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# [***In re Loestrin 24 FE Antitrust Litig.***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5N3V-B9W1-F04F-602Y-00000-00&context=)

United States District Court for the District of Rhode Island

March 15, 2017, Decided

Master File No. 1:13-md-2472-S-PAS

**Reporter**

2017 U.S. Dist. LEXIS 38558 \*; 2017-1 Trade Cas. (CCH) P79,934

IN RE LOESTRIN 24 FE ***ANTITRUST*** LITIGATION; THIS DOCUMENT RELATES TO: ALL ACTIONS

**Prior History:** [*Rochester Drug Co-Operative, Inc. v. Warner Chilcott Co. (In re Loestrin 24 Fe* ***Antitrust*** *Litig.), 814 F.3d 538, 2016 U.S. App. LEXIS 3049 (1st Cir. R.I., Feb. 22, 2016)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5J4W-JVF1-F04K-H07H-00000-00&context=)

**Core Terms**

***Antitrust***, contraceptives, documents, interchangeable, discovery, therapeutically, substitutability, settlement, parties, market power, generic, equivalents, patent, relevancy, products, effects, courts, drugs, relevant market, anticompetitive, brand, terms, rule of reason, economically, competitive, purchasers, patients

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**Judges:** PATRICIA A. SULLIVAN, United States Magistrate Judge.

**Opinion by:** PATRICIA A. SULLIVAN

**Opinion**

**MEMORANDUM AND ORDER**

PATRICIA A. SULLIVAN, United States Magistrate Judge.

In this case, filed in the wake of the Supreme Court's seminal decision in [*FTC v. Actavis, 570 U.S. 136, 133 S. Ct. 2223, 186 L. Ed. 2d 343 (2013)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=), Plaintiffs, who are direct and indirect purchasers of a branded oral contraceptive known as Loestrin 24 Fe ("Loestrin 24"), seek ***antitrust*** damages and injunctive relief based on what they allege was a large and unjustified reverse payment settlement resolving patent litigation, as well as fraud on the Patent and Trademark Office in procuring the patent covering Loestrin 24, improper Orange Book listing, sham litigation, and an unlawful product hop.[[1]](#footnote-0)1 Before the Court for determination is Defendants' motion to compel product market discovery. Defendants seek documents related to the economic substitutability of Loestrin 24 and its AB-rated generic equivalents and ten other therapeutically interchangeable oral contraceptives. ECF No. 244.

**I. Introduction**

Defendants seek what they describe as a targeted set of qualitative documents regarding the pricing, sales and marketing of ten oral contraceptives that they claim[[2]](#footnote-1)2 are therapeutically interchangeable with Loestrin 24. They are: Alesse, Beyaz, Femcon/Ovcon, Nordette, Ortho Cyclen, Ortho Tri Cyclen, Ortho Tri Cyclen Lo, Ortho-Cept/Desogen, Yasmin, and Yaz. Defendants do not seek data sets reflecting Plaintiffs' purchases or sales of these products, conceding that nationwide data sets are more readily available and are sufficient to satisfy their need for market data. Nor do they seek so-called "down-stream" discovery — that is, discovery that would be relevant to the development of the pass-on defense made largely unavailable by [*Illinois Brick Co. v. Illinois, 431 U.S. 720, 97 S. Ct. 2061, 52 L. Ed. 2d 707 (1977)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-9DJ0-003B-S1WY-00000-00&context=), and [*Hanover Shoe, Inc. v. United Machine Corp., 392 U.S. 481, 88 S. Ct. 2224, 20 L. Ed. 2d 1231 (1968)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-FHW0-003B-S04W-00000-00&context=). Instead, their focus is on documents relevant to economic substitutability among Loestrin 24, its AB-rated equivalents, and these therapeutically interchangeable oral contraceptives.

