

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF RHODE ISLAND

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IN RE LOESTRIN 24 FE	)	MDL No. 13-2472-S-PAS
ANTITRUST LITIGATION	)	
	)	No. 1:13-md-2472-S-PAS
	)	
THIS DOCUMENT RELATES TO:	)	
ALL ACTIONS	)	
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**OPINION AND ORDER**

WILLIAM E. SMITH, Chief Judge.

The plaintiffs in this multidistrict litigation (“MDL”) seek damages from the defendant-pharmaceutical companies for an allegedly anti-competitive scheme relating to Loestrin 24 FE (“Loestrin 24”), an oral contraceptive comprising 24 norethindrone acetate/ethinyl estradiol (1 mg/20 mcg) tablets and four ferrous fumarate tablets.

In June 2013, the United States Supreme Court decided a landmark patent antitrust case, FTC v. Actavis, Inc., 133 S. Ct. 2223 (2013), which held that “reverse payments” – settlement payments in patent infringement suits remitted by patent holders to alleged infringers – are subject to the rule of reason under federal antitrust law. In October 2013, the United States Judicial Panel on Multidistrict Litigation consolidated and transferred the instant litigation to this Court. (See Transfer Order, ECF No. 1.) In September 2014, after briefing and argument, the Court

dismissed the complaints, holding that Actavis applied only to cash payments and reserving judgment on all other issues. See generally In re Loestrin 24 Fe Antitrust Litig., 45 F. Supp. 3d 180 (D.R.I. 2014) ("Loestrin 24 (D.R.I.)"). The First Circuit disagreed, vacating the dismissal and remanding for further proceedings. See generally In re Loestrin 24 Fe Antitrust Litig., 814 F.3d 538 (1st Cir. 2016) ("Loestrin 24").

On remand from the Circuit, the plaintiffs have amended their complaints, and the parties have re-briefed and argued the defendants' motions to dismiss. Before the Court are two Motions to Dismiss<sup>1</sup> seeking to dismiss the four Operative Complaints<sup>2</sup> in this MDL. For the reasons set forth below, and as previously ordered by this Court on July 21, 2017 (ECF No. 299), the Warner Chilcott Defendants' Motion to Dismiss (ECF No. 192) is GRANTED with respect to the parent companies; DENIED WITHOUT PREJUDICE with respect to the End-Payor Plaintiffs' ("EPPs") claims under state law in the twenty-five states and Puerto Rico in which they

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<sup>1</sup> See Lupin Defs.' Mot. to Dismiss, ECF No. 191; Warner Chilcott Defs.' Mot. to Dismiss, ECF No. 192. All docket references are to the sealed or unredacted versions of the documents, where they exist.

<sup>2</sup> "Operative Complaints" refers to the following: Direct Purchaser Class Pls.' Second Am. Consolidated Class Action Compl. and Jury Demand ("DPP Compl."), ECF No. 168; End-Payor Pls.' Second Am. Consolidated Class Action Compl. ("EPP Compl."), ECF No. 169; Walgreen et al. Am. Compl. and Demand for Jury Trial ("Walgreen Compl."), ECF No. 176-1; CVS et al. Am. Compl. and Demand for Jury Trial ("CVS Compl."), ECF No. 177-1.

failed to plead that they have either resided or purchased Loestrin 24 products in the state; DENIED WITHOUT PREJUDICE with respect to arguments that the EPPs failed to state a claim for relief under various state laws for antitrust violations, consumer protection violations, and unjust enrichment; and DENIED in all other respects. The Lupin Defendants' Motion to Dismiss (ECF No. 191) is DENIED.

I. Background<sup>3</sup>

A. The Parties

This MDL litigation consolidates four complaints filed by four sets of plaintiffs. The Direct Purchaser Plaintiffs ("DPPs") are corporate entities that purchased Loestrin 24 directly from Warner Chilcott, one of the defendants.<sup>4</sup> The Retailers, or the opt-out DPPs, comprise the Walgreen Plaintiffs<sup>5</sup> and the CVS

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<sup>3</sup> The Court recites some of the background information from its prior decision in this case, Loestrin 24 (D.R.I.), 45 F. Supp. 3d 180, for general context. Because the Operative Complaints have been amended to include additional claims for relief that attack Defendants' conduct every step of the way, from Warner Chilcott's procurement of the patent to the introduction of a new drug, Minastrin 24, before the '394 patent expired, the factual allegations underlying the additional claims are included.

<sup>4</sup> The DPPs are American Sales Company, LLC, who filed a Complaint on its own behalf and as an assignee of McKesson Corporation; and Rochester Drug Cooperative. (DPP Compl. ¶¶ 16-17.)

<sup>5</sup> The "Walgreen Plaintiffs" are Walgreen Co., on behalf of itself and as the assignee of Cardinal Health Inc. ("Cardinal") and AmerisourceBergen Drug Corporation; The Kroger Co., on behalf of itself and as the assignee of Cardinal; Safeway Inc., on behalf

Plaintiffs.<sup>6</sup> The EPPs are "third-party payors" or "indirect purchasers." They generally comprise employee welfare benefit programs that reimbursed subscribers who purchased Loestrin 24, but also include three individuals who purchased Loestrin 24 for their own use.<sup>7</sup>

Defendants are pharmaceutical companies; due to various mergers and acquisitions in the industry, their relationships to one another have changed over the relevant time period, and even during the course of this litigation. (DPP Compl. ¶¶ 18-30.) Warner Chilcott Company, LLC ("Warner Chilcott")<sup>8</sup> is the current

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of itself and as the assignee of Cardinal and McKesson Corporation ("McKesson"); HEB Grocery Company L.P., on behalf of itself and as assignee of Cardinal and McKesson; Albertson's LLC, on behalf of itself and as the assignee of McKesson. (Walgreen Compl. ¶¶ 17-21.)

<sup>6</sup> The "CVS Plaintiffs" are CVS Pharmacy, Inc.; Rite Aid Corporation; and Rite Aid Hdqtrs. Corp. (CVS Compl. 1.)

<sup>7</sup> The EPPs are the City of Providence; A.F. of L. - A.C.G. Building Trades Welfare Plan; Allied Services Division Welfare Fund; Electrical Workers 242 and 294 Health & Welfare Fund; Fraternal Order of Police, Fort Lauderdale Lodge 31; Insurance Trust Fund; Laborers International Union of North America; Local 35 Health Care Fund; Painters District Council No. 30 Health & Welfare Fund; Teamsters Local 237 Welfare Benefits Fun; United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund; Denise Loy; Melissa Chrestmas; and Mary Alexander. (EPP Compl. 1.)

<sup>8</sup> Along with Warner Chilcott Company, LLC, the Court refers to the following defendants as "Warner Chilcott": Warner Chilcott plc; Warner Chilcott Company, Inc.; Warner Chilcott (US), LLC; Warner Chilcott Laboratories Ireland Limited; Warner Chilcott Holdings Company III, Ltd; Warner Chilcott Corporation; and Warner Chilcott Sales (US), LLC. (DPP Compl. ¶¶ 18-22; CVS Compl. ¶¶ 19-

assignee of the patent covering Loestrin 24, U.S. Patent No. 5,552,394 ("the '394 patent"), and it holds the approved New Drug Application ("NDA") from the Food and Drug Administration (the "FDA") for Loestrin 24. (Id. ¶¶ 7, 19.) Defendant Watson Laboratories, Inc. is a wholly-owned subsidiary of Watson Pharmaceuticals, Inc., which acquired Actavis, Inc. in 2013 and continued operations under the name Actavis, Inc.; the Court refers to these defendants collectively as "Watson," except when explicitly discussing Actavis, Inc. (CVS Compl. ¶ 30.) Warner Chilcott and Watson are currently both part of Defendant Allergan plc.<sup>9</sup> (EPP Compl. ¶ 27.) The remaining defendants are Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively, "Lupin" and, together with Warner Chilcott and Watson, "Defendants"). (CVS Compl. ¶¶ 32-34.) Because Warner Chilcott's and Watson's interests are now aligned, and they have submitted joint briefing, they are collectively referred to as the "Warner Chilcott Defendants." The

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27.)

<sup>9</sup> In January 2013, Watson Pharmaceuticals, Inc. acquired Actavis Inc. and assumed the name Actavis, Inc. for its merged operation. (DPP Compl. ¶ 26.) In October 2013, Actavis, Inc. acquired Warner Chilcott plc and continued to operate under the name Actavis plc. (Id. ¶ 27.) In March 2015, Actavis plc acquired Allergan plc, and announced, in June 2015, that it would change its name to Allergan plc. (Id. ¶ 28.) As noted in the text, the Court refers to Warner Chilcott and Watson as the "Warner Chilcott Defendants" when discussing the arguments presented in their briefing because they submitted joint briefing and to provide a degree of continuity with prior decisions of this Court and the Court of Appeals in this MDL.

EPPs, Walgreen Plaintiffs, and CVS Plaintiffs have named Lupin as a defendant; the DPPs have not. (DPP Compl. ¶ 16-30; EPP Compl. ¶¶ 40-41; Walgreens Compl. ¶¶ 36-37; CVS Compl. ¶¶ 32-34.)

B. Generics and the Hatch-Waxman Act Regulatory Framework

The public relies on pharmaceutical companies to develop and bring to market the medical advances that keep us healthy. For this reason, our patent laws afford substantial protection to firms whose innovation leads to the development of new and beneficial medications. Typically, a company that has developed a beneficial and successful medication will enjoy a period of time during which it can sell it exclusively and at a supracompetitive price, thereby recovering its development costs and turning a profit. This period of exclusivity is considered to be an essential incentive for further healthcare and biopharmaceutical research and innovation. See Wendy H. Schacht and John R. Thomas, Cong. Research Serv., RL30756, Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act") 2-5 (2000).

Once the period of exclusivity expires, however, generic competitors enter the market, severely undercutting the manufacturer's pricing scheme and eliminating most of the innovator's profits. (EPP Compl. ¶ 66.) For example, where there is a single generic competitor, the generic tends to be priced approximately 10% lower than the brand name counterpart. (DPP

Compl. ¶ 56.) And, where there are multiple generic alternatives, the price of the generics typically falls to 50% to 80% below the brand name product, driving the price close to the marginal cost of production. (Id. ¶¶ 56, 70.) It is no mystery then why a brand and first-filing generic may be motivated to conspire to keep the brand's monopoly going, splitting the higher profits amongst themselves. (See id. ¶ 74.)

Because every state has passed a law to either require or permit pharmacies to substitute AB-rated generics for brand name drugs (unless the prescribing doctor orders otherwise), generally within a year of generic market entry, generics will capture 90% of sales and prices will fall by as much as 85%. (DPP Compl. ¶ 57.) Not surprisingly, then, brand manufacturers view generic competition as a serious threat to profits. (Id.) If there is no generic on the market, the pharmacy must fill the prescription with the branded drug, and supracompetitive pricing may continue. (See id. ¶ 59.)

The Drug Price Competition and Patent Term Restoration Act of 1984 (more commonly known as the "Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984), as amended, prescribes the process by which pharmaceutical firms may gain approval from the FDA to bring medications to market. There are four key features to the Hatch-Waxman Act's architecture.

First, a drug manufacturer that wishes to market a new product must submit a New Drug Application ("NDA") to the FDA and undergo a rigorous approval process. See Hatch-Waxman Act, 21 U.S.C. § 355(b)(1)(A) (requiring, inter alia, that the manufacturer provide "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use"). By all accounts, this approval process is arduous and expensive. But, once the FDA has approved an NDA, the manufacturer is entitled to list the drug in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" (also known as the "Orange Book"). (DPP Compl. ¶ 38.) The Orange Book entry provides a measure of protection for the manufacturer by allowing it to list any patents that the manufacturer believes could be asserted against generic competitors. (Id.)

Second, the Hatch-Waxman Act recognized that if manufacturers who have gained FDA approval were allowed to charge supracompetitive prices indefinitely, it would harm consumers. Therefore, the Act creates a mechanism to promote the availability of cheaper generic alternatives by allowing generic manufacturers to bypass many of the onerous aspects of the NDA process. Instead of filing an NDA, a generic manufacturer may instead file an Abbreviated NDA ("ANDA"). See 21 U.S.C. § 355(j). An ANDA incorporates the findings of safety and effectiveness of the previously-approved NDA, and generally assures that the proposed



generic contains the same active ingredients and is otherwise as equally safe and effective as the brand name counterpart. See id. at § 355(j)(2). Thus, the ANDA process allows a generic manufacturer to obtain approval while avoiding the "costly and time-consuming studies" needed to obtain approval for a "pioneer drug." Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990). The FDA assigns a rating of "AB" when it determines a generic drug is therapeutically equivalent to its brand-name counterpart. (Walgreen Compl. ¶ 48.) To be therapeutically equivalent, the ANDA must demonstrate that the generic drug is both pharmaceutically equivalent and bioequivalent, or in other words, that it "contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug . . . ." (Id.)

Third, the Hatch-Waxman Act sets forth procedures for resolving patent disputes between brand and generic manufacturers. A generic manufacturer filing an ANDA must certify to the FDA that the proposed generic does not infringe any patents listed in the Orange Book. See 21 U.S.C. § 355(j)(2)(A)(vii). This certification can be made in one of several ways. The generic manufacturer may represent that: (1) the brand manufacturer has not filed any relevant patents; (2) any relevant patents have expired; or (3) a relevant patent is soon to expire and the generic

will not be marketed until after the expiration. Id. at §§ 355(j)(2)(A)(vii)(I)-(III). Alternatively, the generic manufacturer may represent that the patent covering the brand drug is invalid or will not be infringed by the proposed generic (a so-called "Paragraph IV certification"). Id. at § 355(j)(2)(A)(vii)(IV).

An ANDA filer who relies on a Paragraph IV certification will almost certainly be sued for patent infringement by the brand manufacturer. Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 407 (2012) ("Filing a paragraph IV certification means provoking litigation."). Indeed, if the brand manufacturer brings an infringement suit within 45 days of the generic manufacturer's filing of the ANDA, the Hatch-Waxman Act provides that the FDA must withhold approval of the generic for a 30-month period during which the parties may litigate the validity of the underlying patent. 21 U.S.C. § 355(j)(5)(B)(iii).

Finally, in order to incentivize generic manufacturers that incur the costs and risks stemming from Paragraph IV certification litigation, and to encourage generic competition, the Hatch-Waxman Act affords the first successful Paragraph IV ANDA filer a 180-day post-approval exclusivity period during which that manufacturer is the only authorized generic seller.<sup>10</sup> Id. at

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<sup>10</sup> Importantly, a brand manufacturer is not prohibited from offering its own generic during this 180-day period. (DPP Compl.

§ 355(j)(5)(B)(iv). Because the price of a drug drops precipitously as more and more generics enter the market, this initial period of exclusivity can generate substantial profits for the first generic manufacturer. C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553, 1579 (2006) (describing first-filed ANDA status as “worth several hundred million dollars to a generic firm that successfully challenges the patents on a major drug”).

C. Loestrin 24 and the '394 Patent

The active ingredients in Loestrin 24, norethindrone acetate and ethinyl estradiol, were approved by the FDA as a means of oral contraception in 1973 under the brand names Loestrin 1.5/30 and Loestrin 1/20.<sup>11</sup> (DPP Compl. ¶¶ 1, 100-01.) Loestrin 1.5/30 and Loestrin 1/20 were generally marketed for use over a 21-day period; women would take the oral contraceptive for 21 consecutive days, followed by a placebo pill containing iron for the following 7

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¶ 65.) When a brand manufacturer does so, its generic is referred to as an “authorized generic” or “AG.” A brand manufacturer’s decision not to offer an authorized generic has the potential to increase profits for the initial generic manufacturer. See In re Effexor XR Antitrust Litig., No. CIV.A. 11-5479 PGS, 2014 WL 4988410, at \*21 (D.N.J. Oct. 6, 2014).

<sup>11</sup> Loestrin 1.5/30 denotes that it contains 1.5 mg norethindrone acetate and 30 mcg ethinyl estradiol, whereas Loestrin 1/20 contains 1 mg norethindrone acetate and 20 mcg ethinyl estradiol. (DPP Compl. 30 n.27.)

days, before starting the next cycle. (See id. ¶ 102.) Two additional Loestrin products (viz., Loestrin 21 1.5/30 and Loestrin 21 1/20) were approved by the FDA in 1976; they contained only 21 active tablets of the same composition of Loestrin 1.5/30 and Loestrin 1/20, respectively, and omitted the 7 placebo pills. (Id. ¶¶ 104-06.)

On July 22, 1994, a professor at the Eastern Virginia Medical School ("EVMS"), Dr. Gary Hodgen,

applied for a patent for a method of female contraception characterized by a reduced incidence of breakthrough bleeding by administering a combination of estrogen and progestin for 23-25 consecutive days of a 28-day cycle in which the daily amounts of estrogen and progestin are equivalent to about 5-35 mcg of ethinyl estradiol and about 0.025 to 10 mg of norethindrone acetate.

(Id. ¶ 117 (emphasis omitted).) Dr. Hodgen assigned the patent application to EVMS. (Id.) Occasional intermenstrual bleeding, also referred to as "breakthrough bleeding" or "spotting," is vaginal bleeding that occurs mid-cycle, as opposed to during menstruation, and can be a common occurrence associated with many oral contraceptives. (Id. ¶ 119.)

Dr. Hodgen, in support of his application, submitted data from a 1992 study conducted with ten monkeys. (Id. ¶¶ 122, 124.) In that study, scientists from EVMS administered Loestrin 1/20 active tablets (ground up and adjusted to account for lower body weight) to monkeys and ostensibly found that the monkeys had a decrease in the incidence of breakthrough bleeding when they

received active ingredient tablets for 24 days, rather than 21 days. (Id. ¶¶ 124-25.)

According to Plaintiffs' allegations, "[b]eginning on or around January 1993" scientists at EVMS conducted a human study in which two groups comprising fifteen women each followed one of two low dose oral contraceptive regimens for three months. (See, e.g., id. ¶¶ 127, 129.) The first group received a regimen of 25 days of Loestrin 1/20 tablets followed by 3 placebo tablets; the second group followed a monthly regimen of 21 Loestrin 1/20 tablets followed by 7 placebo tablets. (Id. ¶ 129.) The study participants in the first group knew they were following a regimen of 25 days of Loestrin 1/20 tablets followed by 3 placebo tablets; participants were not required to keep the study design or methods confidential. (Id. ¶ 130.) The scientists found no significant differences between the two groups in the women's incidence of breakthrough bleeding. (Id. ¶ 132.) The study was published in the Journal of the Society for Gynecologic Investigation in March 1996. (Id. ¶ 133.)

Dr. Hodgen submitted an application to the Patent and Trademark Office ("PTO") in July 1994.<sup>12</sup> (Walgreen Compl. ¶ 3.)

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<sup>12</sup> Plaintiffs define the applicants for the invention covering Loestrin 24 differently. The EPPs define the applicants as "including Hodgen, counsel, and others substantially involved in [the '394 patent's] prosecution"; the DPPs allege that Dr. Hodgen and his attorney were responsible for the fraudulent omissions and misrepresentations during the patent prosecution. (EPP Comp.

Within the application, he included "minimal data" from the monkey study, and did not disclose the results of the human study to the PTO. (DPP Compl. ¶¶ 122, 126.) According to Plaintiffs' Complaints, "the patent examiner focused on two issues: [(1)] the amount of ethinyl estradiol and norethindrone acetate in oral contraceptives disclosed in the prior art; and [(2)] whether the invention decreased breakthrough bleeding." (See, e.g., id. ¶ 135.) With respect to the first issue, the examiner noted that a prior art reference (namely, the Craft reference) disclosed a contraceptive regimen of 50 mcg of ethinyl estradiol and 3 mg of norethindrone acetate. (Id. ¶ 136.) The examiner further noted that a second prior art reference, EPO 253,607, also known as the "Upton reference," disclosed a contraceptive regimen of administering 15 mcg ethinyl estradiol with progestin each day, with a 24-day dosing regimen. (Id.) With this information, the patent examiner made an initial determination that the Craft and Upton references rendered all claims obvious. (Id.) The applicants responded, in pertinent part, as follows:

[T]he claimed regimen leaves the patient with a total estrogen exposure per annum which is well below the total annual dose of estrogen in all other combination formulations commercially available in this country. Those all contain at least 30 mcg EE (Craft uses 50 mcg) and a regimen of 21 dosing day plus a 7-day pill free interval. . . . In contrast to Craft, the present

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¶ 144; DPP Compl. ¶ 3.) The Walgreen and CVS Plaintiffs identify the applicants as Dr. Hodgen and Parke-Davis. (Walgreen Comp. ¶ 80; CVS Compl. ¶ 77.)

invention employs a lower estrogen dosage which does not participate in this contraceptive efficacy but instead controls unscheduled bleeding.

