IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: ANDROGEL ANTITRUST LITIGATION (NO. II)	MDL DOCKET NO. 2084 ALL CASES 1:09-MD-2084-TWT
FEDERAL TRADE COMMISSION, Plaintiff, v. ACTAVIS, INC., et al., Defendants.	CIVIL ACTION FILE NO. 1:09-CV-955-TWT

OPINION AND ORDER

The Federal Trade Commission brought this antitrust action against the Defendants Solvay Pharmaceuticals, Inc., Watson Pharmaceuticals, Inc., Paddock Laboratories, Inc., and Par Pharmaceutical Companies, Inc. The FTC claims that the Defendants, in underlying patent lawsuits, entered into unlawful, anti-competitive "reverse-payment settlement agreements." Both prior to and after the filing of this suit, the FTC produced a number of general studies concerning patent lawsuits and settlement agreements between brand-name and generic drug manufacturers. Although the studies themselves are public, certain information underlying the studies is not.

The Defendants' Motion asks the Court to decide whether the Defendants may obtain this underlying information through discovery. The Court concludes that they may not. Accordingly, the Defendants' Motion to Compel [Doc. 333] is DENIED.

I. Background

The facts of this case have already been laid out in detail on multiple occasions.[1] Thus, the Court will provide only a brief summary. Besins Healthcare, S.A. – a Belgian pharmaceutical company – developed the formulation for a testosterone replacement drug called AndroGel.[2] In August of 1995, the Defendant Solvay Pharmaceuticals, Inc. licensed, from Besins, the U.S. rights to the AndroGel formula.[3] Then, in August of 2000, Solvay and Besins applied for a U.S. patent relating to AndroGel,[4] and a patent was issued on January 7, 2003.[5]

In May of 2003, the Defendants Watson Pharmaceuticals, Inc. and Paddock Laboratories, Inc. each filed an application with the Food and Drug Administration

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[1] See, e.g., In re AndroGel Antitrust Litig. (No. II), 888 F. Supp. 2d 1336 (N.D. Ga. 2012); F.T.C. v. Watson Pharm., Inc., 677 F.3d 1298 (11th Cir. 2012) rev'd sub nom. F.T.C. v. Actavis, Inc., 133 S. Ct. 2223 (2013).

[2] Second Am. Compl. ¶¶ 1, 32.

[3] Second Am. Compl. ¶ 32.

[4] Second Am. Compl. ¶ 39.

[5] Second Am. Compl. ¶ 42.

to market a generic version of AndroGel.[6] The Defendant Par Pharmaceutical Companies, Inc. reached a deal with Paddock in which "Par agreed to share litigation costs with Paddock, market Paddock's generic [alternative to AndroGel] following launch, and share in the resulting profits."[7] In August of 2003, Solvay and Besins each filed a patent infringement lawsuit against Watson and Paddock.[8]

In late January of 2006, Watson received final FDA approval for its generic version of AndroGel.[9] At this point, both Watson and Par/Paddock started preparing to launch their respective AndroGel generics.[10] This continued until Solvay, Watson, and Par reached settlement agreements in the patent suits whereby Watson and Par agreed to delay the market entry date of their AndroGel generics until August of 2015.[11] In return, Watson received roughly $19 million during the first year of the agreement, "rising to over $30 million annually by the end of the deal."[12] As part of

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6 Second Am. Compl. ¶ 44.

7 Second Am. Compl. ¶ 46.

8 Second Am. Compl. ¶ 47.

9 Second Am. Compl. ¶ 52.

10 Second Am. Compl. ¶ 55.

11 Second Am. Compl. ¶ 65.

12 Second Am. Compl. ¶ 66.

its deal with Solvay, Watson agreed to promote AndroGel.[13] Par – which negotiated with Solvay on behalf of Paddock – reached an agreement with Solvay whereby "Par would co-promote AndroGel to doctors and receive $10 million annually, and Paddock would serve as a back-up manufacturer for AndroGel and receive $2 million annually."[14]

The FTC then brought this lawsuit. It claims that the settlement agreements were a means by which Solvay, using its monopoly profits, bought off its competition – all to the detriment of the consumers. According to the FTC, if the patent infringement suits had proceeded, Watson and Par/Paddock likely would have prevailed, and their AndroGel generics would have hit the market well before the expiration of the AndroGel patent. Had this occurred, consumers would have been able to purchase the AndroGel generics at a price far below that of the brand-name AndroGel product. According to the FTC, Solvay conducted an analysis where it determined that, given the value of its AndroGel monopoly, it was economically profitable to simply pay Watson and Par/Paddock to settle the lawsuits and delay the entry date for their Androgel generics.