Defendants argue that the documents they seek will allow them to show that Plaintiffs strategized about and/or were able to adjust their marketing, promotions, formularies and insurance plans to permit or encourage the substitution of lower-price**[\*10]** oral contraceptives for Loestrin 24, resulting in robust price competition. They contend that the requests are limited to product marketing and promotional strategies, communications with PBMs about encouraging patients to ask for cheaper alternatives, and formularies, including documents reflecting discussions of formulary tiers or other adjustments for the purpose of pushing consumers to cheaper therapeutically interchangeable oral contraceptives. Supported by two declarations from an economist, Dr. Sumanth Addanki, ECF Nos. 245-3 ¶¶ 6-7; 272-2 ¶ 8,[[3]](#footnote-2)3 Defendants assert that these documents will inform the analysis of economic substitutability for the purpose of defining the relevant product market, which they contend is an essential building block of their defense that the settlements in issue did not run afoul of state or federal ***antitrust*** laws.

Plaintiffs disagree. They ask the Court to deny the motion because the requested documents are totally irrelevant and therefore disproportionately burdensome to produce. Citing Judge Stefan Underhill's thoughtful decision in [*In re Aggrenox* ***Antitrust*** *Litigation, 199 F. Supp. 3d 662 (D. Conn. 2016)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KDV-P4H1-F04C-W0MK-00000-00&context=), they argue that their claim is laser-focused on the market for Loestrin 24 and its AB-rated generic equivalents. They**[\*11]** allege that Defendant Warner's patent gave it market power in that market, that the market power can readily be proven by establishing that Loestrin 24 was sold at a supracompetitive price, which is direct evidence of market power, and that the market power was illegally exercised through large reverse payment settlements with Watson and Lupin for the purpose of delaying generic entry and sustaining Warner's ability to continue to earn monopoly profits, shared with Watson and Lupin under the terms of the settlements.

Relying on the Aggrenox holding that Actavis progeny may be structured by trial courts to proceed in a streamlined and focused fashion, [*id. at 669*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KDV-P4H1-F04C-W0MK-00000-00&context=), Plaintiffs contend that the only questions affecting liability are whether the Loestrin 24 patent created market power and whether Defendants acted wrongfully to extend the patent monopoly beyond its valid life. Therefore, the existence of a broader product market, however competitive it may be, has no bearing on the issues in the case. [*Id. at 667-68*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KDV-P4H1-F04C-W0MK-00000-00&context=). Because the effect of competition with economically substitutable oral contraceptives is already baked into the price of Loestrin 24,[[4]](#footnote-3)4 Defendants do not need the requested discovery. [*Id. at 667*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KDV-P4H1-F04C-W0MK-00000-00&context=). To order it, Plaintiffs**[\*12]** argue, would impose a disproportionate burden contrary to the directive of *Fed. R. Civ. P. 26(b)(1)*.

**II. Law and Analysis**

**A. Relevance**

In Actavis, the Supreme Court focused on the "complexities," holding that "the 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," as well as that "[t]he existence and degree of any anticompetitive consequence may also vary as among industries." [*133 S. Ct. at 2237*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=). Actavis makes clear that reverse payment settlements may amount to the illegal use of market power in the narrow market for the branded drug and its AB-rated generic equivalent. [*Id. at 2227, 2234*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=). However, the Court eschewed the FTC's urging that that it adopt a truncated decisional framework. [*Id. at 2237*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=) (rejecting "quick look" or *per se* approach). Rather, it decreed that, for the present, the traditional rule-of-reason framework should be deployed and directed lower courts to structure the approach to these cases "so as to avoid, on the one hand, the use of ***antitrust*** theories too abbreviated to permit proper analysis, and,**[\*13]** on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question — that of the presence of significant unjustified anticompetitive consequences." [*Id. at 2238*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=). As our Circuit observed, "Actavis left many questions unanswered as to how these cases would be litigated and "le[ft] to the lower courts the structuring of the present rule-of-reason ***antitrust*** litigation." [*In re Loestrin 24 Fe* ***Antitrust*** *Litig., 814 F.3d 538, 545 (1st Cir. 2016)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5J4W-JVF1-F04K-H07H-00000-00&context=) (quoting [*Actavis, 133 S. Ct. at 2238*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=)).