(Id. ¶ 137 (alteration and emphasis in original).) The applicants did not disclose that Loestrin 1/20 contains 20 mcg of ethinyl estradiol and that it had been publicly available since the 1970s.

(Id.)

With respect to the second issue, in response to the applicants' rejoinder, the patent examiner addressed whether the invention reduced breakthrough bleeding. (Id. ¶ 138.) The examiner again rejected the claims because the amount of ethinyl estradiol disclosed in the claims (35 mcg) was similar to that taught by the Craft reference (50 mcg) and the applicants had not shown "that a dosage regimen different by only 15 mcg less of estrogen has unexpected contraceptive and reduced breakthrough bleeding results." (Id. (emphasis omitted).)

The EPPs allege in their Complaint that two U.S Patents and one publication teach of doses of ethinyl estradiol that "fall within the claimed ranges and weight rations of the '394 patent," as well as European Patent No. 253,607, which discloses a 24-day dosing regimen. (See EPP Compl. ¶¶ 132, 134 (citing the WO 93/17686 publication, U.S. Patent No. 5,108,995, and U.S. Patent No. 4,826,831).) They also allege that the prior art was such that "[o]ne of ordinary skill would thus have expected that administering a combination of estrogen and progestin for 23-25

days, or specifically 24 days, would be safe and effective.” (Id. ¶ 136; see also id. ¶¶ 131-42.)

On February 5, 1996, the patent examiner issued a Notice of Allowability for all claims. The patent issued in September 1996. (DPP Compl. ¶ 134.) The resulting patent, the ‘394 patent, is titled “Low Dose Oral Contraceptives with Less Breakthrough Bleeding and Sustained Efficacy.” (Id. ¶ 118.) As mentioned, Loestrin 24 has 24 tablets containing 1 mg of norethindrone acetate and 20 mcg of ethinyl estradiol, as well as 4 placebo tablets containing iron. (Id. ¶ 109.) Thus the active tablets mimic Loestrin 1/20 and Loestrin 21. Warner Chilcott owned the ‘394 patent from 2003, when its predecessor acquired it, through Watson’s generic entry in July 2014.<sup>13</sup> (EPP Compl. ¶¶ 155, 172.)

In April 2005, Warner Chilcott submitted an NDA and, in February 2006, received FDA approval to market the dosing regimen that would become Loestrin 24. (DPP Compl. ¶ 108.) At approximately the same time, Warner Chilcott listed Loestrin 24 in the Orange Book. (See id. ¶¶ 113-16.) According to the DPPs, “[b]efore listing the ‘394 patent, Warner Chilcott knew that it was invalid and/or unenforceable.” (Id. ¶ 116.) Warner Chilcott earned over \$1.75 billion in revenue between 2006 and 2012 from

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<sup>13</sup> Pfizer acquired Warner Lambert in 2000. Galen Holdings plc acquired the ‘394 patent from Pfizer, along with the entire Loestrin franchise, in March 2003. In July 2004, Galen Holdings changed its name to Warner Chilcott. (DPP Compl. ¶ 146.)



sales of branded Loestrin 24, and its sales were approximately \$247 million annually in 2009. (Id. ¶ 112; CVS Compl. ¶ 126.)

D. Watson Challenges the '394 Patent

In June 2006, just several months after Warner Chilcott's NDA was approved, Watson notified Warner Chilcott that it had filed an ANDA to market a generic version of Loestrin 24 based on a Paragraph IV certification that the generic would not infringe the '394 patent.<sup>14</sup> (DPP Compl. ¶¶ 168, 171.) Not unpredictably, Warner Chilcott responded by filing suit against Watson.<sup>15</sup> (Id. ¶ 172.) By doing so, Warner Chilcott triggered the 30-month stay provision of the Hatch-Waxman Act, preventing the FDA from approving Watson's ANDA for at least 30 months. (See id. ¶ 172.)

In January 2009, at approximately the same time that the 30-month stay would have expired (that would have allowed the FDA to move forward on Watson's ANDA), and before the parties briefed the

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<sup>14</sup> Plaintiffs attribute Watson's expeditious filing to the fact that the '394 patent claimed only a "narrow method" (viz., three extra days of tablets) of administering active ingredients that have been available as oral contraceptives for decades. (DPP Compl. ¶ 170.)

<sup>15</sup> See Warner Chilcott Co. v. Watson Pharms., Inc., C.A. No. 2:06-cv-3491-HAA-ES (D.N.J.). Watson alleged that the applicants intentionally concealed from the PTO a public use of the claimed invention; the applicants intentionally misrepresented and withheld material information from the PTO about the amount of estrogen in the prior art; and the applicants intentionally withheld a prior art teaching that oral contraceptives could be taken for longer than 21 days for purported enhanced efficacy. (DPP Compl. ¶ 177.)

substantive issues in the case, the parties filed a dismissal stipulation and entered into a settlement agreement (the "Watson Agreement"). (Id. ¶¶ 183-84, 187.) Pursuant to the Watson Agreement, Watson agreed to delay the launch of a Loestrin 24 generic until the earliest of: (1) January 2014, approximately six months prior to the expiration of the '394 patent; (2) "180 days before a date on which Warner Chilcott grants rights to a third party to market a generic version of Loestrin 24 in the United States"; or (3) "the date on which another generic version of Loestrin 24 enters the market." (Id. ¶ 188.) In exchange for this, Warner Chilcott and Watson entered into a series of deals that, in the DPPs' calculation, were worth at least \$66 million. (Id. ¶¶ 9, 189-218.) Specifically, the Watson Agreement provided that Warner Chilcott (1) would not launch an authorized generic Loestrin 24 within Watson's first 180 days on the market,<sup>16</sup> which the DPPs estimate to be worth at least \$41.34 million to Watson;<sup>17</sup> (2) would not grant a license to any other generics for at least

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<sup>16</sup> A pledge by a brand manufacturer not to launch an authorized generic is often referred to as a "no authorized generic agreement" or "no-AG agreement." (DPP Compl. 3 n.1.)

<sup>17</sup> The DPPs include a detailed explanation of how they calculated the value of the no-AG agreement to Watson in their Complaint. (Id. ¶¶ 194-99.) The Walgreen Plaintiffs, to give another example, "conservatively" value this piece of the deal at \$41.2 million. (Walgreen Compl. ¶ 127.)

the first six months Watson had entered the market;<sup>18</sup> (3) agreed to pay Watson annual fees and a percentage of net sales in connection with the co-promotion of a separate Warner Chilcott drug called Femring, a deal valued by the DPPs to be worth about \$25 million to Watson;<sup>19</sup> and (4) would give Watson the exclusive right to market and sell a separate Warner Chilcott oral contraceptive known as Generess Fe, memorialized in a patent license and finished product supply agreements, in exchange for Warner Chilcott receiving 15% of net sales until the launch of a generic Generess product or if Watson exercised a buy-out right; this was valued by the DPPs to be worth tens of millions to Watson. (DPP Compl. ¶¶ 9, 205, 210-11.) The EPPs value the sum of these deals as worth at least \$216.67 million to Watson; the DPPs value it as worth tens or hundreds of millions to Watson; and the Retailers value the sum of the deals at approximately \$266 million to Watson. (EPP Compl. ¶ 4; DPP Compl. ¶¶ 9, 192, 199; CVS Compl.

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<sup>18</sup> The EPPs refer to this provision as an acceleration clause and are the only Plaintiffs to challenge it as a reverse payment. (EPP Compl. ¶¶ 188-89 & n.11.)

<sup>19</sup> In the Femring deal, Watson received the exclusive right, along with Warner Chilcott's subsidiary Galen (Chemicals) Limited to promote Femring in the United States from January 9, 2009 through December 31, 2011. Warner Chilcott agreed to pay Watson 50% of the net sales of Femring to the extent net sales exceeded \$10 million and 5% of the net sales above \$10 million for 12 months after the co-promotion agreement ended. In addition, Warner Chilcott was to compensate Watson \$5.5 million as a sales and marketing support fee, paid in quarterly installments. (DPP Compl. ¶¶ 214-16 & n.43.)

¶¶ 124, 131-32.) Plaintiffs allege that these “side deals” occurred contemporaneously with the settlement of the ‘394 patent infringement suit. (See, e.g., DPP Compl. ¶ 205.)

Plaintiffs allege that Warner Chilcott entered into agreements, or “reverse payments,” as a quid pro quo for Watson’s agreement to abandon its invalidity, unenforceability, and infringement claims, as well as Watson’s agreement to delay generic competition to Loestrin 24. (DPP Compl. ¶¶ 189, 191.) They further allege that Watson could not have obtained these payments if it had prevailed in the patent infringement suit against Warner Chilcott. (Id. ¶ 190.) Plaintiffs plead that litigation costs for similar patent infringement suits cost approximately \$6 to \$10 million, from complaint to verdict. (Id. ¶¶ 192, 199 (citing American Intellectual Property Lawyers Association, 2013 Report of the Economic Survey 34 (2013)); EPP Compl. ¶ 197 (“Warner Chilcott’s future expected litigation costs at the time of the settlement with Watson were much less than that because, among other reasons, the patent case had been pending for years.”).)

The DPPs point to a 2002 FTC report suggesting that generic manufacturers won 73% of the Hatch-Waxman patent litigation suits decided on the merits from 1992 to 2002. (DPP Compl. ¶ 49 (citing FTC, Generic Drug Entry Prior to Patent Expiration: An FTC Study, at vi-vii (July 2002)); John R. Allison, Mark A. Lemley & David L. Schwartz, Understanding the Realities of Modern Patent Litigation,

92 Tex. L. Rev. 1769, 1787 (2014) (noting that generic challengers prevailed in 74% of patent infringement suits filed in 2008 and 2009 and decided on the merits).)

E. Lupin Challenges the '394 Patent

Six months after Warner Chilcott and Watson announced the Watson Agreement, in June 2009, Lupin notified Warner Chilcott that it too had filed an ANDA seeking to market a generic alternative to Loestrin 24. (DPP Compl. ¶ 220.) Like Watson, Lupin based its ANDA on a Paragraph IV certification that Lupin's generic would not infringe the '394 patent. (Id.) And, as before, Warner Chilcott responded by filing suit.<sup>20</sup> (Id. ¶ 221 & n.44.) Again, merely by filing suit, Warner Chilcott triggered a 30-month stay of the Lupin generic under the Hatch-Waxman Act. (See id. ¶ 222.)

In October 2010, Warner Chilcott dismissed the suit, and Warner and Lupin entered into an agreement (the "Lupin Agreement"). (Id. ¶ 225.) Pursuant to that agreement, Lupin agreed not to market its Loestrin 24 generic until July 2014, the same month the '394 patent was to expire and six months after Watson had been authorized to market its generic. (Id. ¶ 226.)

Like Watson, Lupin is alleged to have benefitted from its agreement to delay the introduction of its generic. First, Warner

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<sup>20</sup> See Warner Chilcott LLC v. Lupin Ltd., C.A. No. 1:09-cv-673-JCJ (D. Del.).

Chilcott granted Lupin a license to market Femcon Fe, a separate oral contraceptive manufactured by Warner Chilcott, beginning on the earlier of 180 days after Teva Pharmaceutical Industries, Ltd (the first filer) entered the market with a generic equivalent, or January 1, 2013. (EPP Compl. ¶ 214.) The EPPs value this at approximately \$15 million to Lupin. (Id. ¶ 5(a).) Plaintiffs allege that, but for this agreement, Lupin would not have been able to enter the market until, at a minimum, January 31, 2012, at the end of the 30-month stay. (See, e.g., EPP Compl. ¶ 214.) Second, Lupin was given the right to sell a generic version of Asacol 400, an anti-inflammatory drug to be supplied by Warner Chilcott, if a generic version of Asacol 400 was launched by another generic manufacturer in the United States. (DPP Compl. ¶ 228.) The EPPs value this deal as being worth at least \$50 million to Lupin. (EPP Compl. ¶ 5(b).) Third, Warner Chilcott agreed to pay \$2 million in attorneys' fees to Lupin. (DPP Compl. ¶ 229.)<sup>21</sup>

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<sup>21</sup> The EPPs allege that Warner Chilcott paid Lupin \$4 million. (EPP Compl. ¶ 5(c).) Defendants clarify that the Lupin Agreement provided for \$4 million in attorneys' fees and litigation costs, \$2 million for each of the Loestrin 24 and Femcon patent lawsuits. (Warner Chilcott & Watson Defs.' Omnibus Mem. Supporting Dismissal of all Claims in all Pls.' Compls. ("Warner Chilcott Mot. to Dismiss") 52 n.39, ECF No. 198 (quoting Lupin Agreement, Ex. H to the Decl. of Alison Hanstead ¶ 22).) For the purposes of this Opinion, it makes no difference whether Warner Chilcott and Lupin believed Warner Chilcott to be paying \$2 million or \$4 million toward litigation costs and attorneys' fees.

The EPPs and the Retailer Plaintiffs challenge the Lupin Agreement as a reverse payment. (See, e.g., EPP Compl. ¶¶ 355-63; Walgreen Compl. ¶¶ 146-47.) The DPPs do not.

F. Mylan Challenges the '394 Patent

In April 2011, six months after the Lupin Agreement was announced, Mylan Pharmaceuticals Inc. ("Mylan"), together with Famy Care Ltd., notified Warner Chilcott that Mylan and Famy Care Ltd. had filed an ANDA for a generic Loestrin 24 and included in its notice letter a Paragraph IV certification. (DPP Compl. ¶ 233; EPP Compl. ¶ 227.) In June 2011, Warner Chilcott filed suit against Mylan alleging infringement of the '394 patent. (DPP Compl. ¶ 234 & n.45; EPP Compl. ¶ 228.) The 30-month stay was triggered, and the case proceeded through claim construction. (DPP Compl. ¶¶ 235-36.) While this suit was pending, the Federal Circuit ruled in a similar patent suit that the patent covering another low-dose, extended-regimen oral contraceptive was invalid for obviousness. (EPP Compl. ¶¶ 234-36.) Warner Chilcott and Mylan entered into a settlement agreement and dismissed the case just weeks before it was scheduled for trial. (DPP Compl. ¶ 239.) Mylan agreed to dismiss its suit challenging the '394 patent, and delay entry of its generic version of Loestrin 24 until July 22, 2014 - the month the '394 patent was set to expire. (EPP Compl.

¶ 241.)

G. Warner Chilcott Introduces Minastrin 24

Before generic Loestrin 24 could enter the market, Warner Chilcott created a second, similar product. According to Plaintiffs, this second product had no safety, efficacy, or other benefit of any sort for consumers, and it was formulated as a step in the broader anticompetitive scheme. (See, e.g., EPP Compl. ¶¶ 244-45.) In July 2012, Warner Chilcott submitted an NDA for a second oral contraceptive comprised of 24 norethindrone acetate/ethinyl estradiol (1 mg/20 mcg) tablets and four ferrous fumarate tablets; this drug was later marketed under the brand name Minastrin 24. (DPP Compl. ¶ 252.) Minastrin 24 was different from Loestrin 24 in two ways: Warner Chilcott added spearmint and a sweetener to the inactive pills (there was no change to the active pills), and its proposed labeling instructed women to chew the pill before swallowing. (Id. ¶ 253.) In essence, the only differences between the active pills in Loestrin 24 and Minastrin 24 were their method of use (chew vs. swallow) and markings. (Id. ¶¶ 255-56 (quoting the FDA as stating that, "[t]he NA and EE tablets of the proposed product [Minastrin 24] have the same components, composition, doses, and dosing regimen as the NA and EE tablets of Loestrin@24 Fe[ ]"); see also EPP Compl. ¶ 250 (quoting the FDA as stating "with the exception of tablet debossing and insignificant manufacturing changes, the proposed drug product



[Minastrin 24] is identical to approved Loestrin 24 Fe[ ]" (internal citation omitted).) The inactive pills solely serve as reminder pills, there is no medical reason to take the pills, and they may be discarded. (DPP Compl. ¶ 254; EPP Compl. ¶ 248.)

The FDA approved the Minastrin 24 NDA in May 2013. (DPP Compl. ¶ 252.) Minastrin 24 and Loestrin 24 are not AB-rated and, therefore, pharmacies cannot substitute Minastrin 24 for generic Loestrin 24. (Id. ¶ 268.) Warner Chilcott launched Minastrin 24 in July 2013, sending its sales force out to "aggressively switch" Loestrin 24 prescriptions to those for Minastrin 24. (Id. ¶¶ 266, 273.) It stopped promoting Loestrin 24 and promoted Minastrin 24 instead. (Id. ¶ 273.)

In August 2013, Warner Chilcott withdrew branded Loestrin 24 from the market. (Id. ¶ 267.) The DPPs' Complaint states that "Warner Chilcott did not remove existing Loestrin 24 supplies from the market but instead ceased manufacturing and distributing Loestrin 24." (Id.) In June 2014, after receiving new three-year marketing exclusivity, Warner Chilcott changed the Minastrin 24 labeling to state that women could either chew or swallow the pills. (Id. ¶¶ 270, 282.)

Plaintiffs allege that Warner Chilcott's sole motivation in this alleged "product hop" was to impair generic competition. (Id. ¶¶ 277, 280.) But for its impairing generic competition, it would have been a money-losing endeavor for Warner Chilcott. (EPP Compl.

¶ 270; DPP Compl. ¶ 280.) Plaintiffs claim that the Minastrin 24 product hop involved extra costs (developing, patenting, gaining FDA approval of, and marketing Minastrin 24) and lost revenue (from branded sales of Loestrin 24), at least in the short run, for Warner Chilcott. (DPP Compl. ¶¶ 278-80.) Warner Chilcott's motivation is further revealed by its withdrawal of the request for FDA approval for Minastrin 24 on two occasions, at least once for "business reasons," that corresponded with settlement negotiations with Watson and Lupin. (EPP Compl. ¶¶ 273-75.)

The Complaints allege that "Warner Chilcott successfully converted virtually all of Loestrin 24 prescriptions to Minastrin 24 before Watson's generic entered in January 2014." (DPP Compl. ¶ 288.)

#### H. Harm to Consumers

According to Plaintiffs, the net effect of the alleged anticompetitive scheme, from the '394 patent application to the Minastrin 24 product hop, was to delay generic competition until at least January 2014. (See, e.g., EPP Compl. ¶¶ 281-85; DPP Compl. ¶ 288.) Absent these various efforts, Plaintiffs allege, Loestrin 24 would have faced generic competition as early as September 2009, when the FDA approved Watson's ANDA. (DPP Compl. ¶¶ 15, 325.) At that time, Warner Chilcott would have lost its monopoly - other generic versions of Loestrin 24, including an authorized generic would have entered the market - and consumers

would have paid less for oral contraceptives comprising 24 norethindrone acetate/ethinyl estradiol (1 mg/20 mcg) and four ferrous fumarate tablets by:

(i) substituting purchases of less-expensive AB-rated generic Loestrin 24 for their purchases of more-expensive branded Loestrin 24; (ii) receiving discounts on their remaining branded Loestrin 24 purchases; (iii) purchasing generic Loestrin 24 at lower prices sooner; and (iv) purchasing less expensive generic Loestrin 24 instead of more expensive branded Minastrin 24.

(DPP Compl. ¶¶ 325, 328, 331.) As a result, Plaintiffs were injured by paying overcharges for the oral contraceptive. (Id. ¶ 15.)

Plaintiffs argue that Defendants' scheme and unlawful payments harmed Plaintiffs by allowing Defendants to:

(a) delay the entry of less expensive generic versions of Loestrin 24 in the United States; (b) fix, raise, maintain or stabilize the price of Loestrin 24; and (c) allocate 100% of the U.S. market for Loestrin 24 and its generic equivalents to Warner Chilcott.

(Walgreen Compl. ¶ 163.)