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[13] Second Am. Compl. ¶ 66.

[14] Second Am. Compl. ¶ 74.

The Motion to Compel currently before the Court concerns certain studies produced and published by the FTC relating to reverse payments in patent infringement settlements. In particular, the FTC has conducted a number of studies concerning patent lawsuits and settlements involving brand name and generic pharmaceutical manufacturers. At least two of these studies were referenced in the FTC's Second Amended Complaint. First, the FTC referred to a "study of all patent litigation initiated between 1992 and 2000 between brand-name drug manufacturers and . . . generic applicants" which indicated that "when cases were litigated to a decision on the merits, the generics prevailed in cases involving 73 percent of the challenged drug products."[15] In addition, to show that reverse-payment settlements are not an organic part of pharmaceutical patent litigation, the FTC referred to another study which stated that "in fiscal year 2004, following FTC enforcement actions challenging exclusion payments, 14 pharmaceutical patent settlements were filed with the FTC . . . and none involved an exclusion payment."[16]

In discovery, the Defendants requested the FTC studies on which the FTC planned to rely during the litigation, as well as the "drafts, underlying data, notes or communications" relating to these studies (the "underlying information"). In response,

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[15] Second Am. Compl. ¶ 30.

[16] Second Am. Compl. ¶ 101.

the FTC provided a list of twenty-seven studies. However, the FTC did not produce any non-public information underlying the studies. The Defendants, dissatisfied with the FTC's response, eventually filed this Motion to Compel.

In their respective Briefs, the parties disagree on the role that these studies – and the underlying information – will play in this litigation. According to the FTC, these studies will be tangentially related to its claims – if at all. It points out that the studies were initially used to resolve a purely legal issue: the applicable legal standard for antitrust claims arising from reverse payment settlements. Additionally, the FTC contends that its experts will be familiar with the relevant literature base, which will include its studies. Thus, these studies *may* form a part of the experts' background knowledge which they may draw from in forming their opinions. However, the FTC has stated that its experts will not be given the information on which the studies are based. Furthermore, the FTC has indicated that it will not refer to the studies or the underlying information to establish any element of its specific claims. The Defendants, however, claim that the FTC is downplaying the significance of these studies. In addition to pointing out that the studies made an appearance in the FTC's Second Amended Complaint, the Defendants argue that the FTC's refusal to forego reliance on them suggests that even the FTC acknowledges their relevance. And if the studies are relevant, the Defendants argue, then they will need the information upon

which the studies are based in order to test and rebut them. The Court must resolve two questions. First, is the non-public information underlying the FTC studies at issue "relevant" to any claim or defense? Second, if the information is relevant, do the burdens of producing the requested information outweigh any benefit the information may provide?

II. Discussion

A. Relevance

The Defendants argue that they are entitled to the requested information under Federal Rule of Civil Procedure 26(b)(1). Under this Rule, parties "may obtain discovery regarding any nonprivileged matter that is *relevant to any party's claim or defense*."[17] In assessing relevance, the Court must "focus on the specific claim or defense alleged in the pleadings."[18] The "party seeking the discovery has the burden of showing that the requested material is relevant."[19]

Here, the Defendants have failed to establish that the information underlying the FTC studies at issue is relevant to the specific claims in this case. This information concerns *other* lawsuits and *other* settlement agreements between *other* parties.

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[17] Fed. R. Civ. P. 26(b)(1) (emphasis added).

[18] System Fuels, Inc. v. United States, 73 Fed. Cl. 206, 215 (2006) (internal quotation marks omitted) (emphasis added).

[19] Carnes v. Crete Carrier Corp., 244 F.R.D. 694, 696 (N.D. Ga. 2007).

