

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF RHODE ISLAND

IN RE LOESTRIN 24 FE ANTITRUST :  
LITIGATION : MDL No. 2472  
: :  
THIS DOCUMENT RELATES TO: : Master File No. 1:13-md-2472-WES-PAS  
ALL ACTIONS :

**MEMORANDUM AND ORDER**

PATRICIA A. SULLIVAN, United States Magistrate Judge.

Invoking Fed. R. Civ. P. 37, Direct Purchaser Plaintiffs, End Payor Plaintiffs and Retail Plaintiffs (“Plaintiffs”) have moved to compel the Warner and Watson Defendants (“Defendants”)<sup>1</sup> to search for, collect and produce certain documents through August 31, 2017, as well as to search for, collect and produce a more narrow set of documents back to February 1, 2006.<sup>2</sup> ECF No. 328The motion also asks the Court to require Defendants to produce certain policies without any limitation as to time period. Based on the parties’ briefs and the arguments presented at the hearing, the motion is granted in part and denied in part as described below.

Some preliminary observations are in order. First, in the interest of brevity, the Court assumes the reader’s familiarity with prior decisions of this Court and of the First Circuit Court of Appeals in this case, as well as with the parties’ briefs submitted in connection with the motion; thus, with apologies to the uninitiated, the Court has used without elaboration acronyms

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<sup>1</sup> Because of a series of corporate acquisitions, consolidations and name changes, the original Warner and Watson Defendants that are the targets of this motion have evolved into a single entity now known as Allergan, plc. Because the parties refer to them as “Defendants” in their briefs, the same convention is used in this memorandum and order. It must be noted that this appellation does not include defendants Lupin Ltd. and Lupin Pharmaceuticals Inc., which are not targets of this motion to compel.

<sup>2</sup> The motion to compel does not pertain to the production of Defendants’ data, which Plaintiffs need to permit their experts to analyze the longitudinal effects of the challenged conduct on price, sales volume and market share, among various financial trends. Similarly, there is no dispute regarding Defendants’ obligation to produce the documents contained in the regulatory files for the products in issue. The pending dispute is focused only on so-called “speaking” documents, that is, documents such as emails, PowerPoint presentations, reports, charts, summaries, memoranda and other documents that “speak” about events in issue.

and other terminology defined in those sources. Second, this motion is the culmination of a vibrant meet and confer process, facilitated by repeated conferences with the Court; the process was approached by all parties in good faith and was characterized by significant compromises, for which the parties should be commended. As a result of the meet and confer process, what remains in dispute is at the outer edges of relevancy. Third, as the Court noted during the hearing on the motion, Defendants have presented the Court with declarations not only from outside counsel, but also (more importantly) from the in-house paralegal directly involved with the document collection. These persuasively establish that the incremental work to extend the searching, collection and production as sought by Plaintiffs' motion – forward to August 31, 2017, as to twenty-eight Requests; back to February 1, 2006, as to four Requests; and with no time limit as to one Request – would impose a substantial burden. Finally, in considering the parties' arguments, the Court is mindful that “civil discovery rules do not anticipate perpetual production.” In re ATM Fee Antitrust Litig., No. C 04-02676 CRB, 2007 WL 1827635, at \*6 (N.D. Cal. June 25, 2007). When burdensome discovery is focused on events so remote from the period “embraced within the complaint’s narrative” as to render speculative the likelihood of any benefit to offset the expense, Fed. R. Civ. P. 26(b)(1) requires that such discovery should be denied. Inline Packaging, LLC v. Graphic Packaging Int’l, Inc., No. 15-CV-3183, 2016 WL 7042117, at\*6 (D. Minn. July 25, 2016).

One aside: Plaintiffs express fear that a ruling in favor of Defendants will leave them vulnerable to being sandbagged as Defendants will use documents responsive to the subject Requests from the periods which they have not been compelled to search or produce from. This fear is unfounded – as the Court made clear at the hearing, Defendants must live or die (if necessary) on the positions that they have taken. That is, Defendants may not use documents

responsive to the Requests in issue that are not produced because they are from periods as to which Plaintiffs' motion was denied. To illustrate, Plaintiffs seek certain documents for the period between January 9, 2011, and August 31, 2017, related to the January 2009 Warner/Watson Generess deal. The Court has found that the period after January 2011 is remote from the January 2009 formation of the deal and denied Plaintiffs' motion as to these Generess-deal Requests. Having persuaded the Court that relevant documents are extremely unlikely to be turned up by searching focused after January 9, 2011, Defendants may not later support their defense that the Generess deal was not an illegal reverse payment by deploying a document responsive to this set of Requests, which has not been produced because it falls into the period from January 9, 2011 to August 31, 2017.