#### I. Claims for Relief

The DPPs bring claims against Defendant Warner Chilcott for violating § 1 of the Sherman Antitrust Act (the "Sherman Act"), 15 U.S.C. § 1, by entering into the Watson Agreement, and § 2 of the Sherman Act for engaging in an exclusionary, anticompetitive scheme designed to create and maintain a monopoly in the market for Loestrin 24 drugs. (DPP Compl. ¶¶ 346, 353-55.) Under this

latter claim, Plaintiffs attack Warner Chilcott's listing of the drug in the Orange Book; filing a "sham" lawsuit against generic manufacturers of Loestrin 24; the reverse payment to Watson; reformulating Loestrin 24 into Minastrin 24; aggressively switching sales from Loestrin 24 to Minastrin 24; and removing Loestrin 24 from the market months before expected generic entry. (Id. ¶ 346.)

The EPPs bring seven claims sounding in state antitrust law, state consumer protection law, and unjust enrichment against Warner Chilcott, Watson, and Lupin. More specifically, the EPPs allege: (1) a monopolization and monopolistic scheme under state law, or state antitrust claims under state law (EPP Compl. ¶¶ 338-52); (2) conspiracy and combination in restraint of trade under state law against Warner Chilcott and Watson (id. ¶¶ 346-54); (3) conspiracy and combination in restraint of trade under state law against Warner Chilcott and Lupin (id. ¶¶ 355-63); (4) conspiracy and combination in restraint of trade under state law against all Defendants (id. ¶¶ 364-73); (5) unfair or unconscionable acts and practices under state law against all Defendants (id. ¶¶ 374-79); (6) unjust enrichment against all Defendants (id. ¶¶ 380-91); and (7) grounds for declaratory and injunctive relief under federal law against Warner Chilcott (id. ¶¶ 392-97).

The Walgreen and CVS Plaintiffs, separately, bring claims against Warner Chilcott for violating § 2 of the Sherman Act by

monopolization and attempt to monopolize (Walgreen Compl. ¶¶ 197-208; CVS Compl. ¶¶ 195-206); against Warner Chilcott and Watson, as well as Warner Chilcott and Lupin, for violating § 1 of the Sherman Act by conspiring to restrain trade through the reverse payments (Walgreen Compl. ¶¶ 209-24; CVS Compl. ¶¶ 207-22); and against all Defendants for conspiring to restrain trade in violation of § 1 of the Sherman Act (Walgreen Compl. ¶ 225-29; CVS Compl. ¶¶ 223-27).

## II. Legal Standard

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "[N]aked assertion[s]," "[t]hreadbare recitals of the elements of a cause of action," and "mere conclusory statements" are insufficient to survive dismissal. Id. (internal citations omitted). That being said, "the pleadings need not contain 'detailed factual allegations' but must provide 'more than labels and conclusions, and a formulaic recitation of the elements of the cause of action will not do.'" Loestrin 24, 814 F.3d at 549 (quoting Twombly, 550 U.S. at 555). As the First Circuit has stated in this very case,

it is important to note that Twombly addressed the specific question of "what a plaintiff must plead in order to state a claim under § 1 of the Sherman Act,"

and [the First Circuit] has cautioned against converting Twombly's mandates into a requirement that antitrust plaintiffs provide evidentiary support or set forth other "plus factors" to demonstrate the plausibility of their Sherman Act claims[.]

Id. at 549 (internal citations omitted). Plaintiffs must plead facts sufficient "to raise a reasonable expectation that discovery will reveal evidence" of the Sherman Act violations. Twombly, 550 U.S. at 556.

### III. Discussion

#### A. Market Power

Defendants argue that Plaintiffs have failed to plausibly allege that Warner Chilcott exercised market power in a relevant economic market, taking particular aim at Plaintiffs' narrowly defined market comprising only Loestrin 24, Minastrin 24, and their AB-rated generic equivalents. (See Warner Chilcott & Watson Defs.' Omnibus Mem. Supporting Dismissal of all Claims in all Pls.' Compls. ("Warner Chilcott Mot. to Dismiss") 3-5, ECF No. 198.) Defendants argue that the relevant market is properly defined as the wider oral contraceptive market - which they characterize as a "fragmented and highly competitive" market. (See id. at 10.) In this broader market, they contend Loestrin 24 did not enjoy sufficient market power to exercise a monopoly. But Defendants concede, as they must, that courts generally treat this fact-intensive issue as one to be decided on a motion for summary judgment (if no genuine issue of material fact exists) or at trial.

(See Warner Chilcott & Watson Defs.' Omnibus Reply Mem. ("Warner Chilcott Reply") 8 & n.6, ECF No. 212 (citing, for example, In re Nexium (Esomeprazole) Antitrust Litig., 968 F. Supp. 2d 367, 389 (D. Mass. 2013) (Nexium I); Andrx Pharm., Inc. v. Elan Corp., 421 F.3d 1227, 1235 (11th Cir. 2005)).)

To state a claim for relief under § 1 of the Sherman Act, a plaintiff must plead sufficient facts to demonstrate that "the defendant had market power in the relevant market, and the specific intent to restrain competition." CVD, Inc. v. Raytheon Co., 769 F.2d 842, 851 (1st Cir. 1985). Under § 2 of the Sherman Act, similarly, a plaintiff must demonstrate that "the defendant had the specific intent to monopolize the relevant market, and a dangerous probability of success." Id.

Market power, sometimes called monopoly power, "is the abilities (1) to price substantially above the competitive level and (2) to persist in doing so for a significant period without erosion by new entry or expansion." In re Aggrenox Antitrust Litig., 199 F. Supp. 3d 662, 665 (D. Conn. 2016) ("Aggrenox II") (quoting IIB Areeda & Hovenkamp, Antitrust Law, ¶ 501, at 111 (3rd ed. 2007) (emphasis in original)).<sup>22</sup> A plaintiff may demonstrate

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<sup>22</sup> The leading antitrust treatise, Areeda and Hovenkamp on Antitrust Law, notes that "[c]ourts often define market power as the ability (1) to control prices or (2) to 'exclude competition.'" IIB Areeda & Hovenkamp, Antitrust Law, ¶ 501, at 111 (3d ed. 2007) ("Areeda"); see, e.g., United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 391 (1956) (defining market power as "the power

market power in two ways: “[a] plaintiff can either show direct evidence of market power (perhaps by showing actual supracompetitive prices and restricted output) or circumstantial evidence of market power.” Coastal Fuels Inc. v. Caribbean Petroleum Corp., 79 F.3d 182, 196-97 (1st Cir. 1996) (citing Rebel Oil Co., Inc. v. Atlantic Richfield Co., 51 F.3d 1421, 1434 (9th Cir. 1995)); see also In re Aggrenox Antitrust Litigation, 94 F. Supp. 3d 224, 246 (D. Conn. 2015) (“Aggrenox I”) (“[W]hen direct evidence is available that a party profitably charges supracompetitive prices, the existence of market power can be established from that fact alone.” (citing Tops Markets, Inc. v. Quality Markets, Inc., 142 F.3d 90, 97-98 (2d Cir. 1998))); accord Actavis, 133 S. Ct. at 2236-37 (“[T]he size of the [reverse] payment from a branded drug manufacturer to prospective generic is itself a strong indicator of power . . . .” If a large reverse payment is demonstrated it “may well” suggest “market power derived from the patent.”) (quotation and citation omitted).

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to control prices or exclude competition”). This definition, however, has been called “needlessly confusing” because the power to exclude competition does not “itself bring[] substantial market power.” Aggrenox II, 199 F. Supp. 3d at 665 (quoting Areeda ¶ 501). For example, in Aggrenox II, the court noted that a patent holder may be able to exclude competitors from a market for which there is low or no demand. Id. at 664-65 (citing Areeda ¶ 501). In that circumstance, however, the patent holder has not established market power because it would be unable to charge supracompetitive prices. See id. (citing Areeda ¶ 501).



A "relevant market" is properly defined as consisting of "commodities reasonably interchangeable by consumers for the same purposes." Nexium I, 968 F. Supp. 2d at 395 (quotation omitted); see also Brown Shoe Co. v. United States, 370 U.S. 294, 325 (1962) ("The outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it."). Products are not reasonably interchangeable merely because they share similar forms or functions, but rather "[s]uch limits are drawn according to the cross-elasticity of demand for the product in question - the extent to which purchasers will accept substitute products in instances of price fluctuation and other changes." Nexium I, 968 F. Supp. 2d at 387-88 (quoting George R. Whitten, Jr., Inc. v. Paddock Pool Builders, Inc., 508 F.2d 547, 552 (1st Cir. 1974)).

There is no strict prohibition on defining a relevant market as a single-drug market. See, e.g., Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 482 (1992) ("This Court's prior cases support the proposition that in some instances one brand of a product can constitute a separate market."); Geneva Pharms. Tech. Corp. v. Barr Labs., Inc., 386 F.3d 485, 496-500 (2d Cir. 2004) (defining the relevant market as the generic versions of a particular drug, excluding the branded version of the drug); In re Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279,

1319 n.40 (S.D. Fla. 2005) (defining a relevant market as a branded drug and its generic counterpart); In re Cardizem CD Antitrust Litig., 105 F. Supp. 2d 618, 680-81 (E.D. Mich. 2000), aff'd, 332 F.3d 896 (6th Cir. 2003) (holding a branded drug and its generic version to be a plausible relevant market); Nexium I, 968 F. Supp. 2d at 388 (holding a single branded drug and its generic to be a plausible relevant market).

In the instant case, Plaintiffs' Complaints allege the following. Warner Chilcott had monopoly power in the relevant market and, at relevant times, enjoyed a market share of 100%. (DPP Compl. ¶¶ 300, 309.) Plaintiffs define the relevant market as oral contraceptives with 24 active tablets containing 1 mg norethindrone acetate and 20 mcg ethinyl estradiol and four inactive iron tablets. As defined, this market comprises Loestrin 24, Loestrin 24's AB-rated generic equivalents, Minastrin 24, and Minastrin 24's AB-rated generic equivalents (collectively, the "Loestrin 24 drugs"), as well as narrower markets therein. (Id. ¶¶ 300-01.)

In support of their allegation that Warner Chilcott had market power sufficient to exclude competitors and control prices of Loestrin 24 drugs, Plaintiffs rely on direct evidence of market power. They allege that direct evidence shows that:

- (i) generic versions of each [of the Loestrin 24 drugs] would have entered the market at substantial discounts to the brand versions but for the defendants'

anticompetitive conduct; (ii) the gross margin on each drug was at all times at least 60%; and (iii) the defendants never lowered the price of the drugs to the competitive level in response to the pricing of other branded or generic drugs.

(Id. ¶ 302.) According to Plaintiffs, this resulted in Warner Chilcott selling branded Loestrin 24 drugs in excess of marginal costs and in excess of the competitive prices, thereby allowing them to enjoy high profit margins. (Id. ¶ 306.) Plaintiffs further allege that, “[a]t competitive prices, Loestrin 24 drugs do not exhibit significant, positive, cross-elasticity of demand with respect to price with any other oral contraceptive other than AB-rated generic versions of those Loestrin 24 drugs.” (Id. ¶ 304.) Plaintiffs say that only the entry of AB-rated generic Loestrin 24 drugs would have undercut Warner Chilcott’s ability to maintain supracompetitive prices for Loestrin 24 drugs. (Id. ¶ 305.) This market had high barriers to entry due to patent protection; the high cost of entry and expansion; the cost of marketing and physician detailing; and AB-rated generic substitution laws. (Id. ¶ 308.) Loestrin 24 and Minastrin 24 are not reasonably interchangeable with other drugs, according to Plaintiffs, other than their AB-rated generic versions, due to “attributes [that] significantly differentiat[e] them from other oral contraceptives and mak[e] them unique as against other oral contraceptives”; indeed, according to Plaintiffs, “[t]he FDA does not consider Loestrin 24 drugs and other oral contraceptives

interchangeable," in light of variations in their active ingredients and dosages. (Id. ¶ 310.) Moreover, oral contraceptives differ in their efficacy, safety, and side effect profiles. These differences drive a doctor's recommendation, as well as a woman's decision, to continue taking a particular oral contraceptive. (Id. ¶ 312.)

While there are many oral contraceptives on the market, this is not a typical market because the consumer generally neither fully chooses nor pays for the product. In the typical case, a doctor chooses the oral contraceptive her patient will buy and the patient's insurer pays for it. (See id. ¶ 313.) As a result, the pharmaceutical marketplace exhibits a disconnect between the product selection and the payment obligation, with the consequence that price does not drive prescriptions for oral contraceptives, as it would in most other markets. (Id. ¶ 313.) Even though other oral contraceptives were available on the market, including lower-priced generics that were not AB-rated to Loestrin 24, Loestrin 24's sales increased from 2008 to 2011, and its price increased each year. (Id. ¶ 319.)

Thus, in these circumstances, and at this preliminary stage of the case, the Court concludes that Plaintiffs have met their burden by plausibly alleging that Warner Chilcott charged supracompetitive prices for Loestrin drugs without losing sales, and thus Warner Chilcott had market power in the relevant market.

Having said this, it may very well turn out, after discovery, that the Loestrin drugs are in fact reasonably economically interchangeable with other oral contraceptives, or some subset of oral contraceptives. But, this is a fact-sensitive issue that is not appropriately decided on a motion to dismiss. See Eastman Kodak Co., 504 U.S. at 482 (noting that "[t]he proper market definition" required "factual inquiry into the 'commercial realities' faced by consumers"); Nexium I, 968 F. Supp. 2d at 388 (stating that the interchangeability of the drug with other drugs is "such a factually intensive determination [it] is better left for resolution by a jury").<sup>23</sup>

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<sup>23</sup> In a thoughtful decision in In re Aggrenox Antitrust Litigation, Judge Underhill concluded that the relevant market in that post-Actavis case was "determined by the nature of the challenged [reverse payment settlement] agreement, that the only relevant market . . . [was] therefore the market of Aggrenox and its generic equivalents, and that no discovery or evidence relating to other drugs as potential substitutes [was] relevant." Aggrenox II, 199 F. Supp. 3d at 663; see also id. at 665-66 (noting that the relevant market would "be implicitly defined by the scope of the disputed patent[,]" which was the market in which the allegedly unlawful reverse payment "acted as an anticompetitive restraint"). While the Court notes this interesting approach, it takes no position at this time on whether, in this case, it will exclude indirect evidence at summary judgment or trial, when the question of defining the relevant market will be ripe for decision. Notably, in Judge Underhill's earlier decision on the Aggrenox defendants' motion to dismiss, he made clear that market power is "clearly a fact-intensive inquiry, and for that reason 'courts hesitate to grant motions to dismiss for failure to plead a relevant product market.'" Aggrenox I, 94 F. Supp. 3d at 246 (quoting Todd v. Exxon Corp., 275 F.3d 191, 199-200 (2d Cir. 2001)).

## B. Reverse Payment

All Plaintiffs allege that the terms of the Watson Agreement constituted a large and unjustified reverse payment made in exchange for Watson's promise to delay entry of its AB-rated generic version of Loestrin 24 for almost five years. (See, e.g., DPP Compl. ¶ 218.) The EPPs and Retailer Plaintiffs also challenge the Lupin Agreement as an unlawful reverse payment. (EPP Compl. ¶¶ 215-19; Walgreen Compl. ¶¶ 144-45; CVS Compl. ¶ 141-42.) Defendants move to dismiss these claims.

Reverse payments are subject to the rule of reason. Actavis, 133 S. Ct. at 2237-38. The rule of reason is applied in a three-step process: a plaintiff must first "prove anticompetitive effects," by demonstrating "a payment for delay, or, in other words, payment to prevent the risk of competition." King Drug Co. of Florence v. Smithkline Beecham Corp., 791 F.3d 388, 412 (3d Cir. 2015) ("Lamictal"), cert. denied, 137 S. Ct. 446 (2016) (citing Actavis, 133 S. Ct. at 2235-36). "[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." Actavis, 133 S. Ct. at 2237. Second, if the plaintiffs satisfy the first step, "the burden then shifts to the [d]efendants to show that a challenged payment was justified

by some precompetitive objective"; and third, "the burden shifts back to the [p]laintiffs to establish, under the rule of reason, that the settlement is nevertheless anticompetitive on balance." In re Nexium (Esomeprazole) Antitrust Litig., 42 F. Supp. 3d 231, 262-63 (D. Mass. 2014) ("Nexium II").

Before the Court sets out to address whether Plaintiffs have plausibly alleged a large and unjustified reverse payment, there are several threshold issues to address.

First, the parties disagree about the significance of the "five sets of considerations" addressed in Actavis. 133 S. Ct. at 2234. In the instant case, the First Circuit expressly rejected a reading of the five considerations as "guid[ing] the inquiry as to whether a settlement payment satisfies the rule of reason[.]" Loestrin 24, 814 F.3d at 551 n.12. Rather, the First Circuit agreed with the DPPs that the Supreme Court proffered these considerations "only as justifications for why subjecting reverse payments to antitrust scrutiny outweigh the public policy in favor of settlements . . . [and, thus,] the five considerations should not overhaul the rule of reason, nor should they create a new five-part framework in antitrust cases." Id. at 551 n.12 (internal citation omitted) (emphasis added); see also id. at 544 ("The Supreme Court acknowledged the 'general legal policy' in favor of settlements, but determined that 'five sets of considerations' weighed in favor of subjecting reverse payment settlements to

antitrust scrutiny." (quoting Actavis, 133 S. Ct. at 2234-37)). As a result, the Court meets the Warner Chilcott Defendants' argument that the five guideposts discussed in Actavis "set[] forth key considerations [that the Court must address here] for discerning between traditional settlements (as to which there is no concern) and unusual settlements (as to which further scrutiny may be required)," with a healthy dose of skepticism. (See Warner Chilcott Reply 15; see also Warner Chilcott Mot. to Dismiss 36.) The Warner Chilcott Defendants seize the Supreme Court's statement that "[w]here a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." Actavis, 133 S. Ct. at 2236. Rather than adopting the Warner Chilcott Defendants' emphasis on the distinction between traditional and nontraditional settlement terms, however, the Court adheres to the First Circuit's guidance in Loestrin 24.

Second, the Court must choose a framework within which to analyze the alleged unlawful reverse payments under the Watson and Lupin Agreements, given their complexity. On this, the parties seem to agree that the Court must look at each component of the two deals, as well as each settlement agreement as a whole, to determine whether plausible claims have been set forth that the



Watson and Lupin Agreements constitute large and unjustified reverse payments.<sup>24</sup>

This is well supported by the case law. On the one hand, there is support for analyzing each component of a complex, non-cash reverse payment settlement to determine whether it is cognizable under Actavis. See, e.g., In re Actos End Payor Antitrust Litig., No. 13-CV-9244 (RA), 2015 WL 5610752, at \*12-13, 18 (S.D.N.Y. Sept. 22, 2015) ("Actos"), aff'd in part, vacated in part on other grounds 848 F.3d 89 (2d Cir. 2017) (holding that an acceleration clause is not subject to antitrust scrutiny where Plaintiffs conceded that they could be procompetitive in some circumstances, but noting that no-AG clauses are subject to antitrust scrutiny). Indeed, the First Circuit, in the instant case, directed this Court to address on remand the subsequent issue of "whether the individual provisions of the settlement agreements . . . would have been adequately alleged as unlawful reverse

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<sup>24</sup> See, e.g., Mot. Hr'g Tr. 33:16-22, Jan. 13, 2017, ECF No. 266 (Warner Chilcott's attorney advancing a framework under which the Court "look[s] at each alleged payment [to] see what are the allegations, are they plausible as to whether this is first of all cognizable at all; but, if it is, to what extent have they plausibly alleged the payment exceeds fair value. And then you basically look at them in total and say, well, together do they plausibly amount to something that's large"); Mem. in Supp. of DPPs' Obj. to Warner Chilcott & Watson Defs.' Mot. to Dismiss All Claims in All Pls.' May 9, 2016 Compls. 53, ECF No. 206-2 ("Even if this Court should find that one of the provisions does not constitute a reserve-payment, such a finding would still not warrant dismissal . . . .").

payments.” Loestrin 24, 814 F.3d at 548; see also id. (“[T]he district court . . . did not address the subsequent question of whether the individual provisions of the settlement agreements – including the no-AG agreement, the acceleration clause, and the various side deals – would have been adequately alleged as unlawful reverse payments were Actavis to extend to non-cash payments.”). There is similar support for looking at the whole of the settlement to determine its alleged effect on competition. See Aggrenox I, 94 F. Supp. 3d at 243 (“A settlement agreement may be very simple or tremendously complex, and it may involve all manner of consideration; and if, when viewed holistically, it effects a large and unexplained net transfer of value from the patent-holder to the alleged patent-infringer, it may fairly be called a reverse-payment settlement.”); see also In re Opana ER Antitrust Litig., 162 F. Supp. 3d 704, 718 (N.D. Ill. 2016) (“Opana”) (declining the defendants’ invitation to assess the components of the settlement in a “piecemeal fashion” to determine whether “each individual payment fails to rise to the level of a large and unjustified payment” and choosing instead to “determine whether, when taken as a whole, the total payment . . . was large and unjustified”); In re Niaspan Antitrust Litigation, 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014) (“Niaspan”) (“[D]efendants may not improperly ‘dismember’ plaintiffs’ Consolidated Amended Complaints by examining each of the three settlement agreements in isolation. Rather, the

Licensing Agreement must be read in conjunction with the Co-Promotion and Manufacturing Agreements executed that same day.”) (internal citations omitted).