Developed almost a century ago in [*Chicago Board of Trade v. United States, 246 U.S. 231, 38 S. Ct. 242, 62 L. Ed. 683 (1918)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-5YH0-003B-H0VW-00000-00&context=), the rule of reason directs courts to look at an agreement to reduce or exclude competition to determine whether its adverse competitive effects are offset by countervailing procompetitive virtues. [*FTC v. Ind. Fed'n of Dentists, 476 U.S. 447, 459, 106 S. Ct. 2009, 90 L. Ed. 2d 445 (1986)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6V80-0039-N3PM-00000-00&context=). In applying the rule of reason, similar to an analysis under *§ 2* of the Sherman Act, courts should inquire "into market definition and market power . . . to determine whether an arrangement has the potential for genuine adverse effects on competition, [as] 'proof of actual detrimental effects, such as a reduction of output,' can obviate the need for an inquiry into market power, which is but a 'surrogate for detrimental effects.'" [*Id. at 460-61*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6V80-0039-N3PM-00000-00&context=) (quoting 7 P. Areeda, ***Antitrust*** Law ¶ 1511, p. 429 (1986)). In [*In re Nexium (Esomeprazole)* ***Antitrust*** *Litigation, 42 F. Supp. 3d 231 (D. Mass. 2014)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5D2K-NTJ1-F04D-D04Y-00000-00&context=), aff'd, [*842 F.3d 34 (1st Cir. 2016)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5M73-M0F1-F04K-H003-00000-00&context=), the district court**[\*14]** summarized the shifting burdens in a rule of reason/monopolization reverse payment case as follows: first, the plaintiffs must present evidence that the accused brand made a settlement payment to a generic that exceeded anticipated future litigation costs and lacked "any other convincing justification," [*Actavis, 133 S. Ct. at 2237*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=); next, the burden shifts to the defendants to show that the challenged payment was justified by some procompetitive objective; then, the burden shifts back to the plaintiffs to establish, under the rule of reason, that the settlement is nevertheless anticompetitive on balance. [*Nexium, 42 F. Supp. 3d at 262-63*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5D2K-NTJ1-F04D-D04Y-00000-00&context=).

Traditionally, the examination of anticompetitive effects relies on the definition of the relevant product market in which they occur. [*Id. at 263*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5D2K-NTJ1-F04D-D04Y-00000-00&context=) (citing [*Addamax Corp. v. Open Software Found., Inc., 888 F. Supp. 274, 283 (D. Mass. 1995)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3RV4-96W0-001T-50CM-00000-00&context=) ("To state a Sherman Act claim under the rule of reason, [plaintiff] bears the initial burden of establishing that [defendant's] actions have 'an actual adverse effect on competition as a whole in the relevant market.'") (quoting [*Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., Inc., 996 F.2d 537, 543 (2d Cir. 1993)))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-FV00-003B-P4GG-00000-00&context=). That inquiry in turn examines the reasonable economic interchangeability of a set of products, looking not at the similarity of their forms or functions, but rather at "the extent to which purchasers will accept substitute products in instances**[\*15]** of price fluctuation and other changes." [*George R. Whitten, Jr., Inc. v. Paddock Pool Builders, Inc., 508 F.2d 547, 552 (1st Cir. 1974)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-T990-0039-X0VW-00000-00&context=); see [*Bayer Schering Pharma AG v. Sandoz, Inc., 813 F. Supp. 2d 569, 575 (S.D.N.Y. 2011)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:8391-7G41-652J-D3ND-00000-00&context=) (product market limited to two oral contraceptives (Yaz and Yasmin) not plausible in light of interchangeable alternatives; claim of conspiracy in violation of *§ 1* of Sherman Act dismissed).

