlier issuance of the '482 patent, by August 1998, because Pfizer would not have asked for numerous extensions, and an earlier judgment of non-infringement of the '482 patent in favor of Apotex, because of the earlier issuance date. This would have triggered Purepac's exclusivity so that other generics could have entered the market in December 2002, two years before the actual entry date, driving down the price of gabapentin.

Pfizer argues that Plaintiffs' but-for scenarios are wholly speculative. Further, Pfizer contends that Plaintiffs cannot establish that any alleged antitrust misconduct caused their injury because Plaintiffs' purported injury is wholly attributable to Purepac and the Hatch-Waxman

regulatory regime. Purepac did not obtain FDA approval for its product until September 2003 and thereafter delayed its product launch. As a result, generics could not have entered the market until October 2004, regardless of Pfizer's alleged misconduct. The Hatch-Waxman regulations prevented generics from obtaining FDA approval until Purepac's 180-day exclusivity expired.

This Court has already held that Plaintiffs need only show that the alleged anticompetitive conduct "materially caused their alleged injuries," or "flows from Warner-Lambert's anti-competitive conduct," not that Defendants were the sole cause of injury. *In re Neurontin Antitrust Litigation*, 2009 WL 2751029, at *11. Moreover, causation is a factual issue for the jury. *Rivas v. City of Passaic*, 365 F.3d 181, 193 (3d Cir. 2004). Because there are disputed issues of fact as to whether Pfizer's overall scheme actually delayed generic entry or whether there were intervening causes, summary judgment is denied as to causation. (*See, e.g.*, DS ¶¶ 48-46.)

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion for Summary Judgment, Plaintiffs' Motion for Partial Summary Judgment, and Plaintiffs' Motion to Strike are denied. An appropriate Order will issue.

/s/ Faith S. Hochberg

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