Here, because the Operative Complaints set forth plausible allegations that the Watson and Lupin Agreements were global, complex settlement agreements, the Court proceeds in two steps. First, the Court looks at each component of the Watson and Lupin Agreements to determine whether they were “adequately alleged as unlawful reverse payments,” Loestrin 24, 814 F.3d at 548; that is, whether they are appropriately part of the calculus when the Court proceeds to the second step. For example, a reasonable cash payment exchanged to cover litigation expenses would be excluded from any further antitrust scrutiny, but such a payment would of course factor into the second step of the analysis in as much as it specifically addresses litigation costs, which, in turn, means that other components of the settlement agreement do not. Second, the Court takes a broad and holistic look at the deal to determine whether the entire deal, taken as a whole, amounted to a large and unjustified reverse payment. Specifically, the Court gives the arrangement a careful look with an eye toward “the likelihood of a reverse payment bringing about anticompetitive effects” in light of “its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other

convincing justification." Actavis, 133 S. Ct. at 2237; see also id. at 2236 ("Where a reverse payment reflects traditional settlement considerations, such as fair value for services, there is not the same concern[.]"); In re Lipitor Antitrust Litig., 46 F. Supp. 3d 523, 546 (D.N.J. 2014) ("Even if the reverse payment is shown, any traditional settlement considerations or services provided by the generic are deducted to determine whether there is a net positive payment flowing from the patentee to the alleged infringer.").<sup>25</sup>

Third, much of the parties' briefing addresses the level of particularity with which a reverse payment must be pleaded. On this, the First Circuit has been clear; all that is required is:

that the plaintiffs plead information sufficient "to estimate the value of the term, at least to the extent of determining whether it is 'large' and 'unjustified.'" Consistent with Twombly, which declined to "require heightened fact pleading of specifics," we do not require that the plaintiffs provide precise figures and calculations at the pleading stage. Requiring such a high burden would impose a nearly insurmountable bar for plaintiffs at the pleading stage because "very precise and particularized estimates of fair value and

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<sup>25</sup> This is consistent with the framework posed in Aaron Edlin et al., Activating Actavis, 28 Antitrust 16, 18 (Fall 2013):

The payment prong involves the following steps: (a) valuing any consideration flowing from the patentee to the claimed infringer, which may be made over time and may take forms other than cash; (b) deducting from that payment the patent holder's avoided litigation costs; and (c) deducting from that payment the value of goods, services, or other consideration provided by the claimed infringer to the patent holder as part of the same transaction (or linked transactions).

anticipated litigation costs may require evidence in the exclusive possession of the defendants, as well as expert analysis." Nevertheless, the plaintiffs must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under Actavis.

Loestrin 24, 814 F.3d at 552 (internal citations omitted). Though the First Circuit does not require Plaintiffs to attach a dollar figure to the value of the alleged unlawful reverse payment, for most of the settlement components, Plaintiffs have nevertheless done so by placing relatively specific valuations on each of the components as well as the whole.

Fourth, the Court must determine whether it should value the alleged reverse payment from the perspective of the patent holder, the alleged infringer, or both, for this inquiry.<sup>26</sup> (See, e.g., Retailer Mem. in Opp'n to the Warner Chilcott/Watson Mot. to Dismiss Brief ("Retailers Brief") 26, ECF No. 207.) The text of Actavis suggests that the Court should consider both in considering an alleged unlawful reverse payment. See Actavis, 133 S. Ct. at 2235 ("The payment may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market."). The Court's use of the word

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<sup>26</sup> At the hearing on these motions, the Warner Chilcott Defendants suggested that "it needs to be looked at really from both sides. But . . . in many ways the most important perspective is from the perspective of the patent holder." (Mot. Hr'g Tr. 36:24-37:2, Jan. 13, 2017, ECF No. 266.)

"induce" suggests that the value to the alleged infringer is paramount, whereas the emphasis on the "share of its monopoly profits" supports the notion that the brand must be alleged to have sacrificed some amount of its anticipated profits in order to maintain its monopoly.

With these principles in mind, the Court turns to the Watson and Lupin Agreements.

1. The Watson Agreement

As outlined above, the Watson Agreement provided Watson with a no-AG provision; a six-month period of generic exclusivity; the Femring promotional deal; and the Generess promotional deal.

a. No AG-Agreement

The Warner Chilcott Defendants argue that a no-AG agreement is not an unlawful reverse payment as a matter of law. (See generally Warner Chilcott Mot. to Dismiss 59-82.) The Court disagrees. Here, Plaintiffs value the no-AG deal at more than \$40 million to Watson. (See, e.g., DPP Compl. ¶¶ 194-99; Walgreen Compl. ¶ 127.) The Complaints plausibly allege that a no-AG agreement is both very valuable to a generic manufacturer (and thus may induce it to stay out of the market) and amounts to a sacrifice by a brand manufacturer, rendering the potential anticompetitive effect plain. On a 12(b)(6) motion to dismiss, this is sufficient. See Aggrenox I, 94 F. Supp. 3d at 245 ("If some particular transfer of money would be unlawful – for whatever

reason – its unlawfulness is not cured merely because the value is transferred in the form of exclusive licenses instead of cash, irrespective of whether the grant of an exclusive license would otherwise be valid. . . . The issue is not whether the form of the payment was legal, but whether the purpose of the payment was legal.”); see also Lamictal, 791 F.3d at 409 (holding that a no-AG agreement, “because it may represent an unusual, unexplained transfer of value from the patent holder to the alleged infringer that cannot be adequately justified – whether as compensation for litigation expenses or services, or otherwise – is subject to antitrust scrutiny under the rule of reason.” (internal footnote omitted)); Opana, 162 F. Supp. 3d at 718; In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. CV 14-MD-02503-DJC, 2015 WL 5458570, at \*7-9 (D. Mass. Sept. 16, 2015) (“Solodyn”); Niaspan, 42 F. Supp. 3d at 752-53.

The Warner Chilcott Defendants argue that this theory is inconsistent with Plaintiffs’ product hop theory (Warner Chilcott Reply 26-27); even if that is so, Plaintiffs may plead alternative theories. See Fed. R. Civ. P. 8(d). But it is also plausible on the face of the Operative Complaints that the two theories are not inconsistent at all. Plaintiffs plausibly allege that Warner Chilcott, faced with the realities of the no-AG provision in the Watson Agreement and with generic entry looming, opted to roll out its product hop, presumably to stem its looming losses. Had the

Watson Agreement not existed, perhaps it would not have used the product hop to alter the competitive landscape, or would have done so at a different point in time. But the fact that a product hop would have been less lucrative with an authorized generic on the market does not render the scheme implausible.

b. Acceleration Clause

The EPPs challenge the acceleration clause in the Watson Agreement as part of the unlawful reverse payment. (EPP Compl. ¶¶ 177-79, 188-90.) They allege that, with the acceleration clause in place, other generics did not have the opportunity, and thus the incentive to try, to enter the market before Watson's scheduled entry of January 22, 2014. "By eliminating the possibility of obtaining a period of de facto exclusivity, the clause very substantially diminished, if not altogether eliminated, the incentive for later generic filers to enter before January 22, 2014." (Id. ¶¶ 189-90.) The EPPs further allege that "[b]ut for the anticompetitive effects of the acceleration clause, later filing generics, such as Mylan and Lupin, would have entered or obtained licensed entry dates earlier than" Watson's entry date of January 22, 2014; Watson would not have settled for an entry date as late as it did; and Watson would have entered earlier than January 2014. (Id. ¶ 194.) The EPPs do not attach a dollar figure to the acceleration clause. The Warner Chilcott Defendants challenge this assertion, arguing that acceleration clauses are



procompetitive and thus not subject to antitrust scrutiny. (Warner Chilcott Mot. to Dismiss 82-87.)

The Court concludes that the EPPs have plausibly alleged that the acceleration clause had anticompetitive effects. It may be that with more factual and expert discovery, the Warner Chilcott Defendants can establish that there were no anticompetitive effects, or that, on the second prong of the rule of reason analysis, the "challenged payment was justified by some precompetitive objective." Nexium II, 42 F. Supp. 3d at 262-63. But at this juncture, the Court is not prepared to hold that an acceleration clause like the one in the Watson Agreement may never be cognizable as a component of a complex settlement agreement amounting to a large and unjustified reverse payment. Accordingly, the acceleration clause may be considered, a least for the time being, as a component in the greater calculus. But see Actos, 2015 WL 5610752, at \*16 (holding that the acceleration clause was not cognizable as a large and unjustified payment).

c. Promotional Deals

Defendants contend that Plaintiffs failed to allege that four promotional or license agreements within the Watson and Lupin Agreements (viz., the Femring, Generess, Asacol, and Femcon deals)<sup>27</sup> are unlawful reverse payments under Actavis. (Warner

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<sup>27</sup> The Femcon deal is addressed below with the other components of the Lupin Agreement.

Chilcott Mot. to Dismiss 25.) They argue that (1) these agreements represent payments from the generic to the brand; (2) they are "traditional and commonplace;" (3) they allow for the entry of new competition; (4) they do not represent a sacrifice by Warner Chilcott; (5) they are not plausibly alleged to be for anything but fair value; and (6) it is not plausible that they were entered into in exchange for the generic's delay in entering the market. (Id. at 45-46, 55-59.) After careful consideration, these arguments do not carry the day.

Of importance, Defendants miss the mark on their claim that promotional deals of this sort cannot constitute reverse payments. If brand manufacturer A offers generic manufacturer B a licensing deal that is valued at \$100 million to B over five years, and represents a sacrifice of \$80 million to A over five years, in exchange for which B agrees to not enter the market with its generic drug, it is of no moment that B is expected to pay A \$10 million in royalties over five years. Such a deal does not reflect the fair value of the license agreement; it represents a sacrifice of A's potential monopoly profits; and represents a payment to B in order to induce it to stay out of the market. Indeed, Actavis itself dealt with a reverse payment consisting of a cash payment and promotional deals to generics, which demonstrates "that the Supreme Court recognized that a disguised above-market deal, in which a brand manufacturer effectively overpays a generic

manufacturer for services rendered, may qualify as a reverse payment subject to antitrust scrutiny . . . ." Loestrin 24, 814 F.3d at 549.

Plaintiffs have also sufficiently alleged that each of the promotional deals was not for fair value. While Defendants spill much ink here, under the rule of reason framework, once Plaintiffs have alleged facts supporting a not-for-fair-value, large, and unjustified payment, the burden shifts to Defendants "to produce evidence to justify the payment by showing it was no more than the brand-name manufacturer's own saved litigation costs or was fair value for services the generic manufacturer promised to perform and was not a payment for delay." Solodyn, 2015 WL 5458570, at \*7. "Such justifications, as with any affirmative defense, cannot be resolved on a motion to dismiss unless the facts establishing the defense are clear on the face of the plaintiffs' complaint, which they are not in this case." Id. (citing Blackstone Realty LLC v. FDIC, 244 F.3d 193, 197 (1st Cir. 2001)).

With respect to the Femring Deal, the DPPs value the deal to be worth approximately \$25 million to Watson. (DPP Compl. ¶¶ 214-16.) They further allege that, "[t]he Femring deal provided substantial compensation to Watson that was, in and of itself, in excess of the fair value of Watson's cost of performance[,] and it served no other purpose than to induce Watson's delayed entry of generic competition. (DPP Compl. ¶¶ 216, 218.) The EPPs allege

that the Femring deal "provided compensation to Watson that was in excess of the fair value of the promotional services that Watson was required to perform." (EPP Compl. ¶ 186.) The Retailers allege the "payments were far in excess of Watson's cost of performance or the fair market value of that performance." (Walgreen Compl. ¶ 134; CVS Compl. ¶ 131.) That Plaintiffs do not expressly plead that it amounted to lost monopoly profits to Warner Chilcott is not dispositive on a motion to dismiss; such a reasonable inference may be drawn.

With respect to the Generess Fe Deal, the Watson Agreement provided Watson with the exclusive right to market and sell another Warner Chilcott oral contraceptive, Generess Fe. Under the deal, Watson had the right to retain 85% of the net sales from Generess, as well as the right to retain 100% of net sales either upon the launch of a generic Generess product or if Watson exercised a buy-out right; the DPPs value this piece of the deal at "tens of millions" to Watson. (DPP Compl. ¶¶ 9, 205, 210-11.) There can be no serious question that Plaintiffs have alleged that the deal was not for fair value. For example, the DPPs allege that "[t]his transfer of value from Warner Chilcott to Watson ha[d] no rational explanation other than to provide additional compensation to Watson for delaying its generic Loestrin 24." (DPP Compl. ¶ 207; see also id. ¶ 211.) The EPPs allege that the royalty rate was "below market," and the deal cannot "be justified solely as

compensation for the services to be performed by Watson under the deal" because the deal "made no business or economic sense for Warner Chilcott absent Watson's agreement to preserve" Warner Chilcott's Loestrin 24 monopoly. (EPP Compl. ¶¶ 4, 185.)

The Warner Chilcott Defendants argue that "there is a disconnect between Actavis's discussion of reverse payments and Plaintiffs' allegations of forward payments, i.e., payments from the generic settler to the brand." (Warner Chilcott Reply 22; see also Warner Chilcott Mot. to Dismiss 45-49.) The Warner Chilcott Defendants' argument misses the mark. It is not the form but the purpose of a reverse payment that renders it subject to antitrust scrutiny. See generally Loestrin 24, 814 F.3d 538; Aggrenox I, 94 F. Supp. 3d at 245 ("The issue is not whether the form of the payment was legal, but whether the purpose of the payment was legal."). Plaintiffs have plausibly alleged facts that set forth a deal in which the Generess Fe promotional deal was one component of a larger, complex settlement agreement in which this exclusive right to market and sell Generess may have been offered to Watson in excess of the fair value cost of Watson's performance. In other words, though the actual payment may be in the form of Watson's right to retain 85% of the net sales of the Generess product, if it were customary under such an agreement for Watson to retain a lower percentage of the net sales for its marketing and sales efforts, it nonetheless may signal a large and unjustified reverse

payment. That Plaintiffs have not expressly pleaded an exact value to Watson for this promotional deal is, again, not dispositive.

2. Lupin Agreement

The Lupin Agreement comprises three components: the Femcon deal, the Asacol deal, and a cash payment of \$4 million by Warner Chilcott to Lupin toward attorneys' fees and litigation expenses for both the Loestrin 24 and Femcon patent infringement suits. The EPPs and Retailer Plaintiffs challenge the Lupin Agreement as an unlawful reverse payment. Defendants defend these side deals as separate from Lupin's settlement in the Loestrin 24 litigation, noting that the side deals contain "a number of contingencies reflecting complicated business judgments as to their strategic value to either company and require significant future performance by both parties." (Omnibus Mem. of Law in Supp. of Lupin Defs.' Mot. to Dismiss the End Payor and Retailer Pls.' Compls. ("Lupin Mot. to Dismiss") 1, ECF No. 199-1.)

a. Causation

Lupin argues that the reverse payment claim should be dismissed as to the Lupin Agreement because Lupin did not obtain FDA approval to sell a generic version of Loestrin 24 until October 28, 2015. (Mot. Hr'g Tr. 54:1-55:18, Jan. 13, 2017, ECF No. 266.) Accordingly, it argues, the EPPs and Retailer Plaintiffs have not pleaded that its delayed generic entry was the result of the Lupin Agreement reverse-payment settlement. This argument was not

raised in Lupin's memorandum in support of its motion to dismiss, and appears for the first time in its reply brief. See DRI LR Cv 7(b)(3) ("A reply memorandum shall consist only of a response to an objection and shall not present additional grounds for granting the motion, or reargue or expand upon the arguments made in support of the motion."); see also Pratt v. United States, 129 F.3d 54, 62 (1st Cir. 1997) (noting that arguments not advanced in the appellant's opening brief are deemed waived).

The Operative Complaints do not establish, as a matter of law, that a delay in FDA approval caused the delay in generic entry to the exclusion of the reverse payment. Assuming arguendo that the Court took judicial notice of the fact that the FDA did not grant Lupin approval to sell a generic version of Loestrin 24 until October 2015, the facts alleged in the Operative Complaints do not preclude the possibility that the Lupin Agreement contributed to the October 2015 entry date. It is plausible that the entry date provided for in the Lupin Agreement affected the FDA's and Lupin's behavior during the approval process. If the Lupin Agreement had provided for an earlier entry date, Lupin may have been able to obtain FDA approval earlier. Because Lupin's arguments are not conclusive on the face of the Operative Complaints, and reasonable inferences can be made in Plaintiffs' favor, the Court declines to dismiss these claims on this basis.

b. Femcon Deal

The Femcon deal granted Lupin a license to market Femcon Fe, a separate oral contraceptive manufactured by Warner Chilcott, beginning the earlier of 180 days after the first filer, Teva Pharmaceutical Industries, Ltd, entered the market with a generic equivalent, or January 1, 2013. (EPP Compl. ¶ 214.) The EPPs value this at approximately \$15 million to Lupin. (Id. ¶ 5(a).) The EPPs and Retailers allege that, but for this agreement, Lupin would not have been able to enter the Femcon market until at least January 31, 2012, at the end of the 30-month stay, and as late as March 23, 2016, when Lupin received final FDA approval for its ANDA. (See, e.g., id. ¶ 214.) The EPPs allege that the royalty payment, which would flow from Lupin to Warner Chilcott, would be “below market rates” and that the “usual and customary” rate for similar agreements is 80-90% of the gross margin for units sold, which is higher than the royalty of 50% of gross margin for units sold provided in the Femcon and Asacol deals. (Id. ¶¶ 5, 216, 220.) With these allegations, the EPPs and Retailers have set forth “information sufficient to estimate the value of the term, at least to the extent of determining whether it is large and unjustified.” Loestrin 24, 814 F.3d at 552 (internal quotations and citation omitted).

Defendants point out that Lupin and Warner Chilcott were settling two distinct patent suits - one concerning Loestrin 24



and the other concerning Femcon. The Loestrin 24 and Femcon settlement agreements were documented in a single agreement, with the Asacol deal attached, and they were executed on the same day. The Asacol and Femcon deals were both contingent upon the date for entry into the Loestrin 24 market. (Warner Chilcott Mot. to Dismiss 53-54 (citation omitted).) But, as noted above, the complexity of a settlement agreement is no reason to escape antitrust scrutiny. Ultimately, a jury may need to parse out the Femcon settlement and the Loestrin 24 settlement. But for now, Plaintiffs have plausibly alleged sufficient facts to establish that the Femcon promotional deal was part of an unlawful reverse payment to Lupin to induce it to stay out of the Loestrin 24 market, perhaps as well as the Femcon market.

c. Asacol Deal

The Asacol deal, or the second component of the larger Lupin Agreement, gave Lupin the right to sell a generic version of Asacol 400, an anti-inflammatory drug, to be supplied by Warner Chilcott, if a generic version of Asacol 400 was launched by another generic manufacturer in the United States. (EPP Compl. ¶ 217.) The EPPs value this deal as being worth at least \$50 million to Lupin; the Retailers allege that Lupin expected to earn \$100 million annually from the Asacol agreement. (EPP Compl. ¶ 5(b); Walgreen Compl. ¶ 144.) Defendants argue that because the deal was contingent upon the success of a third-party generic securing FDA approval to

enter the market, the agreement "was highly contingent" and "[a]ny claimed 'value' to Lupin would have to account for this uncertainty." (Warner Chilcott Mot. to Dismiss 51.)