Plaintiffs contend that the Loestrin 24 molecules (nonethindrone acetate and ethinyl estradiol) constitute the market. They may — or may not — turn out to be right. Consistent with this claim, their complaints each include averments alleging that, to the extent that proof of monopoly power requires defining a relevant product market, that market is limited to Loestrin 24 and its AB-rated equivalents. ECF No. 164 ¶ 303 (also includes Minastrin in market definition); ECF No. 165 ¶ 303; ECF No. 174 ¶ 179; ECF No. 175 ¶ 182. Defendants argue vigorously that this snapshot of the market ignores the economic reality that Loestrin 24's price is disciplined by actual price competition with an array of other oral contraceptives. They seek the documents to allow them to rebut Plaintiffs' averments with evidence that the relevant product market is oral contraceptives that are economically interchangeable with Loestrin 24 and its AB-rated equivalents. Contrary to**[\*16]** the Aggrenox holding that proof of a supracompetitive price and an unduly "large" reverse payment are susceptible of simple proof, they contend that they need the requested discovery to explain the real market dynamic to the fact finder so that their rebuttal showing that the price was competitive and the reverse payment was not "large" can be understood in the context of a highly competitive product market in which many therapeutically interchangeable oral contraceptives compete.

Courts should be wary of conflating the scope of discovery (permitting inquiry regarding what is relevant to both claims and defenses) with what is plausibly alleged in a complaint (ignoring the answer and affirmative defenses), what may be ruled out of the case at summary judgment or what should be excluded from the evidence offered at trial. For example, a court may permit a complaint to proceed past a motion to dismiss by finding plausible a pleading alleging a narrow relevant market limited to the brand and its AB-rated equivalents. E.g., [*In re Nexium (Esomeprazole)* ***Antitrust*** *Litig., 968 F. Supp. 2d 367, 387-88 (D. Mass. 2013)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:59BB-KNF1-F04D-D05Y-00000-00&context=). That does not mean that discovery in such a case must be limited to that narrow market. Compare [*Meijer, Inc. v. Warner Chilcott Holdings, Co., III, Ltd., 245 F.R.D. 26, 31, 33 (D.D.C. 2007)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4PPY-NPR0-TXFP-H2G4-00000-00&context=) (product market discovery regarding Ovcon and potentially substitutable**[\*17]** contraceptives ordered to be provided because broader product market definition raised as defense), with [*Meijer, Inc. v. Barr Pharms., Inc., 572 F. Supp. 2d 38, 62 (D.D.C. 2008)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4TB2-H890-TX4N-G139-00000-00&context=) (jury could find relevant market limited to Ovcon and its AB-rated equivalents). In at least one case, broader product market discovery regarding substitutes resulted in evidence that persuaded the court to reject the single drug market based on robust economic competition. [*Mylan v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421, 436-38 (3d Cir. 2016)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KTJ-FRX1-F04K-K30Y-00000-00&context=) (affirming summary judgment in favor of defendants in Doryx ***antitrust*** case). And, except for Aggrenox, when such discovery has been denied, it was not because the issue of the relevant product market was deemed entirely irrelevant, but rather because the specific documents requested were found to be cumulative of information more easily available from other sources. E.g., [*In re Asacol* ***Antitrust*** *Litig., Civil Action No. 15-12730-DJC, 2017 U.S. Dist. LEXIS 952, \*8-9 (D. Mass. Jan. 4, 2017)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5MJK-CPG1-F04D-D0D4-00000-00&context=) (filed in this case at ECF No. 258-4).