I. End-Date Disputes – Requests Regarding Alleged Product Hop

Warner Requests 20, 21, 22, 23, 26, 29, 31, 36, 37, 38, 39, 40, 41, 42 and 43 concern Plaintiffs' claim that the July/August 2013 launch of Minastrin 24 and withdrawal of Loestrin 24 from the market constitutes an anticompetitive product hop. Plaintiffs ask the Court to order that the Defendants be ordered to collect and produce responsive speaking documents through August 31, 2017, while Defendants have offered to compromise by searching, collecting and producing through May 31, 2015, for documents<sup>3</sup> related to the Minastrin 24 NDA (Request 20) and through December 31, 2015, for the remainder.

Plaintiffs do not dispute that the charged conduct occurred in the late summer of 2013; however, they argue that the effects<sup>4</sup> of the product hop continue to the present. In pressing the

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<sup>3</sup> It must be noted that the parties have reached agreement with respect to these Requests regarding production of the Minastrin 24 Fe NDA and supplements, as well as of all responsive company regulatory files. As a result, these are not in issue.

<sup>4</sup> With no dispute about the production of the data necessary to measure the effects of the product hop, this argument is focused only on Defendants' analysis and rumination regarding those effects.

motion to compel, they are looking for speaking documents – correspondence and other writings – after the alleged hop, internal and external, that are relevant to understanding the rationale behind the hop, including whether Minastrin 24 was an improvement over Loestrin 24. Defendants’ proposal of May 31, 2015, provides a two year buffer after the FDA approval of Minastrin 24; their proposal of December 31, 2015, provides a nearly three-year buffer for the balance of the Requests in issue. Plaintiffs justify their motion for a more than four-year buffer by pointing to the March 2017 launch of generic Minastrin 24, but do not explain why that 2017 event would trigger the creation of speaking documents relevant to the product hop that occurred four years before. See New York v. Actavis PLC, 787 F.3d 638, 655 (2d Cir. 2015) (product hop analysis focused on time period when product switch occurred); In re Asacol Antitrust Litig., 233 F. Supp. 3d 247, 268 (D. Mass. 2017) (alleged anticompetitive product switch assessed as of time when switch occurred).

While the ripple effects set in motion by anticompetitive conduct may affect a market into infinity, civil discovery regarding that conduct may not be ordered to flow effectively in perpetuity. See In re ATM Fee Antitrust Litig., 2007 WL 1827635, at \*6 (limiting obligation of defendants to supplement production despite length of time case had been pending); In re Microcrystalline Cellulose Antitrust Litig., 221 F.R.D. 428, 430 (E.D. Pa. 2004) (denying plaintiffs’ request for sales data for six years after end of conspiracy; three years of data sufficient to conduct meaningful “before and after” analysis). When the parties cannot agree, the Court must set an end date that targets the challenged conduct, with an adequate buffer before and after to ensure that relevant documents explaining the conduct can be retrieved and produced. In a serious antitrust case like this one, significant and costly discovery is unquestionably proportional, yet consideration of proportionality does not disappear just because

the stakes are high, the issues are important and Defendants are well heeled. See Fed. R. Civ. P. 26(b)(1). Rather, the incremental costs of searching and reviewing documents responsive to search terms must be considered when the requested discovery is so remote from the operative events as to render speculative the conclusion that a search will turn up any relevant material. See In re Microcrystalline Cellulose Antitrust Litig., 221 F.R.D. at 430.

Considering the parties' arguments, including the sample documents provided by Plaintiffs, the Court finds that the periods after May 31, 2015, for material related to the Minastrin 24 NDA and after December 31, 2015, for the balance (as proposed by Defendants) through August 31, 2017, are exceedingly remote from the conduct that renders these Requests relevant. Therefore, non-duplicative relevant material is exceedingly unlikely to be turned up by searching that Defendants have established will impose a not-insubstantial burden. Accordingly, the motion to compel is denied as to these Requests.