As an initial matter, that the FDA has not approved a generic version of Asacol is, in itself, irrelevant. The deal must be valued at the time the parties entered the deal, and it must have been worth something to Lupin, or else they would not have invested the effort and legal fees in the matter.<sup>28</sup> On the other hand, it is implausible that the parties to the Lupin Agreement were unaware of the possibility that the contingency may never be met. On the face of the Operative Complaints, however, it is plain that the Asacol deal represented a sacrifice by Warner Chilcott and a benefit to Lupin in order to induce it to stay out of the generic market. On these facts, Plaintiffs adequately pleaded their claim and the Asacol deal will be considered when assessing the Lupin Agreement as a whole.

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<sup>28</sup> Addressing a component of the Watson Agreement, Warner Chilcott argues, as it must, that "agreements are judged at the time of the settlement." (Warner Chilcott Mot. to Dismiss 71.) Lupin's argument at the hearing on these motions that "both the potential value at the time of the agreement and the actual value eventually reached is zero" is unconvincing, and of course, does not reflect the allegations set forth in the Operative Complaints. (Mot. Hr'g Tr. 53:12-14, Jan. 13, 2017, ECF No. 266.) Exactly how much the deal should be discounted to account for this contingency is a fact-intensive inquiry that will be sorted out with discovery. It is enough, at this stage, for the EPPs and Retailers to have alleged facts plausibly supporting the expected value to Lupin at the time of the agreement. See Loestrin 24, 814 F.3d at 552.

3. The Sum of the Whole(s)

In their Operative Complaints, Plaintiffs plausibly allege that the Watson and Lupin Agreements, viewed as two complex settlement agreements, amounted to both a payment to the generic manufacturers to induce a generic-entry delay, as well as a sacrifice of monopoly profits, on the whole, to protect a perceived weakness in the '394 patent. For the Watson Agreement, the DPPs value the sum of the deals at tens or hundreds of millions to Watson (DPP Compl. ¶¶ 9, 192, 199); the Retailers value them to be worth \$266 million to Watson (e.g., CVS Compl. ¶¶ 124, 131-32); the EPPs value the sum at \$216.67 million to Watson (EPP Compl. ¶ 4). With respect to the Lupin Agreement, the EPPs value the Femcon deal to be worth approximately \$15 million, and the Asacol deal approximately \$50 million, to Lupin. (EPP Compl. ¶¶ 5(a)-(b).) These represent rather precise estimates of the value of each component of the deal, given Plaintiffs have not had the benefit of discovery, accompanied by a step-by-step calculation of how they reached those figures. See Loestrin 24, 814 F.3d at 552 (stating that Plaintiffs must "plead information sufficient to estimate the value of the term, at least to the extent of determining whether it is large and unjustified," but "not requir[ing] that [P]laintiffs provide precise figures and calculations" (citation and quotation marks omitted)). Moreover, Plaintiffs have sufficiently alleged that the Agreements were not

otherwise justified by "avoided litigation costs or fair value for services." Actavis, 133 S. Ct. at 2236.

In light of the standard for dismissal on a 12(b)(6) motion, the Court concludes that Plaintiffs have met their burden and have adequately alleged that the sum total of the Watson Agreement constituted a large and unjustified payment, as did the Lupin Agreement (challenged by the EPPs and Retailers only). Plaintiffs have satisfied their burden to allege facts that, with the benefit of fact and expert discovery, have the reasonable expectation of proving their prima facie case under the rule of reason. See Twombly, 550 U.S. at 556 (holding that a complaint must plead facts sufficient "to raise a reasonable expectation that discovery will reveal evidence" of a Sherman Act violation).

C. Fraud on the PTO, Sham Litigation, and Orange Book Claims

Generally, under the Noerr-Pennington doctrine, "a Sherman Act violation cannot be 'predicated upon mere attempts to influence the passage or enforcement of laws.'" Amphastar Pharm. Inc. v. Momenta Pharm., Inc., 850 F.3d 52, 56 (1st Cir. 2017) (quoting E.R.R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 135 (1961) ("Noerr"))(citing United Mine Workers v. Pennington, 381 U.S. 657, 670 (1965) ("Pennington")). Though Noerr and Pennington addressed citizen activity in the executive and legislative branches, the Supreme Court has extended the protection to patent holders filing suit in federal court. See

Amphastar Pharm. Inc., 850 F.3d at 56 (citing Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 510 (1972)).

But as with most rules, there are exceptions. A patent holder may be subject to antitrust liability for the anticompetitive effects of bringing a patent infringement suit where a plaintiff demonstrates "(1) that the asserted patent was obtained through knowing and willful fraud within the meaning of Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp., 382 U.S. 172, 177 (1965), or (2) that the infringement suit was 'a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor,' Noerr Motor Freight, Inc., 365 U.S. at 144." Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1068 (Fed. Cir. 1998) (additional citations omitted). Plaintiffs assert both theories here.

1. Walker Process Claims

To plead a claim for relief under § 2 of the Sherman Act on a Walker Process theory, a plaintiff must allege two conditions. "First, the plaintiff must show that the defendant procured the relevant patent by knowing and willful fraud on the PTO or (in the case of an assignee) that the defendant maintained and enforced the patent with knowledge of the fraudulent manner in which it was obtained." Ritz Camera & Image, LLC v. SanDisk Corp., 700 F.3d 503, 506 (Fed. Cir. 2012). Notably, it is the enforcement of a patent procured by fraud that may give rise to a Sherman Act claim;

mere procurement without more does not "affect the welfare of the consumer and cannot in itself violate the antitrust laws." FMC Corp. v. Manitowac Co., 835 F.2d 1411, 1418 & n.16 (Fed. Cir. 1987); see also Walker Process, 382 U.S. at 174. "Second, the plaintiff must prove all the elements otherwise necessary to establish a Sherman Act monopolization charge." Ritz Camera & Image, LLC, 700 F.3d at 506 (citations omitted). Under the second condition, "[t]he 'other elements' necessary to establish an attempted monopolization claim are: '(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power.'" TransWeb, LLC v. 3M Innovative Properties Co., 812 F.3d 1295, 1306 (Fed. Cir. 2016) (quoting Spectrum Sports, Inc. v. McQuillan, 506 U.S. 447, 456 (1993)).

a. Plaintiffs' Allegations of Fraud on the PTO

Plaintiffs allege that the applicants for the '394 patent, including Dr. Hodgen and others involved with its patent prosecution, breached their duty under 37 C.F.R. § 1.56 and common law "by intentionally misrepresenting material facts, failing to disclose material information, and submitting false information to the PTO with the intent to deceive." (See, e.g., EPP Compl. ¶ 144.) Broadly speaking, this includes: (1) the fraudulent omission of the 1993 human study, either because its findings undercut patentability or because it constituted invalidating

public use (DPP Compl. ¶¶ 126, 141; EPP Compl. ¶¶ 147-56; CVS Compl. ¶ 78; Walgreen Compl. ¶ 81); (2) the intentional withholding of prior art that teaches a regimen of more than 21 days for oral contraceptives (EPP Compl. ¶¶ 166-69); and (3) false statements and material withholding of information about the amount of estrogen in prior art oral contraceptives (id. ¶¶ 157-65).

To state a claim for fraud on the PTO, a plaintiff must allege "(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." C.R. Bard, Inc. v. M3 Sys., 157 F.3d 1340, 1364 (Fed. Cir. 1998).<sup>29</sup>

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<sup>29</sup> Fraud on the PTO arises in two arenas: when plaintiffs assert it in suits alleging antitrust liability, like the instant case, and when defendants assert inequitable conduct as an equitable defense in patent infringement actions. See Nobelpharma AB, 141 F.3d at 1070; see also Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1330 (Fed. Cir. 2009). Both Defendants and Plaintiffs cite cases that discuss inequitable conduct in parsing out the elements of Walker Process fraud on the PTO, but they do not always agree on their significance.

Prior to 2011, the Federal Circuit explained that inequitable conduct serves as a "shield," whereas "Walker Process fraud is a more serious finding of fraud [that] potentially exposes a patentee to antitrust liability and thus serves as a sword." Nobelpharma AB, 141 F.3d at 1070. Thus, the Federal Circuit asserted that Walker Process fraud is "a more serious offense than inequitable conduct." Id. In 2011, in Therasense, the Federal Circuit addressed "problems created by the expansion and overuse of the inequitable conduct doctrine . . . ." Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1285 (Fed. Cir. 2011). The court noted that, over time, courts had started applying lower standards

"Such a misrepresentation or omission must evidence a clear intent to deceive the examiner and thereby cause the PTO to grant an invalid patent." Nobelpharma AB, 141 F.3d at 1070. To establish Walker Process fraud there must be "independent and clear evidence of deceptive intent together with a clear showing of reliance, i.e., that the patent would not have issued but for the misrepresentation or omission." Id. at 1071. And to satisfy Rule 9(b) of the Federal Rules of Civil Procedure, a plaintiff must plead the "who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1328 (Fed. Cir. 2009). The Warner Chilcott Defendants move to dismiss all Plaintiffs' Walker Process fraud claims. The Court addresses their arguments in turn.

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for intent and materiality in inequitable conduct cases, which had "inadvertently led to many unintended consequences." Id. at 1290. The court tightened the standards for those elements and clarified that "[i]ntent and materiality are separate requirements"; intent may not be inferred from materiality alone; and but-for materiality must be demonstrated to prove inequitable conduct. Id. at 1290-91. The Federal Circuit has since remarked that "[a]fter Therasense, the showing required for proving inequitable conduct and the showing required for proving the fraud component of Walker Process liability may be nearly identical." TransWeb, LLC v. 3M Innovative Properties Co., 812 F.3d 1295, 1307 (Fed. Cir. 2016) (citation omitted). It is plain, therefore, that after Therasense, inequitable conduct mandates something that approaches, or is identical to, the more exacting requirements of Walker Process fraud. Thus, post-Therasense cases analyzing inequitable conduct may be instructive on Walker Process fraud, but the Court remains cautious that courts may have endorsed lower thresholds for intent and materiality in pre-Therasense inequitable conduct cases.



b. Specific Individual with Intent to Defraud the PTO

The Warner Chilcott Defendants first argue that Plaintiffs failed to plead that any specific individual prosecuting the '394 patent intended to deceive the PTO. This argument gets no traction. With respect to the failure to disclose the 1993 human study, the DPPs allege that: "Hodgen's omission and misrepresentations were made with knowledge that they were false and misleading, and with the specific intent that the PTO rely on the monkey study and issue a patent. There is no other reasonable explanation for the failure to report a failed human study that the inventor personally conducted. The failed study was intentionally withheld because it undercut patentability." (DPP Compl. ¶ 141.) Dr. Hodgen and the applicants are alleged to have known also that the human study constituted invalidating public use, as Dr. Hodgen was aware of the study and it took place more than one year prior to the patent application. (Id. ¶ 126; EPP Compl. ¶¶ 148-56.)

Plaintiffs further allege that the '394 applicants withheld material prior art from the PTO in failing to disclose the so-called Molloy reference (see infra, at 75). (See, e.g., EPP Compl. ¶¶ 166-68.) Plaintiffs allege that a December 1990 letter by Dr. Hodgen to Warner-Lambert reveals that both Dr. Hodgen and Roger Boissoneault, who later became CEO of Warner Chilcott, had knowledge of the Molloy reference, but that the applicants did not

disclose the Molloy reference to the PTO during the '394 patent prosecution because it undercut patentability. (EPP Compl. ¶¶ 155, 168.)

Plaintiffs further allege that the applicants defrauded the PTO by withholding or misrepresenting the fact that there were commercially available oral contraceptives that contained at least 30 mcg of ethinyl estradiol and that the claimed invention would reduce total estrogen exposure per annum. (See, e.g., EPP Compl. ¶ 165.) They allege that Dr. Hodgen and the other applicants knew their statement was false because Loestrin 1/20 was commercially available in the United States, oral contraceptives with a similar composition of estrogen were available in Europe, and Loestrin 1/20 exposes women to half as much estrogen as the dosing regimen claimed in the '394 patent. (Id. ¶ 162.)

The facts underlying each set of fraud allegations support a reasonable inference that a specific individual, namely, Dr. Hodgen, "(1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." Exergen Corp., 575 F.3d at 1328-29.<sup>30</sup> While Plaintiffs

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<sup>30</sup> The instant case is readily distinguishable from Exergen, in which the pleadings were deemed insufficient for alleging that "Exergen, its agents and/or attorneys" were responsible for the alleged fraudulent acts. Exergen Corp., 575 F.3d at 1329. Here, Dr. Hodgen is plainly a "specific individual."

may still have ground to cover in order to prove that the applicants had the intent to deceive the PTO, courts have cautioned that “[s]cienter or intent to defraud is usually an issue of fact that should not typically be resolved on a pretrial motion.” See In re Effexor XR Antitrust Litig., No. CIV.A. 11-5479 PGS, 2014 WL 4988410, at \*26 (D.N.J. Oct. 6, 2014). There is little question that Plaintiffs’ pleadings are adequate on this score.

c. Omission of the 1993 Human Study

Plaintiffs allege that the applicants’ failure to disclose a 1993 human study conducted by Dr. Hodgen was a material omission, either because it failed to show a statistically significant reduction in breakthrough bleeding (DPP Compl. ¶¶ 126, 141) or because it represented invalidating use (EPP Compl. ¶ 153; CVS Compl. ¶ 78; Walgreen Compl. ¶ 81). They further allege the patent would not have been issued but for the material omission and the applicants omitted the information with the intent to deceive the PTO. (See, e.g., DPP Compl. ¶¶ 141, 147.) In support of its allegations that the failure to disclose the 1993 human study was a material omission, Plaintiffs detail the ‘394 patent prosecution as follows.

During the patent examination, the examiner focused on two issues: the amount of the ethinyl estradiol and norethindrone acetate in oral contraceptives disclosed in the prior art, and whether the invention decreased breakthrough bleeding. (DPP

Compl. ¶ 135.) After initially concluding that prior art rendered all claims obvious in light of the references disclosing similarly low amounts of ethinyl estradiol and norethindrone acetate, the examiner focused on whether the invention demonstrated an unexpected decrease in breakthrough bleeding. (DPP Compl. ¶¶ 136, 138.) The examiner again rejected the claims because of the similar amount of ethinyl estradiol in the prior art and because "the applicants [had not] shown that it was unexpected that decreasing the amount of ethinyl estradiol reduces the incidence of breakthrough bleeding[.]" (Id. ¶ 138.) The examiner stated:

The applicant's remarks have been considered but are unpersuasive. Claim 1 recited a possible dosage of 35 mcg of estrogen which is only 15 mcg lower than the 50 mcg dosage taught by Craft et al. It has not been demonstrated that a dosage regimen different by only 15 mcg less of estrogen has unexpected contraceptive and reduced breakthrough bleeding results.

(Id. (emphasis omitted).)

Presumably after additional correspondence, the application's claims were thereafter allowed. The '394 patent specification states, "[i]t is the object of the present invention to provide a new estrogen-progestin combination and regimen for oral contraceptive use which maintains the efficacy and provides enhanced control of endometrial bleeding." (Id. ¶ 120 (emphasis in original).) Claim 1 of the '394 patent, upon which Claims 2-12 depend, recites:

A method of female contraception which is characterized

by a reduced incidence of breakthrough bleeding after the first cycle which comprises monophasically administering a combination of estrogen and progestin for 23-25 consecutive days of a 28 day cycle in which the daily amounts of estrogen and progestin are equivalent to about 1-35 mcg of ethinyl estradiol and about 0.025 to 10 mg of norethindrone acetate, respectively, and in which the weight ratio of estrogen to progestin is at least 1:45 calculated as ethinyl estradiol to norethindrone acetate.

(Id. ¶ 121 (emphasis altered).)

The Warner Chilcott Defendants move to dismiss Plaintiffs' Walker Process fraud claims concerning the 1993 human study on the basis that the patent examiner did not consider breakthrough bleeding to be an independent ground for patentability, and thus, would have issued the patent even if she had known about the 1993 human study. In other words, the omission was not material. (See Warner Chilcott Mot. to Dismiss 94 ("[T]he '394 applicants focused on the differences in the dosage amounts and length of administration, not the intended efficacy in reducing breakthrough bleeding.")) In support of their argument, the Warner Chilcott Defendants point to two sets of documents beyond the scope of the Operative Complaints: the prosecution history for the '394 patent and the Loestrin 24 patent infringement suit between Warner Chilcott and Mylan, which commenced after Warner Chilcott settled with Watson and Lupin.

The Warner Chilcott Defendants ask the Court to consider the patent prosecution history as incorporated by reference into the

Operative Complaints for purposes of deciding this motion. The Warner Chilcott Defendants argue that the patent examiner's response that "it has not been demonstrated that a dosage regimen differing by only 15 mcg less of estrogen [has unexpected] reduced breakthrough bleeding" shows the examiner was not persuaded that the lower dosage of estrogen reduced breakthrough bleeding. (See id. at 100.) If she was not persuaded, evidence further undermining Loestrin 24's ability to reduce breakthrough bleeding cannot be material. In rejoinder, the DPPs contend that the bracketed text ("has unexpected"), omitted from the Warner Chilcott Defendants' opening brief, reveals that the examiner was addressing the patent's claim and proposed estrogen dosage in relation to higher estrogen dosages taught by prior art. The DPPs argue that the examiner accepted the false representation that a lower dosage reduced breakthrough bleeding but questioned whether it was unexpected.

The Warner Chilcott Defendants further ask the Court to delve into the suit between Warner Chilcott and Mylan, in which the U.S. District Court for the District of New Jersey held a Markman hearing on claim construction and concluded that the '394 patent's reference to reduced breakthrough bleeding was a non-limiting preamble term. See Opinion 8, Warner Chilcott Co. LLC v. Mylan Inc., et al., 3:11-cv-03262-JAP-TJB, ECF No. 81 (D.N.J. Apr. 8, 2013) (stating that "Mylan has not identified anything in the

prosecution history that the Court considers to be evidence of clear reliance on reduced breakthrough bleeding as patentably significant," and concluding that the reduced incidence of breakthrough bleeding was a non-limiting preamble term). If reduced breakthrough bleeding did not provide an independent basis for patentability, the Warner Chilcott Defendants argue, the study's omission was not material. (See Warner Chilcott Mot. to Dismiss 100.)

To establish Walker Process fraud, Plaintiffs must establish that the fraudulent omission or fraudulent misrepresentation was material, i.e., "that the patent would not have issued but for the patent examiner's justifiable reliance on the patentee's misrepresentation or omission." Dippin' Dots, Inc. v. Mosey, 476 F.3d 1337, 1346-47 (Fed. Cir. 2007). The Court declines to consider the patent prosecution file or take judicial notice of the claim construction decision in the Mylan suit. It is clear from the parties' arguments that the issue of materiality is replete with issues of fact that would require the Court to decide, as a matter of law, whether the patent examiner would not have allowed the patent but for the omission of the 1993 human study. Such a decision is better reserved for summary judgment or trial, on a full record after fact and expert discovery. See In re DDAVP Direct Purchaser Antitrust Litig., 585 F.3d 677, 692 (2d Cir. 2009) ("Even if the district judge was correct that the earlier record

did not show fraud, the record in this case could be different following discovery." ). Here, on the face of the Operative Complaints, it is plausible that the patent examiner would have determined an unsuccessful human study suggesting that Loestrin 24 provides no statistically significant reduction of breakthrough bleeding material and, as a result, would have declined to issue the patent. This is so even if a clinical study was not required to patent the invention. "[E]ven if one was skeptical about the truth of the facts, they survive on a motion to dismiss." See Effexor, 2014 WL 4988410, at \*25.

d. 1993 Human Study Constituted Invalidating Public Use

The Warner Chilcott Defendants also challenge the EPPs' and Retailers' claim that the 1993 human study constituted invalidating public use. (Warner Chilcott Mot. to Dismiss 100-02.) They argue that Plaintiffs failed to plead the dates of the 1993 human study to show that it was more than a year before the patent application, that the mere fact that there was no confidentiality agreement is not enough to render it public use, and that Plaintiffs have failed to plead sufficient facts outlining the alleged invalidating public use. (Id.)