Based on my review of the decisions presented by the parties, apart from Aggrenox, no post-Actavis court has denied a timely motion to compel documents pertaining to product market definition in a reverse payment case on grounds that the entire subject of economically interchangeable substitutes for the brand and its AB-rated equivalents is irrelevant.**[\*18]** See [*In re Asacol* ***Antitrust*** *Litig., 2017 U.S. Dist. LEXIS 952 at \*8-9*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5MJK-CPG1-F04D-D0D4-00000-00&context=) (discovery regarding potentially substitutable products assumed to seek relevant information but denied because not proportional); [*In re Suboxone (Buprenorphine Hydrochloride & Naloxone)* ***Antitrust*** *Litig., No. 13-MD-2445, 2016 U.S. Dist. LEXIS 83499, 2016 WL 3519618, at \*7 (E.D. Pa. June 28, 2016)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5K3Y-X9X1-F04F-43H7-00000-00&context=) (overruling magistrate judge's denial of motion to compel documents to permit defendants to develop record on competition with other market participants; "without the benefit of a fully developed record, rulings regarding the market dynamic in this context would be premature and speculative"); In re Wellbutrin XL ***Antitrust*** Litig., No. 2:08-cv-02431-MAM (E.D. Pa. Mar. 12, 2010) (product market documents relevant to competition with other antidepressants ordered to be produced) (filed in this case at ECF No. 245-2); [*Meijer, Inc., 245 F.R.D. at 30-33*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4PPY-NPR0-TXFP-H2G4-00000-00&context=) (discovery regarding contraceptives interchangeable with Ovcon ordered to be produced).

That leaves Aggrenox. Unsurprisingly, when asked to "let a hundred flowers bloom,"[[5]](#footnote-4)5 in the three years since Actavis was decided, trial courts have tried an array of "structures" to tackle the potentially gargantuan proof problems posed by reverse payment settlement ***antitrust*** litigation. E.g., [*In re Nexium (Esomeprazole)* ***Antitrust*** *Litig., 309 F.R.D. 107, 135 (D. Mass. 2015)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5GJV-KPS1-F04D-D0KV-00000-00&context=), aff'd, [*842 F.3d 34 (1st Cir. 2016)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5M73-M0F1-F04K-H003-00000-00&context=) (one hundred forty-nine page opinion describing trial court's approach**[\*19]** to first post-Actavis reverse payment settlement claim tried to jury); In re Loestrin [*24 Fe* ***Antitrust*** *Litig., 45 F. Supp. 3d 180, 195 (D.R.I. 2014)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5D2P-5SX1-F04F-601K-00000-00&context=) (adopting interpretation that Actavis requires cash consideration, but inviting parties to request interlocutory appeal under *28 U.S.C. § 1292(b)*), vacated, [*814 F.3d 538 (1st Cir. 2016)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5J4W-JVF1-F04K-H07H-00000-00&context=). Perhaps the most creative, "edgy," as the parties before me described it, Aggrenox holds that not just the discovery, but also the evidence to be presented for the duration of the case, should be limited to the branded drug and its AB-rated equivalents. It relies on a sophisticated analysis of the law, as applied in the unique setting of a reverse payment settlement case, finding that there is no need to articulate a relevant market definition when direct evidence of market power is available. [*199 F. Supp. 3d at 669*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KDV-P4H1-F04C-W0MK-00000-00&context=) & n.4 ("The relevant market serves merely as a proxy for market power when direct evidence of market power is unavailable. Where direct evidence of market power is available, however, a plaintiff need not attempt to define the relevant market.") (quoting [*In re Nexium (Esomeprazole)* ***Antitrust*** *Litig., 968 F. Supp. 2d at 388 n.19*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:59BB-KNF1-F04D-D05Y-00000-00&context=)). In recognition that his order was an experiment worthy of early appellate review, Judge Underhill certified it for discretionary appeal pursuant to *28 U.S.C. § 1291(b)*. Aggrenox explains this unusual step, noting that "the economic issues**[\*20]** discussed above are relatively technical, and their application to ***antitrust*** law is not without debate, nor is the caselaw touching on them uniform." [*Id. at 670*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KDV-P4H1-F04C-W0MK-00000-00&context=). The Second Circuit Court of Appeals declined to accept the appeal. [*In re Aggrenox* ***Antitrust*** *Litig., 16-2864, 2017 U.S. App. LEXIS 16456 (2d Cir. Jan. 9, 2017)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PBT-2NY1-F04K-J05G-00000-00&context=).

Aggrenox has a seductively binary elegance — either the price was supracompetitive or it was not; either the settlement was an excessive payment to exclude competition or it was not. Time may prove that Aggrenox lays out the right way to structure reverse payment ***antitrust*** litigation under the Hatch-Waxman Act. If so, its very spareness will render litigation challenging anticompetitive reverse payment settlements manageable, with the salutary effect of deterring illegal arrangements that adversely impact prices of drugs that are critical for the patients, who are the ultimate consumers.