## II. End-Date Disputes – Requests Regarding ANDAs and Generic Entry

Warner Requests 89, 90, 91, 92, 93, 94, 95 and 96 and Watson Requests 29, 30, 31, 32, 34, 35, 36, 37, 38, 39 and 40 are focused on the challenged January 2009 Warner/Watson “no-AG” agreement by which Warner agreed to forego the launch of an authorized generic Loestrin 24. They seek documents regarding ANDAs for generic Loestrin 24, market entry of generic Loestrin 24 and Defendants' plans for an authorized generic Loestrin 24. Plaintiffs ask the Court to require that all of these searches be conducted through August 31, 2017. While acknowledging that the Watson ANDA for generic Loestrin 24 was divested to Amneal in September 2013, they argue that Actavis agreed to manufacture generic Loestrin 24 for Amneal for a minimum of two years (and possibly for four years). Plaintiffs point out that the “no-AG” period (January to June 2014) is when responsive documents reflecting discussion of projected

authorized generic entry or market share would likely have been generated. In addition, they argue that relevant speaking documents may have been generated right up to the actual generic launches for Loestrin 24 and Minastrin 24 in 2015 and 2017 respectively.

Defendants ask the Court to limit searching to the end of 2013, except for documents related to marketing of an authorized generic Loestrin 24, as to which they argue that searching should stop at the end of 2015. Defendants argue that these Requests are grounded in the January 2009 “no-AG” agreement and that no further discussion of the competitive significance of it would have occurred after the end of 2013 due a sequence of events culminating in October 2013, specifically the acquisition of Actavis by Watson, of Warner by the survivor of the Actavis/Watson acquisition, and the resulting divestiture by Actavis of generic Loestrin 24 (including all rights under Watson’s ANDA) to Amneal.

At the risk of appearing to “split the baby,” the Court finds that relevant material may be found through June 2014, when the six-month “no-AG” agreement provision ended, particularly in light of Defendants’ continuing financial interest based on the Actavis agreement to manufacture generic Loestrin 24 for Amneal. These events remove from the realm of mere speculation the expectation that searching during this period will turn up documents speaking about the effects and impact of the “no-AG” agreement. However, the Court finds that searches to the present based on the actual generic entries of Loestrin 24 in 2015 and Minastrin 24 in 2017 would be improperly focused on these remote events and not on the relevant issue, which is how these remote events (the future entries of the generics) were viewed at the time of the allegedly improper conduct. In re Tamoxifen Citrate Antitrust Litig., 466 F3d 187, 204 (2d Cir. 2006) (for reverse payment claim, discovery should focus on behavior of defendants as of time of settlement agreement), abrogated on other grounds by F.T.C. v. Actavis, Inc., 570 U.S. 136

(2013); Valley Drug Co. v. Geneva Pharms., 344 F.3d 1294, 1306 (11th Cir. 2003) (for reverse payment claim, “reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into”). Adding a buffer to the end of 2014, the Court orders that the motion pertaining to these Requests is granted to the extent that Defendants must search for, collect and produce responsive documents through December 31, 2014, except for documents related to marketing of an authorized generic Loestrin 24, as to which the Court adopts Defendants’ proposed end date of December 31, 2015. Otherwise, the motion pertaining to these requests is denied.

### III. End-Date Disputes – Requests Regarding Alleged Reverse Payment Agreements

Warner Requests 67, 68, 69, 71 and 72 and Watson Requests 5, 6 and 7 seek documents related to Plaintiffs’ allegations that, in January 2009, Warner and Watson entered into the illegal reverse payment agreements, including the so-called “Generess deal.” These Requests target bulls-eye relevant subject matter, including Defendants’ internal discussion of reasons for the agreements and the value of the consideration received. Plaintiffs also seek documents related to transactions sufficiently similar to the Generess deal as to aid in understanding and valuing it. Pointing out that generic Generess did not enter the market until April 2015 and that Watson continues to derive profits from the sale of Generess through the present, Plaintiffs ask the Court to order searching and collection of such documents through August 31, 2017.