Under 35 U.S.C. § 102(b), public use of an invention in the United States more than one year before the date of the patent application renders the invention unpatentable. "The proper test



for the public use prong of the § 102(b) statutory bar is whether the purported use: (1) was accessible to the public; or (2) was commercially exploited." Invitrogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1380 (Fed. Cir. 2005). The public policy supporting the public use bar to patentability is to avoid "the removal, from the public domain, of inventions that the public reasonably has come to believe are freely available." Delano Farms Co. v. Cal. Table Grape Comm'n, 778 F.3d 1243, 1247 (Fed. Cir. 2015) (quoting Tone Bros. v. Sysco Corp., 28 F.3d 1192, 1198 (Fed. Cir. 1994)). The issue at play is "whether the actions taken by the inventor [or some other third party] create a reasonable belief as to the invention's public availability." Id.

Courts and juries examine the following factors to resolve this issue: "the nature of the activity that occurred in public; the public access to and knowledge of the public use; [and] whether there was any confidentiality obligation imposed on persons who observed the use." Id. (quoting Bernhardt, L.L.C. v. Collezione Europa USA, Inc., 386 F.3d 1371, 1379 (Fed. Cir. 2004)). This last factor centers on "the commonsense notion that whether an invention is 'accessible to the public' . . . depends, at least in part, on the degree of confidentiality surrounding its use: '[A]n agreement of confidentiality, or circumstances creating a similar expectation of secrecy, may negate a public use where there is not

commercial exploitation.” Id. (quoting Dey, L.P. v. Sunovion Pharm., Inc., 715 F.3d 1351, 1355 (Fed. Cir. 2013)).

As these factors reveal, this is a fact-intensive inquiry. Though Defendants are correct that courts do not require “a formal confidentiality agreement to show non-public use[,]” courts and juries must weigh the specific facts of each case to determine “whether there were circumstances creating a similar expectation of secrecy.” Delano Farms, 778 F.3d at 1248 (citations omitted).

Here, Plaintiffs have alleged that scientists at EVMS conducted a human study “[b]eginning on or around January 1993.” (DPP Compl. ¶ 127.) Fifteen of the thirty participants followed a regimen of twenty-five days of Loestrin 1/20 tablets followed by three placebo tablets. The treatment spanned three months, and “[p]articipants were not obligated to keep the study design or methods confidential.” (Id. ¶¶ 129-30.) In July 1994, more than one year after the study commenced, Dr. Hodgen applied for what we know to be the ‘394 patent. (Id. ¶ 117.) While Plaintiffs do not provide exhaustive allegations directly addressing each of the factors supporting public use, these facts sufficiently allege a claim that invalidating public use, more than one year before the patent application, had rendered the invention unpatentable. Claims of this sort are typically highly fact-dependent and not likely to be disposed of on a motion to dismiss, and that is the case here. Cf. Dey, 715 F.3d at 1360 & n.5 (reversing grant of

summary judgment for party arguing invalidating public use, declining to grant summary judgment for the non-moving party, and remanding for further proceedings).

e. Failure to Disclose the Molloy Reference

The EPPs and Retailer Plaintiffs also assert that the applicants' failure to disclose prior invalidating art amounted to fraud on the PTO in procuring the '394 patent. (See, e.g., EPP Compl. ¶¶ 166-67; Walgreen Compl. ¶¶ 88-89.) Specifically, they allege that the applicants intentionally concealed an article referred to as the "Molloy reference." (See, e.g., EPP Compl. ¶¶ 138, 166-68 (citing B.G. Molloy et al., "Missed Pill" conception: fact or fiction?, 290 Brit. Med. J. 1474, 1475 (1985)).) The Molloy reference observed: "To reduce the risk of missed pill conception a 28 day pack containing 23 pills and 5 blanks could be substituted for the current 21 day pack. This would still permit a withdrawal bleed without the risk of significant follicular development." (EPP Compl. ¶ 138; see also id. (quoting two other references proposing a regimen of 24 oral contraceptive pills followed by 4 placebo pills).) According to the EPP Complaint, "[t]he prior art's direct recommendations to use 24/4 and 23/5 dosing regimens to minimize the risks of escape ovulation would have motivated one of ordinary skill in the art to implement such a shortened pill-free interval for use with known low-dose products" as set forth in the '394 patent. (EPP Compl.

¶ 139.) Thus, the EPPs and Retailers allege that, given the "plain disclosures and clear motivation to combine those disclosures in the prior art," the '394 patent was invalid for obviousness. (Id. ¶ 142; see also Walgreen Compl. ¶ 89 ("Molloy is material to the patentability of the claims of the '394 Patent because the claims of the patent extend the 21-day schedule to 23-25 days.").)

To round out the fraud allegations, Plaintiffs allege that Dr. Hodgen and Warner Chilcott were aware of the Molloy reference when they applied for the patent and later enforced it, respectively, as evidenced by a December 1990 letter from Dr. Hodgen to Warner-Lambert; the applicants did not disclose the reference to the PTO during the patent prosecution; and the applicants intended to deceive the PTO by withholding the reference. (EPP Compl. ¶ 168.)

The Warner Chilcott Defendants move to dismiss the fraud allegations, contending that the EPPs and Retailers fail to allege intent to deceive the PTO and but-for materiality in light of the applicants' disclosure of other, cumulative references.<sup>31</sup> (Warner Chilcott Mot. to Dismiss 92, 102-04.)

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<sup>31</sup> The Warner Chilcott Defendants ask the Court to consider the '394 patent's full prosecution history, as well as the full text of the prior art reference quoted in the Operative Complaints. (Warner Chilcott Mot. to Dismiss 102-04.) For the reasons stated above with respect to the 1993 human study, the Court declines to consider the materials proffered by the Warner Chilcott Defendants, and except as noted, takes the allegations in the well-pleaded Operative Complaints as true.

To support a claim of Walker Process fraud, there must be "independent and clear evidence of deceptive intent together with a clear showing of reliance, i.e., that the patent would not have issued but for the misrepresentation or omission." Nobelpharma AB, 141 F.3d at 1070-71. "Therefore, for an omission such as a failure to cite a piece of prior art to support a finding of Walker Process fraud, the withholding of the reference must show evidence of fraudulent intent." Id. at 1071. It is rare to have direct evidence of deceptive intent, especially at the pleading stage, and thus "a district court may infer intent from indirect and circumstantial evidence." Therasense, 649 F.3d at 1290. "A reasonable inference is one that is plausible and that flows logically from the facts alleged, including any objective indications of candor and good faith." Exergen Corp., 575 F.3d at 1329 n.5 (citing Greenstone v. Cambex Corp., 975 F.2d 22, 26 (1st Cir. 1992)).

To plead that a withheld reference is material, a pleading should "identify the particular claim limitations, or combination of claim limitations, that are supposedly absent from the information of record." Exergen Corp., 575 F.3d at 1329. "Such allegations are necessary to explain both 'why' the withheld information is material and not cumulative, and 'how' an examiner would have used this information in assessing the patentability of the claims." Id. at 1329-30.

The EPPs and Retailers here plainly plead that the Molloy reference teaches to increase the oral contraceptive regimen from 21 days to 23 days, and the '394 patent claims "extend the 21-day schedule to 23-25 days." (See, e.g., Walgreen Compl. ¶ 89.) The Molloy reference is not so clearly cumulative on the face of the Operative Complaints, nor lacking in materiality, that the Court may say that Plaintiffs have not alleged a plausible basis for relief. See Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1319 (Fed. Cir. 2006) ("As this court has previously noted, the scope and content of prior art and what the prior art teaches are questions of fact.").

Notably, all the cases cited by Defendants in support of their argument that the EPPs and Retailers have failed to adequately allege intent to deceive the PTO were decided on post-trial motions. See, e.g., Nobelpharma AB, 141 F.3d at 1059; C.R. Bard, 157 F.3d at 1340; Hebert v. Lisle Corp., 99 F.3d 1109 (Fed. Cir. 1996); Smith & Nephew, Inc. v. Interlace Med., Inc., 955 F. Supp. 2d 69 (D. Mass. 2013).

For purposes of surviving a motion to dismiss, the EPPs and Retailers have pleaded that the Molloy reference was material and the applicants had the fraudulent intent to deceive the PTO in withholding that reference.

f. Amount of Estrogen

Plaintiffs allege that the applicants fraudulently

misrepresented the amount of estrogen in other commercially available oral contraceptives. Specifically, in response to the examiner's initial determination that all claims were obvious, the applicants responded with a letter stating, in part, that "the claimed regimen leaves the patient with a total estrogen exposure per annum which is well below the total annual dose of estrogen in all other combination formulations commercially available in this country. Those all contain at least 30 mcg EE (Craft uses 50 mcg) . . . ." (DPP Compl. ¶ 137.) Despite the applicants' statement to the patent examiner, Plaintiffs allege, Hodgen and the other applicants knew of a commercially available oral contraceptive that "exposed women to half as much estrogen as claimed in the '394 Patent" - namely, Loestrin 1/20 - but failed to disclose it. (Walgreen Compl. ¶ 86.)

The Warner Chilcott Defendants, in rejoinder, say that we do not have the full story here. Rather, at another point during the prosecution, the applicants disclosed Loestrin 1/20 and its estrogen content to the PTO (which they say is apparent on the face of the patent), as well as prior art references disclosing formulations with less than 30 mcg of ethinyl estradiol. (Warner Chilcott Mot. to Dismiss 105.) Defendants further point the Court to a rejection letter dated November 28, 1995 as proof that the omission could not have been material. (Id.) In that letter, the examiner announced that she had found the applicants' remarks

"unpersuasive." (Id. (citation omitted).)

"A false or clearly misleading prosecution statement may permit an inference that the statement was made with deceptive intent." Dippin' Dots, Inc., 476 F.3d at 1347. "For instance, evidence may establish that a patent applicant knew one fact and presented another, thus allowing the factfinder to conclude that the applicant intended by the misrepresentation to deceive the examiner." Id.

The Warner Chilcott Defendants' arguments are not sustainable merely on the face of Plaintiffs' Operative Complaints, and are better reserved for either summary judgment or trial. On the face of the Operative Complaints, the Plaintiffs plead sufficient underlying facts to support a reasonable inference of intent to deceive the PTO and materiality, and accordingly, these issues will need to be resolved after the benefit of discovery.

g. Warner Chilcott's Purported Knowledge of Fraud

The Warner Chilcott Defendants argue that Plaintiffs have not adequately alleged that Warner Chilcott had knowledge of any fraud on the PTO. (Warner Chilcott Mot. to Dismiss 106.) To establish fraud on the PTO, a plaintiff must plead, and ultimately prove, "no less than . . . intentional fraud involving affirmative dishonesty." Tyco Healthcare Grp. LP v. Mut. Pharm. Co., 762 F.3d 1338, 1350 (Fed. Cir. 2014) (quoting C.R. Bard, Inc., 157 F.3d at 1364). With an assignee, like Warner Chilcott, a plaintiff must



establish, then, "that the defendant maintained and enforced the patent with knowledge of the fraudulent manner in which it was obtained." Ritz Camera & Image, LLC, 700 F.3d at 506; see also Walker Process, 382 U.S. at 179 (Harlan, J., concurring) ("[I]f the defendant was not the original patent applicant, he had been enforcing the patent with knowledge of the fraudulent manner in which it was obtained . . . .").

Plaintiffs here allege that Warner Chilcott knew about the fraudulent omissions and misrepresentations during the '394 patent prosecution because of letters Dr. Hodgen wrote to Warner-Lambert and Roger Boissonneault in 1990 and 1993, respectively. (DPP Compl. ¶¶ 142-44; Walgreen Compl. ¶ 90; EPP Compl. ¶ 168.) At the time of this contact, Mr. Boissonneault was the Vice President of Female Health Care at Parke Davis, which was owned by Warner Lambert; Mr. Boissonneault later served as Warner Chilcott's CEO from 2005 to 2013, during the enforcement of the '394 patent. (DPP Compl. ¶ 144.) "Boissonneault and Hodgen exchanged information about plans to study whether administering Loestrin 1/20 for more than 21 days would reduce the incidence of bleeding and possibly provide additional patent coverage years before Hodgen conducted his studies and applied for a patent." (Id. ¶ 143; see also Walgreen Compl. ¶ 90 ("The Applicants were aware of the Molloy reference, as shown by a letter Hodgen wrote to Warner-Lambert during December 1990.")).) Dr. Hodgen also sent a letter to Mr.

Boissonneault in 1993 in an effort to persuade Parke Davis to pay EVMS for the "technology" used in the 1993 human study. (DPP Compl. ¶ 144.) The DPPs allege that this letter supports their allegation that Mr. Boissonneault knew of Dr. Hodgen's human study in 1993 and provides the basis for a reasonable inference that Mr. Boissonneault knew the study had not shown a decrease in the incidence of breakthrough bleeding. (Id.) Following the letter, Mr. Boissonneault negotiated the terms of an agreement; the DPPs allege that the agreement, dated October 2, 1994, "included a \$1 million payment to EVMS in exchange for an assignment of EVMS's interest in the patent application and any resulting patents to Warner Lambert." (Id. ¶ 145.) Plaintiffs allege that Warner Chilcott and Mr. Boissonneault knew that Dr. Hodgen's 1993 human study had not been disclosed to the PTO during the '394 patent prosecution and that they knew it was a material omission when the '394 patent was listed and enforced. (DPP Compl. ¶¶ 139, 142, 147.)

This is enough upon which to make a reasonable inference that Mr. Boissonneault had knowledge of the 1993 human study at the time of the patent enforcement. Reasonable inferences may further be drawn that Mr. Boissonneault, in light of his position at Warner Chilcott, had actual knowledge that the applicants misrepresented the amount of estrogen available in other commercially available oral contraceptives and that the applicants had fraudulently

omitted the Molloy reference. (See, e.g., Walgreens Compl. ¶ 90; EPP Compl. ¶ 168.)

The sum of all this is that Plaintiffs have sufficiently alleged Walker Process fraud on the PTO, and those claims survive Defendant Warner Chilcott's motion to dismiss.

## 2. Sham Litigation

To survive a motion to dismiss on a sham litigation theory, a plaintiff must plausibly allege that the litigation was (1) "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits;" and (2) subjectively motivated by a desire to "conceal[] an attempt to interfere directly with the business relationships of a competitor through the use [of] the governmental process . . . as an anticompetitive weapon." Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., 508 U.S. 49, 60-61 (1993) (internal citation omitted). Only then does the suit fall within Noerr's exception to immunity from liability. Nobelpharma AB, 141 F.3d at 1071. To be sure, this is a high burden to meet; "[g]iven the presumption of patent validity and the burden on the patent challenger to prove invalidity by clear and convincing evidence, it will be a rare case in which a patentee's assertion of its patent in the face of a claim of invalidity will be so unreasonable as to support a claim that the patentee has engaged in sham litigation." Tyco Healthcare Grp. LP, 762 F.3d at 1345.

Here, Plaintiffs allege that “[a] reasonable pharmaceutical company in Warner Chilcott’s position” would not have had a reasonable expectation of success on the merits in its infringement suit against Watson. (See DPP Compl. ¶ 179 (challenging only the Watson suit); see also EPP Compl. ¶¶ 173-76; 199-206; 230-31 (challenging the Watson, Lupin, and Mylan suits); Walgreen Compl. ¶¶ 100, 110, 115 (challenging the Watson, Lupin, and Mylan suits).) In its suit against Warner Chilcott, Watson had attacked the ‘394 patent on three separate grounds: invalidity; unenforceability; and non-infringement. (DPP Compl. ¶ 181.) According to the DPPs’ Operative Complaint, discovery in the Warner Chilcott-Watson litigation revealed that Mr. Boissonneault learned of the 1993 human study. (See, e.g., id.) The FDA’s medical review of Loestrin 24, made public on March 24, 2008, further confirmed that Loestrin 24 did not provide for a significant reduction in the incidence of breakthrough bleeding. (Id.) The Operative Complaints allege that Watson would have prevailed in that litigation for the reasons alleged by Watson in its suit with Warner Chilcott and due to the defects alleged by Plaintiffs in this suit. (See, e.g., id. ¶ 182.)<sup>32</sup> In sum, the allegations

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<sup>32</sup> In its Complaint, the Walgreen Plaintiffs allege that Dr. Hodgen was also aware that Schering AG was investigating an oral contraceptive regimen using 23 to 25 hormone-containing tablets per 28-day cycle, and that it constituted invalidating prior art. (See Walgreen Compl. ¶ 79.) Defendants argue that it did not constitute invalidating prior art or public use because it was

state that "Warner Chilcott knew that the applicants procured the '394 patent fraudulently before it listed the '394 patent in the Orange Book for Loestrin 24, and before it asserted the patent in lawsuits filed against Watson, Lupin, and Mylan." (EPP Compl. ¶ 169)

Accepting all facts alleged in the Operative Complaints as true, drawing all reasonable inferences in favor of Plaintiffs, and in light of the Court's conclusion that Plaintiffs have alleged facts sufficient to conclude that Warner Chilcott had actual knowledge that the '394 patent was fraudulently procured, Plaintiffs have stated a plausible claim for sham litigation. The facts support the conclusion that the suits against the generic manufacturers were "objectively baseless" and that no reasonable litigant could have expected to succeed on the merits where it understood the '394 patent to have been fraudulently procured. Prof'l Real Estate Investors, 508 U.S. at 60. In other words, Warner Chilcott could not have expected to prove that the generics infringed a valid '394 patent. Moreover, the facts support a conclusion that the patent infringement suits were litigation

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outside the country, and Retailer Plaintiffs appear to allege these facts only as additional support for their sham litigation claim. (See Warner Chilcott Mot. to Dismiss 96 n.73; Retailers' Mem. in Opp'n to Warner Chilcott/Watson Mot. to Dismiss 53, ECF No. 207.) Because the Court allows Retailer Plaintiffs' sham litigation claim to proceed on other grounds, it need not reach the merits of the Warner Chilcott Defendants' arguments on this score.

subjectively motivated by a desire to "conceal[] an attempt to interfere directly with the business relationships of a competitor through the 'use of the governmental process . . . as an anticompetitive weapon.'" Id. at 60-61 (internal citation omitted).

### 3. Orange Book Listing

Plaintiffs allege that Warner Chilcott further committed fraud on the PTO by listing the '394 patent in the Orange Book as the only patent covering Loestrin 24 or a method of using Loestrin 24, even though individuals at Warner Chilcott, including but not limited to then-CEO Roger Boissonneault, knew the '394 patent was invalid or unenforceable. (See, e.g., Walgreen Compl. ¶¶ 72-73.) Plaintiffs allege that, "Warner Chilcott listed the '394 patent in the Orange Book even though it knew that patent could not reasonably be asserted against generic manufacturers because it knew the patent was procured fraudulently, and also that the patent was invalid and unenforceable." (Id. ¶ 93.) They allege that this constituted fraud and inequitable conduct on the PTO. In addition, Plaintiffs allege that Warner Chilcott knew that the '394 patent was not valid, as it was "anticipated and obvious in light of the prior art" before listing the patent in the Orange Book. (Id. ¶ 94.) Plaintiffs allege that "Warner Chilcott's listing of the '394 [p]atent was objectively and subjectively baseless because Warner Chilcott did not believe and could not reasonably have

believed that the '394 [p]atent could be asserted against manufacturers of generic versions of Loestrin 24." (Id. ¶ 97.) It was listed to create an obstacle to generic competition. (Id.) Defendants argue that this claim only survives if Plaintiffs' Walker Process fraud or sham litigation claims survive. See Solodyn, 2015 WL 5458570, \*12 (holding that "listing presumptively valid patents in the Orange Book and enforcing them against infringers are not bases for an antitrust claim" (quoting In re Lipitor Antitrust Litig., No. 3:12-CV-2389 (PGS), 2013 WL 4780496, at \*21 (D.N.J. Sept. 5, 2013))). Because the underlying conduct has survived Defendants' motion to dismiss, Plaintiffs have pleaded fraud on the PTO vis-à-vis Warner Chilcott's Orange Book listing.