Nevertheless, I decline to take such a leap for a threshold discovery issue, which is all that has been referred to me. See *28 U.S.C. § 636(b)(1)(A)*. My job is not to establish the decisional infrastructure for this case; that task remains with the able District Judge to whom the case is assigned.[[6]](#footnote-5)6 Rather, I am guided by Magistrate Judge Judith Dein,**[\*21]** who wrote at an analogous procedural point in the life cycle of a reverse payment settlement ***antitrust*** case: "the complex issue of the relevant product market is not appropriately decided in the context of the instant motion to compel." [*In re Asacol* ***Antitrust*** *Litigation, 2017 U.S. Dist. LEXIS 952 at \*10*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5MJK-CPG1-F04D-D0D4-00000-00&context=); see [*Meijer, Inc., 245 F.R.D. at 31*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4PPY-NPR0-TXFP-H2G4-00000-00&context=) (magistrate judge declines to determine motion to compel based on what later may be admissible; information about other contraceptives relevant and discoverable). Under the cases interpreting the traditional rule of reason, documents related to the parties' competing versions of the relevant product market are relevant. To the extent that the burden of producing them is not out of proportion to their degree of relevance, they must be produced.

I turn next to the question of proportionality.

**B. Proportionality**

Plaintiffs have agreed to produce documents that contain the terms "Loestrin" and "Minastrin," which may include documents that discuss interchangeability; based on relevancy, they refuse to search for interchangeability documents that name one of the other ten oral contraceptives but omit the terms "Loestrin" and "Minastrin." Defendants point out that, if their hypothetical larger product market is a viable construct, Loestrin**[\*22]** 24 is a bit player; therefore, documents strategizing about economic interchangeability of oral contraceptives are likely to name the other oral contraceptives, which are used by a higher percentage of women, and not to mention Loestrin 24 or Minastrin. Because the parties' meet-and-confer discussions regarding these documents have been premised on Plaintiffs' assertion of the relevancy objection, the parties have yet to roll up their collective sleeves to confer about what search terms, custodians, time frame, locations to be searched or other parameters affecting the burden imposed by the requested discovery render the discovery proportional in light of its relevancy to the issue for which it is sought. Defendants have made clear that everything is up for discussion, including the list of oral contraceptives. They have offered a time frame compromise and are willing to tighten up the list of custodians. They have made plain that they do not seek documents located at individual pharmacies. With all of these details in flux, it is premature for the Court to issue an order mandating specific discovery. Instead, I provide several points of guidance below, and invite the parties to return**[\*23]** to the Court for an informal conference followed by a motion, if their meet and confer is not successful in resolving their differences. See Interim Case Management Order Number 5 (ECF No. 236) ¶ 4.

First, it is axiomatic that Plaintiffs need not produce information that is not in their possession, custody or control; the corollary to the axiom is that a search-term-based query for what is not there is both burdensome and disproportional. See [*Meijer, Inc., 245 F.R.D. at 33*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4PPY-NPR0-TXFP-H2G4-00000-00&context=). Retail Plaintiffs and EPPs argue that some of the requested documents simply do not exist or exist only randomly, such as because an employee may have randomly procured a copy of a publicly available formulary. They point out that it would be disproportionately burdensome to run searches through the files of multiple custodians to seek what not only is a needle in a haystack, but also is remotely relevant, in that the random occurrence of a stray document has little bearing on the theme (economic interchangeability) that justified the search. I agree. In their meet-and-confer conferences, the parties should work on developing boundaries to avoid such a resource-wasting exercise, mindful that the Loestrin 24/Minastrin-focused discovery that Plaintiffs**[\*24]** have already agreed to provide may well reveal clues about the degree to which a search focused only on the other oral contraceptives will turn up documents related to economic substitutability of such drugs with Loestrin 24 and its AB-rated equivalents.