For Watson Requests 5, 6 and 7, Defendants counter that internal discussions of the motivation for and valuation of these arrangements necessarily was limited to the period preceding the decision to proceed with the agreements and for a short time thereafter; such rumination would certainly not continue for eight and a half years after the agreements were finalized. They propose December 31, 2011, as the end date for searches regarding

consideration of the reasons and values associated with these agreements by the Watson Board of Directors. For the remainder, they propose December 31, 2013, which creates a buffer of four years after the agreements were finalized. Similarly, with respect to the Requests narrowly focused on the magnitude of royalties or bids to sell associated with the Generess deal,<sup>5</sup> as well as on documents related to analogous transactions, Defendants argue that relevant and responsive documents would have been generated in the run-up to the deal's execution in January 2009, and for a short time after. They also contend that analogous agreements are relevant only to the extent that they were entered into or considered contemporaneously in similar market conditions. Based on these arguments, they propose an end date of January 9, 2011, which creates a buffer of two years after the Generess deal was finalized.

The Court agrees with Defendants' rationale. Plaintiffs have presented nothing beyond speculation to justify the burden of searching for such documents for the more remote periods. Plaintiffs' motion to compel Defendants to search and collect through August 31, 2017, for documents responsive to these requests is denied.

#### IV. Start-Date Disputes

The parties have resolved almost all disagreements regarding the start date for Defendants' collection of relevant material. Two remain.

First, Warner Request 18 seeks analyses and other documents related to the drafts of the January 2009 agreement concerning Loestrin 24 or its generic, as well as concerning the patent infringement action initiated in July 2006. Plaintiffs ask the Court to require that searches be run back to February 1, 2006, which precedes the filing of the infringement action by several months. Defendants have offered to search back to November 1, 2007, which is almost a year

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<sup>5</sup> Defendants point out that for most of the Requests focused on the Generess deal, including the actual royalty rate, the parties have no dispute regarding Defendants' agreement to search through December 31, 2015.



prior to the exchange of the first draft of a settlement agreement. The other start date dispute pertains to Watson Requests 35, 36 and 37. These Requests are focused on documents related to other pharmaceutical companies and generic Loestrin 24, including any ANDA. Plaintiffs ask that Defendants be required to search back to February 1, 2006, while Defendants have offered back to September 1, 2007.

Plaintiffs argue that the earlier start date is reasonable because the FDA approved the Loestrin 24 NDA in February 2006, and Watson notified Warner of the submission of an ANDA in June 2006. Finding this argument persuasive, the Court holds that searching for responsive documents for the period back to February 1, 2006, is sufficiently justified by these milestones as to offset any burden. Accordingly, the Court grants this aspect of Plaintiffs' motion.

V. Dispute Regarding Timing of Request for Production of Antitrust and Other Compliance Policies

Warner Request 99 asks for all internal policies related to compliance with federal and state antitrust laws, FDA and USHHS regulations, as well as business conduct or ethics standards. With no explanation for why so broad a request would turn up relevant materials, Plaintiff argue that every version of every such policy ever created by any of the entities covered by these requests must be the subject of a search. Defendants have offered to produce for the period January 1, 2009, to December 31, 2013, arguing that this encompasses the time period of the challenged conduct and is all that would be relevant. See Bowers v. NCAA, No. 97-2600 (JBS), 2008 WL 1757929, at \*6 (D.N.J. Feb. 27, 2008) (policies in period immediately following alleged conduct considerably more relevant than those that evolved more than decade later). The Court essentially agrees, with one tweak. Finding that January 2009 draws the loop a bit too tight because that is also the month when Warner and Watson entered into the agreements in issue, and for the reasons stated during the hearing, Defendants are ordered to search for, collect

and produce documents responsive to Warner Request 99 for the time period beginning January 1, 2008, through December 31, 2013.

VI. Conclusion

Plaintiffs' motion to compel the Warner and Watson Defendants to collect and produce certain documents through August 31, 2017, (ECF No. 328) is granted in part and denied in part as described herein.

So ordered.

/s/ Patricia A. Sullivan  
PATRICIA A. SULLIVAN  
United States Magistrate Judge  
November 29, 2017