D. Product Hop

The Warner Chilcott Defendants move to dismiss Plaintiffs' product hop claims. They argue that courts should not recognize a product hop theory under antitrust law so as to avoid being in the business of prohibiting "a company from deciding to stop manufacturing and marketing a product." (Warner Chilcott Mot. to Dismiss 118; see also Warner Chilcott Reply 57-58.) If the Court does recognize a product hop theory, the Warner Chilcott Defendants further argue that the facts alleged in the instant case do not state a claim for relief. (Warner Chilcott Mot. to Dismiss 113.) They contend that generic versions of Loestrin 24 have since

entered the market and have been profitable. (See Warner Chilcott Reply 64 (“[T]he very fact that six generics have been approved, to the tune of as many as 5 million generic prescriptions per month . . . . belies any claim that generics did not see a ‘cost efficient’ means of distribution . . . .” (citing DPP Compl. 76, Fig. 6)).)

Plaintiffs’ allegations are succinctly summarized as follows:

(1) Minastrin 24 Fe is chemically and pharmaceutically identical to Loestrin 24 Fe -- the only differences are the addition of flavoring to the placebo pills and an instruction in the labeling to chew the tablets (the tablets themselves were already chewable); (2) in or about August 2013, Warner Chilcott stopped manufacturing and distributing Loestrin 24 Fe and started distributing Minastrin 24 Fe; (3) physicians substantially decreased the number of Loestrin 24 Fe prescriptions they wrote and began prescribing Minastrin 24 Fe instead; and (4) the result was to substantially reduce the number of prescriptions that could be filled with generic Loestrin 24 Fe when it became available in early 2014.

(Retailers’ Mem. in Opp’n to Warner Chilcott/Watson Mot. to Dismiss 55, ECF No. 207.) Plaintiffs further allege that, in executing the product hop, Defendants intended to suppress competition and make monopoly profits. (See DPP Compl. ¶¶ 287-90.)

A product hop occurs when a brand-name drug manufacturer tweaks the drug “to prevent pharmacists from substituting a generic equivalent when presented with a prescription for the newly modified brand-name drug.” In re Asacol Antitrust Litig., No. 15-CV-12730-DJC, 2016 WL 4083333, at \*2 (D. Mass. July 20, 2016) (“Asacol”); see also New York ex rel. Schneiderman v. Actavis PLC,



787 F.3d 638, 643 & n.2 (2d Cir. 2015) ("Namenda") (noting that "conduct by a monopolist to perpetuate patent exclusivity through successive products" is "commonly known as 'product hopping'"). To more effectively stymie generic competition with a product hop, "a brand-name manufacturer often removes the original drug from the market entirely, known as a 'hard switch,' right before patent expiration to deprive potential generic manufacturers a prescription base for their generic drugs." Asacol, 2016 WL 4083333, at \*2.

Product hop claims are analyzed under § 2 of the Sherman Act, which "makes it illegal to 'monopolize, or attempt to monopolize . . . any part of the trade or commerce' among the several States." Diaz Aviation Corp. v. Airport Aviation Servs., Inc., 716 F.3d 256, 265 (1st Cir. 2013) (quoting 15 U.S.C. § 2). "To prove a violation of this statute, a plaintiff must demonstrate (1) that the defendant possesses 'monopoly power in the relevant market,' and (2) that the defendant has acquired or maintained that power by improper means." Town of Concord v. Boston Edison Co., 915 F.2d 17, 21 (1st Cir. 1990) (quoting United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1966)). "Courts refer to unlawful methods of acquiring or maintaining monopoly power as 'exclusionary conduct.'" Solodyn, 2015 WL 5458570, at \*10 (quoting Town of Concord, 915 F.2d at 21). Exclusionary conduct encompasses "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.” Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004) (quoting Grinnell, 384 U.S. at 570-71). Courts apply the rule-of-reason test to determine whether a product hop constitutes exclusionary conduct under § 2 of the Sherman Act. See Namenda, 787 F.3d at 652.<sup>33</sup>

Product hopping is a relatively new theory under the Sherman Act. In 2015, the Second Circuit was the first Circuit to examine the lawfulness of a product hopping scheme in Namenda. See id. at 642, 646. There, the defendant manufactured brand-name Namenda IR, an immediate-release drug indicated for patients with Alzheimer’s disease. Id. at 643. Anticipating the expiration of its patent and the entry of generic competition, the defendant first tried to switch patients from Namenda IR to Namenda XR, an extended release version of the drug that was not therapeutically equivalent, using aggressive marketing, which is also known as a

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<sup>33</sup> As the reader will recall from above, the rule-of-reason test proceeds in three steps: “once a plaintiff establishes that a monopolist’s conduct is anticompetitive or exclusionary, the monopolist may proffer ‘nonpretextual’ procompetitive justifications for its conduct.” Thereafter, “[t]he plaintiff may then either rebut those justifications or demonstrate that the anticompetitive harm outweighs the procompetitive benefit.” Namenda, 787 F.3d at 652; see also Nexium II, 42 F. Supp. 3d at 262-63.

"soft switch." Id. at 647-48. With only 30% of patients expected to switch to Namenda XR by the time generic Namenda IR was due to enter the market, the brand manufacturer refocused its efforts on a "hard switch." Id. at 648. It announced it would discontinue Namenda IR; notified the FDA about its plans; published letters to encourage caregivers and healthcare providers to discuss switching with their patients; and sent a letter to Medicare requesting it remove the formulary list. Id. at 648. The defendant-brand initially gave patients and their doctors approximately six months' notice to switch to Namenda XR. Id.

The Second Circuit, in affirming the district court's grant of a preliminary injunction, held that, though "neither product withdrawal nor product improvement alone is anticompetitive," when a brand manufacturer with monopoly power "combines product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, and to impede competition, its actions are anticompetitive under the Sherman Act." Id. at 653-54 (citations omitted). The Second Circuit held that the hard switch coerced consumers, noting that "[w]ell-established case law makes clear that product redesign is anticompetitive when it coerces consumers and impedes competition." Id. at 652, 654.

Expounding on when the introduction of a new product is anticompetitive, the Second Circuit explained that

the market can determine whether one product is superior to another only "so long as the free choice of consumers is preserved." Had Defendant allowed [the established drug] to remain available until generic entry, doctors and . . . patients could have decided whether the benefits of switching to [the new drug] would outweigh the benefits of adhering to [the existing therapy] using [the] less-expensive generic drug.

Id. at 654-55. The court found the brand-manufacturer's conduct impeded competition given "the unique characteristics of the pharmaceutical market," including state generic drug substitution laws and the cost-efficiencies they create. Id. at 655-56. "For there to be an antitrust violation, generics need not be barred 'from all means of distribution' if they are 'bar[red] . . . from the cost-efficient ones.'" Id. at 656 (quoting United States v. Microsoft Corp., 253 F.3d 34, 64 (Fed. Cir. 2001)). The court acknowledged that it "would be a highly unlikely occurrence" that patients would go back to a generic version of Namenda IR once a generic entered the market, given the difficulty of a "reverse commute." Id. at 656. The court held that "the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification," violates § 2 of the Sherman Act. Id. at 659.

The Warner Chilcott Defendants' principal argument is that courts should not police innovation by, in essence, deciding how

much of a product tweak is sufficiently innovative to withstand antitrust scrutiny. (See Warner Chilcott Mot. to Dismiss 117-18.) The Second Circuit and other courts have acknowledged that “there is tension between the antitrust laws’ objective of enhancing competition by preventing unlawful monopolies and patent laws’ objective of incentivizing innovation by granting legal patent monopolies.” Namenda, 787 F.3d at 659; see also Asacol, 2016 WL 4083333, at \*10. But “[i]ntellectual property rights do not confer a privilege to violate the antitrust laws.” Namenda, 787 F.3d at 660 (quoting In re Indep. Serv. Orgs. Antitrust Litig., 203 F.3d 1322, 1325 (Fed. Cir. 2000)) (internal quotation marks omitted). A patent conveys “a temporary monopoly on individual drugs – not a right to use . . . patents as part of a scheme to interfere with competition ‘beyond the limits of the patent monopoly.’” Id. (quoting United States v. Line Material Co., 333 U.S. 287, 308 (1948)). “As a general rule, courts are properly very skeptical about claims that competition has been harmed by a dominant firm’s product design changes.” Namenda, 787 F.3d at 652 (quoting Microsoft, 253 F.3d at 65). But it is well established that “product redesign is anticompetitive when it coerces consumers and impedes competition.” Id. at 652. Moreover, “[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue,” Trinko, 540 U.S. at 411, and the pharmaceutical industry and its generic substitution laws

are no different. “[G]eneric substitution by pharmacists . . . is authorized by law; is the explicit goal of state substitution laws; and furthers the goals of the Hatch-Waxman Act by promoting drug competition, and by preventing the ‘practical extension of [brand drug manufacturers’] monopoly . . . beyond the expiration of the[ir] patent[s].’” Namenda, 787 F.3d at 657-58 (citations omitted and quotation omitted). In the instant case, Plaintiffs have plausibly alleged a “combination of Defendants’ withdrawal of [Loestrin 24] and introduction of [Minastrin 24] in the context of generic substitution laws” sufficient to state a claim for exclusionary or anticompetitive conduct. See id. at 660 (emphasis in original).

The Warner Chilcott Defendants next argue that the alleged product hop served Warner Chilcott’s business goals by addressing a patient need, namely, providing a chewable alternative for patients; allowing Warner Chilcott to “more effectively compete in a crowded market for oral contraceptives;” and “withdrawing the older product for which there was soon to be several identical competitors.” (See Warner Chilcott Reply 57.) This argument does not aid the Warner Chilcott Defendants on a 12(b)(6) motion; Plaintiffs’ Operative Complaints plainly plead that the business justifications offered are either pretextual or exclusionary and anticompetitive in nature.

Defendants point to a case out of the Third Circuit, the only other Circuit to address the issue, in which Warner Chilcott was also involved. See Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421, 428-29 (3d Cir. 2016) ("Doryx"). In Doryx, the Third Circuit affirmed the grant of a motion for summary judgment in Warner Chilcott's favor on a product hop theory. See generally id.

Doryx was primarily decided on two grounds. The Third Circuit concluded that: (1) the plaintiff had failed as a matter of law to demonstrate that the defendants had market power in the relevant market, id. at 437-38; and (2) the plaintiff-generic manufacturer had failed to produce evidence of anticompetitive conduct because it had not been foreclosed from the market, id. at 438.<sup>34</sup>

A hard look at the Doryx decision reveals that it is readily distinguishable. First, the court concluded that the plaintiff had not been harmed by the product hop, id. at 439; second, it noted that, in that case, "the District Court allowed [the plaintiff]'s claims to proceed against Defendants after denying their motions to dismiss," and only "after a period of exhaustive

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<sup>34</sup> On this second ground, the Third Circuit indicated that Doryx capsules had been available for more than twenty years and generic companies had been free to "engineer their own versions during that time;" had generated substantial profits from the sale of generics; and had not been harmed by the defendant's product changes. Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421, 438-39 (3d Cir. 2016).

discovery, the District Court thoroughly reviewed the record and concluded that Mylan failed to create trial issues of material fact to save any of its Sherman Act claims[,]" id. at 440; and third, the court noted that the Second Circuit, in Namenda, had "persuasively distinguished" the district court's decision in Doryx on the ground that "there was no evidence of consumer coercion, because generics 'had already entered the market at the time of defendants' product reformulation.'" Id. (quoting Namenda, 787 F.3d at 652 n.23). On all scores, Doryx supports Plaintiffs. Here, the Court must take as true the facts alleged in well-pleaded complaints stating that generic versions of Loestrin 24 had not entered the market when Warner Chilcott withdrew branded Loestrin 24 from the market and that the generic market was harmed by the product hop.

The instant case is also distinguishable from the other cases cited by Defendants. In both Walgreen Co. v. AstraZeneca Pharms. L.P., 534 F. Supp. 2d 146, 147-49 (D.D.C. 2008) ("Walgreen Prilosec"), and AstraZeneca AB v. Mylan Labs. Inc., 2010 WL 2079722, at \*2 (S.D.N.Y. May 19, 2010) ("Mylan Prilosec"), the brand manufacturer executed a "soft switch" - in other words, employed aggressive marketing techniques - in anticipation of generic entry. The brand manufacturer never removed Prilosec from the market, and thus never eliminated consumer choice. See Walgreen Prilosec, 534 F. Supp. 2d at 151; see also Mylan Prilosec,



2010 WL 2079722, at \*2. Similarly, in Solodyn, the brand manufacturer discontinued selling certain strengths of its drug approximately two years after generics were introduced. Solodyn, 2015 WL 5458570, at \*13. Accordingly, the district court concluded, in line with the Prilosec cases, that the removal of a certain formulation of a drug after generic introduction was insufficient to plead that the defendant-brand had "limited consumer choice." Id. (citing Walgreen Prilosec, 534 F. Supp. 2d at 151).

To be sure, the level of coercion alleged in some other product hop cases has been more egregious than is alleged here. See, e.g., Namenda, 787 F.3d at 646-48, 656 (upholding preliminary injunction where brand announced the withdrawal of a drug for which the new formulation was not therapeutically equivalent, no other therapeutically equivalent drug was available, and for which the patient population was particularly sensitive to drug changes); In re Suboxone Antitrust Litig., 64 F. Supp. 3d 665, 681-82 (E.D. Pa. 2014) (denying motion to dismiss where, allegedly, the brand manufacturer announced it had removed the established drug formulation in connection with "raising false safety concerns and disparaging" the product). But the facts pleaded here are analogous to the level of consumer coercion in other cases permitted to proceed to discovery. See, e.g., Asacol, 2016 WL 4083333, at \*3-5 (denying a motion to dismiss where defendant

Warner Chilcott, in a factually-analogous case, discontinued the established drug a few months before its patents expired and introduced a new drug, which was alleged to be bioequivalent and thus not medically superior to the established drug, in order to avoid generic competition); Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d 408, 416-17 (D. Del. 2006) ("TriCor") (denying motion to dismiss where brand manufacturer changed TriCor from capsule to tablet to a second tablet, as it also stopped selling capsules, bought back existing supplies from pharmacies, and took steps to prevent pharmacies from filling prescriptions with generic prescriptions).

Here, Plaintiffs have plainly stated a claim for unlawful product hopping, in violation of § 2 of the Sherman Act, because they have alleged that Warner Chilcott executed a hard switch by "withdrawing a successful drug from the market and introducing a reformulated version of that drug" with "the dual effect of forcing patients to switch" from Loestrin 24 to Minastrin 24 "and impeding generic competition, without a legitimate business justification." See Namenda, 787 F.3d at 659.

E. Overarching Scheme

The Warner Chilcott Defendants argue that, where all of Plaintiffs' antitrust claims fail, their allegation of an overarching scheme must also fail. (Warner Chilcott Mot. to Dismiss 130-31; see also Warner Chilcott Reply 68-69 ("[I]f each of

Plaintiffs' theories here is not viable, Plaintiffs' claim is likewise not viable overall.".) Because Plaintiffs' claims stand, this argument necessarily falls as well. Plaintiffs have plausibly alleged an overarching scheme to monopolize.

F. End-Payers' State Law Claims

As explained above, the EPPs are "third-party payors" or "indirect purchasers." They generally comprise employee welfare benefit programs that reimbursed subscribers who purchased Loestrin 24, but also include three individuals who purchased Loestrin 24 for their own use. "In Illinois Brick, the Supreme Court held that indirect purchasers of goods produced by firms engaged in anticompetitive conduct were too remote from that conduct to be regarded as injured" under federal antitrust law. Nexium I, 968 F. Supp. 2d at 409 (citing Illinois Brick Co. v. Illinois, 431 U.S. 720, 746-48 (1977)). In response to Illinois Brick, "some states have passed laws . . . which expressly grant end-payers the right to sue for antitrust violations." Solodyn, 2015 WL 5458570 at \*15; see generally California v. ARC Am. Corp., 490 U.S. 93 (1989) (holding that states may expressly grant indirect purchasers the right to recover under state law). Unable to bring claims under federal law, the EPPs here assert 137 distinct causes of action under state law: state antitrust claims; state consumer protection claims; and state unjust enrichment claims.

The EPPs allege that they are located in 9 states<sup>35</sup>, and they have purchased or provided reimbursement for brand-name Loestrin 24 and Minastrin 24 in 25 states and the District of Columbia.<sup>36</sup> (See EPP Compl. ¶¶ 15-26.)

Defendants argue, on various grounds, that each of the 137 causes of action must be dismissed for failure to state a claim. (See Warner Chilcott Mot. to Dismiss 131.) The Court addresses Defendants' arguments in seriatim.

1. Whether the EPPs' State Law Claims Fail for the Same Reasons the Federal Antitrust Claims Fail

Defendants argue that the state law claims fail for all the reasons the federal antitrust claims fail, as discussed above, because they do not allege any additional facts or wrongdoing. (Warner Chilcott Mot. to Dismiss 131-32.) For the reasons stated above, the underlying federal antitrust claims stand and, thus, the Court will not dismiss the state law claims for failure to allege antitrust wrongdoing.

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<sup>35</sup> The states are: Alabama, Florida, Illinois, Minnesota, New York, North Carolina, Pennsylvania, Rhode Island, and Tennessee.

<sup>36</sup> They are: Alabama, California, Connecticut, Delaware, the District of Columbia, Florida, Illinois, Kansas, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, and Virginia.

2. Whether the EPPs' State Law Claims Are Preempted by Federal Law

Defendants next argue that the EPPs' state law claims alleging fraud on the PTO, sham litigation, improper Orange Book listing, and unlawful reverse payment are preempted by federal patent law. (Warner Chilcott Mot. to Dismiss 134-37.) They argue that state law claims that arise from "unsavory conduct of parties to proceedings in the [PTO]" should be dismissed as preempted because they turn on questions of federal patent law, namely whether the '394 patent was procured by fraud on the PTO. (Id. at 134 (quoting Abbott Labs. v. Brennan, 952 F.2d 1346, 1355, 1357 (Fed. Cir. 1991)).)

With respect to the alleged large and unjustified reverse payment, Defendants further argue that, because the EPPs are "required to plead and prove that their injury was caused by a settlement agreement rather than by the underlying patent," those claims are also preempted by federal patent law. (Id. at 135-36.) Because the EPPs would need to prove causation, thus inviting inquiry into the scope and validity of the '394 patent, Defendants contend that the state law claims are preempted by federal patent law. (Id.) The EPPs counter that, because their "state claims are not predicated upon conduct that is protected or governed by federal patent law and do not impede the accomplishment and execution of Congressional purposes and objectives, they are not

preempted.” (End-Payor Pls.’ Mem. in Opp’n to Defs.’ Mots. to Dismiss End-Payor Pls.’ Second Am. Consol. Class Action Compl. (“EPPs’ Opp’n”) 31, ECF No. 205.) The EPPs further note that their antitrust and consumer protection claims are “independent remedies for improprieties in the marketplace.” (Id. at 33.)

There is a general “presumption against finding pre-emption of state law in areas traditionally regulated by the States[,]” which includes “the long history of state common-law and statutory remedies against monopolies and unfair business practices . . . .” ARC Am. Corp., 490 U.S. at 101. In California v. ARC Am. Corp., the Supreme Court held that federal antitrust laws do not preempt state antitrust law and noted that “nothing in Illinois Brick suggests that it would be contrary to congressional purposes for States to allow indirect purchasers to recover under their own antitrust laws.” Id. at 102-03. Here, however, the issue is whether federal patent law preempts the EPPs’ state law claims for antitrust violations, consumer protection violations, and unjust enrichment, all of which are premised on alleged antitrust wrongdoing.

The federal preemption of state law claims comes in three species: explicit, field, and conflict preemption. See generally English v. General Elec. Co., 496 U.S. 72 (1990). Explicit preemption is readily dismissed here – federal patent law does not explicitly provide for preemption. Hunter Douglas, Inc. v.

Harmonic Design, Inc., 153 F.3d 1318, 1332 (Fed. Cir. 1998) (citing 35 U.S.C. §§ 1-376).<sup>37</sup> The next strain of preemption, field preemption, occurs when state law aims to regulate conduct “in a field that Congress intends the federal government to occupy exclusively.” Id. at 1332. And, finally, a state cause of action is preempted under conflict preemption to the extent it “actually conflicts with federal law,” for example, “when it is impossible for a private party to comply with both state and federal requirements, or when state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’” Id. at 1332 (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)). Here, the EPPs’ claims sound in unfair competition in violation of state consumer protection statutes and state antitrust laws, as well as unjust enrichment. In line with the Federal Circuit, and because the Warner Chilcott Defendants do not suggest Congress intended to preempt these areas of state law, the Court concludes that there is no field preemption of state consumer protection, unjust enrichment, or antitrust laws. See id. at 1333

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<sup>37</sup> On the issue of federal preemption, the First Circuit Court of Appeals, this Court’s regional circuit, controls the outcome here. However, because the First Circuit apparently has not yet had occasion to address the instant issue, the Federal Circuit’s precedent, along with precedent from other courts, is instructive. See Hunter Douglas, Inc. v. Harmonic Design, Inc., 153 F.3d 1318, 1333 (Fed. Cir. 1998) (citing Cable Elec. Prods. Inc. v. Genmark, Inc., 770 F.2d 1015, 1032-33 (Fed. Cir. 1985)).