Second, it is not clear whether the parties agree that the ten oral contraceptives that are the subject of this motion are therapeutically interchangeable in that they are prescribed for the same indication and the same patient population. See n.2 *supra*. Therapeutic interchangeability is a threshold issue in that Defendants' relevant request is for documents that strategize about or discuss how therapeutically interchangeable oral contraceptives may be or are economically substitutable for Loestrin 24 and its AB-rated generic equivalents. While Plaintiffs are right that documents focused exclusively on medical analyses of the science underlying the proposition that the ten oral contraceptives are therapeutic substitutes for Loestrin 24 are only remotely relevant, Defendants are right that they need to know about therapeutic substitutability to properly focus their economic substitutability inquiry. This should be resolvable by a meet**[\*25]** and confer. That is, the parties should be able to agree which oral contraceptives to target for product market discovery tailored to the bull's-eye set — documents that reflect ways in which therapeutically interchangeable oral contraceptives are also economically interchangeable in that patients can be steered to the least expensive among an array of therapeutic substitutes. Moreover, therapeutic interchangeability becomes squarely relevant if proof of economic substitutability is to be rebutted by the argument that the products are not therapeutically interchangeable. However, to the extent that therapeutic interchangeability is undisputed, searches that are exclusively focused on the therapeutic effects of the molecules in each of the ten oral contraceptives are disproportional and should be carved out.

Third, DPPs have presented persuasive declarations (ECF No. 263-1 through -4) that describe their offer to search using ingredient hormones as search terms, rather than the names of the ten listed drugs. They contend that this approach should provide Defendants with most, if not all, of what they need and avoid the burden of screening the overinclusive set that would be derived from**[\*26]** use of the search terms Defendants propose. This plaint is compelling, but buried in the relevancy/irrelevancy debate that was the gravamen of the motion. With relevancy clarified, the parties should revisit these issues. Unless Defendants' search terms will yield results that are demonstrably relevant and not cumulative, the Court will not be inclined to order the time-wasting and burdensome searching described in these declarations.

**III. Conclusion**

Plaintiffs' objection based on relevancy is overruled and Defendants' motion to compel product market discovery (ECF No. 244) is granted, without prejudice to Plaintiffs' assertion of disproportionality as described herein.

So ordered.

/s/ Patricia A. Sullivan

PATRICIA A. SULLIVAN

United States Magistrate Judge

March 15, 2017

**End of Document**

1. 1The claims described in the operative complaints may be briefly summarized. Defendant Warner Chilcott ("Warner") is the drug manufacturer that owns the patent covering Loestrin 24. After Defendant Watson Pharmaceuticals, Inc. ("Watson") filed its notice of intent to introduce a generic version of Loestrin 24, Warner sued for patent infringement. The parties settled on condition that Watson delay entry of its generic version; in exchange, Watson got favorable promotional deals, as well as the promise that Warner would not introduce its own generic version of Loestrin 24. Next, Defendant Lupin Pharmaceuticals, Inc. ("Lupin") announced its intent to introduce a generic version of Loestrin 24; again, Warner sued and, again, the parties settled, agreeing that Lupin would delay the introduction of its generic Loestrin 24 in exchange for attorneys' fees and other benefits to Lupin. Warner used the purchased delay to push its Loestrin 24 prescriptions to Minastrin 24 Fe ("Minastrin"), which would not face generic competition for several years. See generally [*In re Loestrin 24 Fe* ***Antitrust*** *Litig., 814 F.3d 538, 541-42 (1st Cir. 2016)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5J4W-JVF1-F04K-H07H-00000-00&context=).**[\*9]**