(holding that in light of the presumption against preemption, there is no field preemption of "state unfair competition claims that rely on a substantial question of federal patent law" because Congress has not expressed its clear and manifest intention to preempt that area of law); ARC Am. Corp., 490 U.S. at 101 ("Given the long history of state common-law and statutory remedies against monopolies and unfair business practices, it is plain that this is an area traditionally regulated by the States."). Thus, the question here is "whether a state law cause of action conflicts with the purposes of federal patent law," Hunter Douglas, 153 F.3d at 1335, or more specifically, whether there is conflict preemption of the EPPs' state law claims such that they "frustrate 'the accomplishment and execution of the full purposes and objectives of Congress.'" Id. at 1335 (quoting Hines, 312 U.S. at 67). If the alleged state law claims are premised on conduct protected or governed by federal patent law, the actions are preempted. Id. "Conversely, if the conduct is not so protected or governed, then the remedy is not preempted." Id.

Courts have held that when the state law cause of action provides a remedy for conduct that occurs entirely before the PTO - such as inequitable conduct before the PTO - or for "patent-like protection," it is preempted by federal patent law. See, e.g., Semiconductor Energy Lab. Co. v. Samsung Elecs. Co., 204 F.3d 1368, 1380-83 (Fed. Cir. 2000) (holding New Jersey RICO claim preempted



because it "occup[ies] a field identical in scope with the inequitable conduct defense"); Brennan, 952 F.2d at 1357 (holding that state tort action for abuse of process preempted by federal patent law because allegations were confined to bad faith misconduct before the PTO); Daiichi Sankyo, Inc. v. Apotex, Inc., Civil Action No. 030937 (SDW-MCA), 2009 WL 1437815, at \*9 (D.N.J. May 19, 2009) (holding state law tortious interference and unjust enrichment claims preempted where there was no finding of actual fraud and the conduct was "based on nothing more than misconduct before the PTO"); In re Ciprofloxacin Hydrochloride Antitrust Litig., 363 F. Supp. 2d 514, 544 (E.D.N.Y. 2005) (concluding that federal patent law preempted the state law antitrust claim premised on "alleged bad faith conduct before the PTO" because the state law remedies sought were "directed to allegedly tortious conduct before the PTO, not tortious conduct in the marketplace"). In contrast, courts have held that a state claim is not preempted where it is not protected or governed by patent law. Hunter Douglas, 153 F.3d at 1337. A state claim is not protected or governed by patent law when it "address[es] entirely different wrongs[,]" "provide[s] different forms of relief," and "is not an impermissible attempt to offer patent-like protection to subject matter addressed by federal law." Dow Chem. Co. v. Exxon Corp., 139 F.3d 1470, 1478 (Fed. Cir. 1998). For the claim to escape preemption, it must seek a remedy for "bad faith misconduct in the

marketplace," rather than "bad faith misconduct in the PTO." Id. at 1476-78. And to achieve this, the plaintiff must allege and ultimately prove, fraud on the PTO or bad faith in the marketplace, regardless of whether the underlying state claim demands proof of such conduct. Hunter Douglas, 153 F.3d at 1337.

Here, it is plain that the EPPs' state law claims are not preempted by federal patent law. The EPPs allege that the patent was procured by fraud on the PTO and thereafter enforced in the marketplace with bad faith. The state law claims alleged here "require[] entirely different elements" than "those required for inequitable conduct before the PTO," Dow, 139 F.3d at 1477, and "the tort occurred not at the PTO but later in the marketplace, even though the conduct before the PTO might be used to prove it." In re DDAVP Indirect Purchaser Antitrust Litig., 903 F. Supp. 2d 198, 218 (S.D.N.Y. 2012) (quoting Dow, 139 F.3d at 1477-78) (internal citation omitted). Furthermore, state law claims based on Walker Process-type fraud do not frustrate the purposes or objectives of federal patent law for the same reasons their federal counterparts do not. See Walker Process, 382 U.S. at 177-78 (holding that a plaintiff may state a claim under the Sherman Act for a defendant's enforcement of a patent procured by fraud on the PTO, where the plaintiff alleges deliberate fraud and the other elements of a monopolization claim under Section 2 of the Sherman Act).

The preemption argument for the state law claims challenging the alleged unlawful reverse payment is even more tenuous, as the Supreme Court has acknowledged that “[i]t is normally not necessary to litigate patent validity to answer the antitrust question” as “[a] large, unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court to conduct a detailed exploration of the patent’s validity.” Actavis, 133 S. Ct. at 2226. For these reasons, the EPPs’ state law claims are not preempted by federal patent law.

3. Whether the EPPs Adequately Allege Article III Injury as to Twenty-Five States and Puerto Rico

Defendants move to dismiss the EPPs’ claims under the state law of twenty-five states and Puerto Rico.<sup>38</sup> (Warner Chilcott Mot. to Dismiss 137.) Because the EPPs have failed to allege that they either reside in or have purchased Loestrin products in these states and Puerto Rico, Defendants contend the EPPs have no Article III standing and the claims must be dismissed. (Id. at 137-42.)

“The interplay between Article III standing and class standing presents a surprisingly difficult question.” Solodyn,

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<sup>38</sup> Defendants identify the following twenty-five states (and Puerto Rico) in which the EPPs do not reside and have not purchased Loestrin products: Alaska, Arizona, Arkansas, Colorado, Georgia, Hawaii, Idaho, Iowa, Kentucky, Louisiana, Maine, Montana, Nebraska, New Hampshire, New Mexico, North Dakota, Oklahoma, Oregon, Puerto Rico, Utah, Vermont, Washington, West Virginia, Wisconsin, and Wyoming. The EPPs have not pleaded any claims under Indiana law. (Warner Chilcott Mot. to Dismiss 137, 142 & n.96.)

2015 WL 5458570, at \*13. In Ortiz v. Fibreboard Corp., the United States Supreme Court held that where “class certification issues are . . . ‘logically antecedent’ to Article III concerns, . . . Rule 23 certification should be treated first, ‘mindful that [the Rule’s] requirements must be interpreted in keeping with Article III constraints . . . .’” 527 U.S. 815, 831 (1999) (quoting Amchem Products, Inc. v. Windsor, 521 U.S. 591, 612-13 (1997)). In the wake of Ortiz, “[c]ourts have taken different views about how to evaluate Article III and class standing at the motion to dismiss stage where putative class representatives assert claims arising under the laws of states where they neither reside nor allege to have suffered injury.” Solodyn, 2015 WL 5458570, at \*14.

In Plumbers’ Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp., a securities law action, the First Circuit dismissed defendant-trusts from which the named plaintiffs had not themselves purchased certificates, holding that “[t]o the extent claims exist based on such purchases, they belong to the actual purchasers.” 632 F.3d 762, 770-71 (1st Cir. 2011). However, the Court acknowledged Ortiz and clarified that the holding of Plumbers’ Union was with one “qualification”:

The qualification, on which we reserve judgment, is one where the claims of the named plaintiffs necessarily give them – not just their lawyers – essentially the same incentive to litigate the counterpart claims of the class members because the establishment of the named plaintiffs’ claims necessarily establishes those of other class members.

Id. at 770. Several district courts have used this rationale in antitrust suits to defer ruling on standing issues until the Rule 23 analysis. See, e.g., Solodyn, 2015 WL 5458570, at \*14 (deferring consideration of standing where “[a]ll members of the putative class have a common interest in litigating claims arising from the Defendants’ [alleged conduct]” (quoting Nexium I, 968 F. Supp. 2d at 407); Asacol, 2016 WL 4083333, at \*12 (following Solodyn and other courts in deferring the question to class certification); Nexium I, 968 F. Supp. 2d at 407 (“This Court holds that the requisite ‘identity of issues’ and ‘alignment of incentives’ is present amongst the End-Payors here. All members of the putative class have a common interest in litigating claims arising from the Defendants’ allegedly anticompetitive collusion designed to cause the End-Payors to pay supracompetitive prices across the several states.”); Glass Dimensions, Inc. v. State Street Bank & Trust Co., 285 F.R.D. 169, 175 (D. Mass. 2012); see also In re Relafen Antitrust Litig., 221 F.R.D. 260, 269 (D. Mass. 2004) (certifying class that did not have named plaintiffs from each state because “[t]he more traditional inquiry, which . . . would require class counsel to identify representatives from each state involved in a multistate class action, would render class actions considerably more cumbersome to initiate, and in turn, less effective in overcoming a lack of incentives to prosecute

individual rights and in 'achiev[ing] economies of time, effort, and expense.'" (quoting Amchem, 521 U.S. at 615)).

However, courts in other jurisdictions have noted that "deferring [the] standing determination would 'allow named plaintiffs in a proposed class action, with no injuries in relation to the laws of certain states referenced in their complaint, to embark on lengthy class discovery with respect to injuries in potentially every state in the Union.'" Niaspan, 42 F. Supp. 3d at 758 n.20 (citation omitted) (collecting cases). Defendants cite a number of cases in which courts have dismissed claims because the named plaintiffs did not have individual standing. See, e.g., Aggrenox I, 94 F. Supp. 3d at 251; Niaspan, 42 F. Supp. 3d at 757-58; In re HSBC Bank, USA, N.A., Debit Card Overdraft Fee Litig., 1 F. Supp. 3d 34, 48-49 (E.D.N.Y. 2014); In re Dairy Farmers of Am., Inc. Cheese Antitrust Litig., No. 09-CV-3690, 2013 WL 4506000, at \*8 (N.D. Ill. Aug. 23, 2013)); In re Wellbutrin XL Antitrust Litig., 260 F.R.D. 143, 157-58 (E.D. Pa. 2009).

Although there is authority going both ways on this issue, the growing consensus in the First Circuit, including this Court, is to defer the standing analysis to the class certification stage, so long as the named plaintiffs have "essentially the same incentive to litigate the counterpart claims of the class members because the establishment of the named plaintiffs' claims necessarily establishes those of other class members." Plumbers'

Union, 632 F.3d at 770. Here, the scheme and injury alleged by the EPPs – that Defendants’ anticompetitive exclusion and collusion, from procuring the patent by fraud to mounting an unlawful product hop, caused each named EPP to pay more than it otherwise would have in the form of overcharges – is the same across the country. (See EPP Compl. ¶¶ 331-37.) The EPPs have a collective interest in litigating their claims together to attempt to recover. Moreover, “this is not a case where the Named Plaintiffs are attempting ‘to piggy-back on the injuries of the unnamed class members.’ Rather, each of the Named Plaintiffs asserts a personal injury resulting from Defendants’ allegedly [fraudulent conduct].” In re Grand Theft Auto Video Game Consumer Litig. (No. II), No. 06-MD-1739(SWK)(MHD), 2006 WL 3039993, at \*3 (S.D.N.Y. Oct. 25, 2006) (internal citation omitted). Put another way, Defendants are not challenging the EPPs’ standing to bring their own claims; they are challenging their standing to bring claims on behalf of the class. See id. (“The relevant question, therefore, is not whether the Named Plaintiffs have standing to sue Defendants – they most certainly do – but whether their injuries are sufficiently similar to those of the purported Class to justify the prosecution of a nationwide class action.”). This question would be appropriately, and more efficiently, addressed at the class certification stage. Accordingly, the Court denies without prejudice Warner Chilcott’s Motion to Dismiss with respect

to the EPPs' claims under state law in the twenty-five states and Puerto Rico in which the EPPs have not pleaded that they either reside in or purchased Loestrin 24 products in the state.

4. Whether the EPPs Fail to Plead Their State Law Claims with Particularity

Defendants move to dismiss the EPPs' state law claims for failure to plead with particularity. (Warner Chilcott Mot. to Dismiss 142.) The EPPs' Operative Complaint provides ninety-six pages of factual allegations that serve the basis for their asserted claims, followed by a listing of the state laws under which they claim relief for Claims I through V (alleging monopolization, conspiracy in restraint of trade, and unfair and unconscionable acts or practices under state law). (See EPP Compl. 1-96.) For Claim VI, they set forth the basis for their relief under unjust enrichment in twelve paragraphs "under the laws of all states and jurisdictions within the United States except for Indiana and Ohio." (Id. ¶¶ 380-89.) Claim VI, does not, for example, cite an appellate court case from each jurisdiction setting forth the common law elements of unjust enrichment therein.

Courts are split on this issue. Some courts have dismissed claims for listing state laws without pleading how the elements of each state's law are satisfied. See, e.g., Aggrenox I, 94 F. Supp. 3d at 255-56 (dismissing state law claims where the indirect purchasers "listed claims under very many state laws" but failed



to have "truly pleaded claims under those laws"); Actos, 2015 WL 5610752, at \*28 (dismissing state consumer protection claims where "[p]laintiffs fail to account" for the differences in state consumer protection laws). Other courts, including this Court, have concluded that pleadings similar to the one here are sufficiently specific to place the defendants on notice of the conduct claimed. See, e.g., Sheet Metal Workers Local No. 20 Welfare & Benefit Fund v. CVS Health Corp., 221 F. Supp. 3d 227, 236-37 (D.R.I. 2016); Solodyn, 2015 WL 5458570, at \*14-15 (rejecting the defendants' argument that the plaintiffs had failed to plead "specific facts to satisfy the unique elements of each state's laws or to plead causation as required by state consumer protection and unjust enrichment laws" because the claims incorporated by reference include "many allegations of unfair competition and anticompetitive injury" caused by the defendant's allegedly exclusionary and collusive conduct).

The EPPs' Operative Complaint satisfies the pleading standard under Rule 8(a)(2) of the Federal Rules of Civil Procedure as set forth in Twombly, as they have sufficiently pleaded "'a short and plain statement of the claim showing that the pleader is entitled to relief' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" Twombly, 550 U.S. at 545 (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957); citing Fed. R. Civ. P. 8(a)(2)); see also In re Bayer Corp.

Combination Aspirin Prod. Mktg. & Sales Practices Litig., 701 F. Supp. 2d 356, 378-79 (E.D.N.Y. 2010) ("Plaintiffs have drawn the connection between the statutes and defendant's offending conduct. This is sufficient for defendant and the Court to draw inferences that the elements exist.").

Accordingly, Warner Chilcott's Motion to Dismiss is denied insofar as it alleges that the EPPs have failed to plead their state law claims with particularity. At the class certification stage, the EPPs will need to delve into the specifics of each statute to prove that the class representatives are sufficiently typical; for the moment, their pleading is sufficient.

5. Whether the EPPs Have Failed to State a Claim for Relief under State Law for Antitrust, Consumer Protection, and Unjust Enrichment

With respect to the EPPs' many claims under state law, Defendants assert the following grounds for dismissal:

- EPPs' state antitrust claims (a) seek damages in states that follow the federal Illinois Brick bar against indirect purchasers pursuing such claims, (b) fail to allege primarily intrastate conduct, and/or (c) fail to allege concerted action.
- EPPs' state law consumer protection claims (a) fail to plead a basis for standing, (b) fail to allege consumer deception or reliance as required, and (c) fail to allege primarily intrastate conduct. These claims also fail because the relevant state consumer laws variously (d) do not address antitrust-related conduct, (e) impose pre-pleading or other state-specific requirements that EPPs have

not met, and/or (f) do not permit class action claims or a private right of action.

- EPPs' unjust enrichment claims (a) fail to plead a basis for standing, (b) cannot be used as an end-run against certain states' prohibitions against indirect purchasers proceeding with antitrust damages claims, (c) fail to allege the requisite relationship between EPPs and Defendants as required in certain states, (d) fail to allege a direct benefit conferred by EPPs on Defendants as required in many states, and, finally (e) totally ignore individual state requirements in favor of trying to plead an omnibus federal common law cause of action that does not exist, including that some states do not even recognize unjust enrichment as an independent cause of action.

(Warner Chilcott Mot. to Dismiss 132-33.) Defendants further argue that the EPPs have failed to "satisfy the heightened pleading standard of Rule 9(b) to state a claim under the Florida Deceptive and Unfair Trade Practices Act." (Id. at 143.) Rather than delve into the merits of each of these arguments in relation to each of the states' laws, the Court concludes that it will be more efficient to address these issues at the class certification stage. (It is conceivable, for example, that the Court could deny class certification, which would obviate the need to consider the arguments with respect to some of the states.) Accordingly, Warner Chilcott's Motion to Dismiss with respect to these issues is denied without prejudice to raising them again when the Court addresses class certification.

#### G. Claims against Parent Companies

Plaintiffs have failed to allege any specific facts setting

forth a plausible theory of liability as to parent companies Allergan and Actavis. The full extent of Plaintiffs' allegations are as follows: Watson Pharmaceuticals, Inc. acquired Actavis, Inc. in January 2013, and continued operations under the name Actavis, Inc. (DPP Compl. ¶ 26.) In October 2013, Actavis, Inc. acquired Warner Chilcott plc and continued operations under the name Actavis plc. (Id. ¶ 27.) "As part of Actavis's acquisition of Warner Chilcott . . . Actavis entered into Consent Orders with the FTC that required Actavis to divest four pharmaceutical products including Loestrin 24 and its generic equivalents." (Id. ¶ 245.) "Allergan plc markets branded and generic pharmaceuticals throughout the United States . . . ." (See, e.g., id. ¶ 28.) The EPPs further allege that Actavis "assur[ed] its shareholders and potential investors that Warner Chilcott had embarked on a multifaceted scheme that would successfully protect these drugs from generic competition," as the end of its patent exclusivity approached. (EPP Compl. ¶ 9.)

While the DPPs argue that Allergan plc and Actavis, Inc. are liable because they assumed some or all of the liabilities of Warner Chilcott and Watson, and they are "liable for alleged wrongful actions after the mergers," this is not sufficient to plead liability. (See Mem. in Supp. of DPPs' Obj. to Warner Chilcott & Watson Defs.' Mot. to Dismiss All Claims in All Pls.' May 9, 2016 Compls. 54 n.302, ECF No. 206-2.) The Operative

Complaints contain no specific allegations supporting liability as to the parent companies for alleged wrongdoing after the acquisitions, nor have they provided any support for any other theory under which a parent company would be liable for the actions of its subsidiary under these facts. See Solodyn, 2015 WL 5458570, at \*20 (dismissing parent-company defendant based on allegations that it continued “to adhere to the unlawful agreements’ after the acquisition, including by making payments pursuant to the challenged agreements”). Accordingly, the Warner Chilcott Defendants’ Motion to Dismiss is GRANTED on this ground, and Allergan and Actavis are DISMISSED as Defendants.

H. Lupin’s Request for Limited Discovery

Finally, Lupin requests a period of limited discovery (viz., 60 days of focused discovery on the Ascol and Femcon deals, Lupin’s performance under the agreements, and sales under the agreements to date) to decide what it terms the “threshold issue.” (Lupin Mot. to Dismiss 11-13.) The Court is not persuaded by Lupin’s arguments that its course should proceed differently from the other Defendants, and accordingly denies the request for limited discovery.

IV. Conclusion

For the reasons set forth below, and as previously ordered by this Court on July 21, 2017, the Warner Chilcott Defendants’ Motion to Dismiss (ECF No. 192) is GRANTED with respect to the parent

companies; DENIED WITHOUT PREJUDICE with respect to the End-Payor Plaintiffs' claims under state law in the twenty-five states and Puerto Rico in which they failed to plead that they have either resided or purchased Loestrin 24 products in the state; DENIED WITHOUT PREJUDICE with respect to arguments that the EPPs failed to state a claim for relief under various state laws for antitrust violations, consumer protection violations, and unjust enrichment; and DENIED in all other respects. The Lupin Defendants' Motion to Dismiss (ECF No. 191) is DENIED.

IT IS SO ORDERED.



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William E. Smith  
Chief Judge  
Date: August 8, 2017