   Federal ***antitrust*** claims challenging these settlement agreements, as well as Defendant Warner's conduct during the patent prosecution, Warner's patent defense against Watson and Lupin, and a purported product hopping scheme, as violative of ***§§ 1*** and ***2*** of the Sherman Act, ***15 U.S.C. §§ 1***, ***2***, were brought by several large pharmaceutical and grocery companies, which are retail purchasers of Loestrin 24 (CVS Pharmacy, Inc., Rite Aid Corp., Rite Aid Hdqtrs Corp., Walgreen Co., The Kroger Co., Safeway Inc., HEB Grocery Co. L.P., Albertson's LLC) ("Retail Plaintiffs"), as well as by putative classes of Direct Purchaser Plaintiffs ("DPPs"), which comprise companies that purchase drugs, including Loestrin 24, and other products for resale or distribution. Claims seeking injunctive relief under ***§ 2*** of the Sherman Act and damages and injunctive relief under the ***antitrust*** laws and common law of unjust enrichment of various states were brought by putative classes of End Payor Plaintiffs ("EPPs"); they consist of health and welfare benefit plans, which have indirectly purchased, paid for, and reimbursed the purchase of Loestrin 24, and individuals who purchased or paid some or all of the purchase price of Loestrin 24. All of the claims arise in the context of the ***regulatory*** framework established by the Drug Price Competition and Patent Term Restoration Act of 1984, [*Pub.L. No. 98-417, 98 Stat. 1585*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5CD7-HSN0-01XN-S4FK-00000-00&context=), commonly known as the Hatch-Waxman Act. [↑](#footnote-ref-0)
2. 2The Retail Plaintiffs do not dispute that the listed oral contraceptives are therapeutically interchangeable with Loestrin 24. ECF No. 256 at 6. EPPs acknowledge that there are therapeutic alternatives to Loestrin 24, but do not specifically acknowledge that the ten drugs proposed by Defendants are among them. ECF No. 257 at 6. DPPs argue that therapeutic substitutability is irrelevant but also complex if viewed from the perspective of whether patients can switch from one product to another. ECF No. 262 at 15 & n.37. Like EPPs, they do not concede that the ten drugs listed by Defendants are necessarily therapeutically interchangeable, nor do they expressly assert that they are not. [↑](#footnote-ref-1)
3. 3Plaintiffs counter with the declaration of an equally well-credentialed economist, Dr. Meredith Rosenthal, who avers that the documents sought are neither "necessary or sufficient" for a determination of the ***antitrust*** market in issue. ECF No. 263-5 ¶¶ 9, 26. While such an averment may well be pertinent at a later phase of the case (particularly at summary judgment or trial), the only question for a threshold discovery dispute is whether the documents are relevant to Plaintiffs' claims (Dr. Rosenthal says they are not) or to Defendants' defenses (Dr. Addanki says they are). [↑](#footnote-ref-2)
4. 4This proposition derives from the so-called "Cellophane Fallacy," an economic principle positing that proof that substitutes will enter a market in response to a meaningful price increase does not prove that the pre-increase price was set at a competitive level. [*Aggrenox, 199 F. Supp. 3d at 667*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KDV-P4H1-F04C-W0MK-00000-00&context=). Rather, cross-elasticity of demand among certain drugs "may . . . be the product of monopoly power rather than a belief on the part of consumers that the products are good substitutes for one another." [*United States v. Eastman Kodak Co., 63 F.3d 95, 105 (2d Cir. 1992)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-CRH0-001T-D3YX-00000-00&context=). [↑](#footnote-ref-3)
5. 5"Let a hundred flowers bloom and a hundred schools of thought contend." English Oxford Living Dictionaries, [*https://en.oxforddictionaries.com/definition/hundred*](https://en.oxforddictionaries.com/definition/hundred) flowers (viewed on Mar. 15, 2017) (attributed to 1956 speech of Chinese Communist Party Chairman Mao Zedong by [*https://en.wikipedia.org/wiki/Hundred\_Flowers\_Campaign*](https://en.wikipedia.org/wiki/Hundred_Flowers_Campaign) ). [↑](#footnote-ref-4)
6. 6My discovery decision should not be read as a rejection of the analytical framework adopted in Aggrenox. To the contrary, as the case proceeds, the parties remain free to propose to the Court that Aggrenox-based streamlining is appropriate and should be adopted. [↑](#footnote-ref-5)