Indeed, the Defendants provide no plausible scenario for how this information could establish the "presence of significant unjustified anticompetitive consequences"[20] to the Defendants' settlement agreements.[21] To be sure, in another case, the Defendants suggested the opposite. In FTC v. Cephalon, Inc.,[22] – before the Eastern District of Pennsylvania – the Defendants and thirty-three other pharmaceutical companies intervened and sought a protective order when Cephalon filed a similar motion to compel.[23] The Defendants argued:

> The materials at issue here . . . have nothing to do with the . . . agreements, or the patents or product markets at issue here. The only reason these materials are requested by Cephalon is that the FTC and private plaintiffs apparently intend to refer to certain conclusions from the FTC Studies, which in turn were based (at least in part) on the [the intervenors'] confidential materials.
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> The FTC's general views about patent settlements and patent litigation in the pharmaceutical industry, as expressed in the studies, have no

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[20] F.T.C. v. Actavis, Inc., 133 S. Ct. 2223, 2238 (2013).

[21] At oral argument, the Defendants attempted to provide an example. They referenced an FTC study which indicates that settlement agreements that provide for compensation to the generic manufacturer prohibit generic entry for roughly seventeen months longer than agreements that do not provide compensation. The Defendants hypothesized that the FTC could use this as evidence to show that the settlement agreements in this case resulted in a delay of generic entry. But the FTC has explicitly said, multiple times, that it will not use the studies in this manner. See, e.g., Pl.'s Resp. Br., at 1, 12.

[22] No. 2:08-cv-2141, 2015 WL 1724597 (E.D. Pa. April 15, 2015).

[23] Pl.'s Resp. Br., Ex. 2.

> relevance to any issue in this litigation. The FTC's studies do not tend to show that the specific . . . agreements at issue here are unlawful. Nor do they help prove the likely outcome of Cephalon's patent claims or that [the generic] would have entered the market sooner absent the agreements. Nor do they address the specific agreements at issue in this litigation or the specific competitive issues raised by these agreements.[24]

Nevertheless, to support their position here, the Defendants make multiple arguments. First, the Defendants point out that at least two studies were cited in the FTC's Second Amended Complaint.[25] But this alone does not mean that the studies, or the underlying information, are relevant to the specific claims here. A review of the two cited paragraphs demonstrates this point. The Defendants first cite to paragraph 30:

> There are many . . . examples of successful patent challenges by generic drug companies. Indeed, empirical studies have shown that when pharmaceutical patent infringement claims are tested in the courts, the alleged infringer prevails in the majority of cases. An analysis of Federal Circuit decisions from 2002 through 2004 in which the court made a final ruling on the merits of a pharmaceutical patent claim (validity, infringement, or enforceability) found that the alleged infringers had a success rate of 70 percent. An FTC study of all patent litigation initiated between 1992 and 2000 between brand-name drug manufacturers and Paragraph IV generic applicants found similar results: when cases were litigated to a decision on the merits, the generics prevailed in cases involving 73 percent of the challenged drug products.[26]

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[24] Pl.'s Resp. Br., Ex. 5 at 14-15.

[25] Defs.' Mot. to Compel, at 9.

[26] Second Am. Compl. ¶ 30.

This paragraph simply provides general background information concerning the success rate of challenges brought by generic manufacturers against the brand-name manufacturers' patents. Nothing in it speaks to the specific facts of this case. The Defendants also cite to paragraph 101:

> Exclusion payments are not a natural by-product of incentives created by the Hatch-Waxman Act. Rather, pharmaceutical patent litigation can be, and often is, resolved without exclusion payments from branded companies to generic companies. For instance, in fiscal year 2004, following FTC enforcement actions challenging exclusion payments, 14 pharmaceutical patent settlements were filed with the FTC under the Medicare Modernization Act and none involved an exclusion payment.[27]

Again, this paragraph says nothing about the settlement agreements at issue here. As noted earlier, the purpose of this paragraph was simply to demonstrate that reverse payment settlements are not a practical necessity in pharmaceutical patent litigation.

The Defendants then argue that the underlying information is relevant because the FTC's experts may rely on its studies.[28] This argument also fails. To begin, it is currently unclear whether and how the experts will utilize these studies in forming their opinions. In addition, it is equally unclear how expert reliance upon these *general* studies may render them relevant to the specific claims at issue here. True, the experts may be familiar with the FTC studies, and so those studies may form part of

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[27] Second Am. Compl. ¶ 101.

[28] Defs.' Mot. to Compel, at 9.

the backdrop against which the experts perform their analysis. But such indirect reliance cannot be enough to render the studies "relevant," as that term is used in Fed. R. Civ. P. 26(b)(1). If it were enough, then *all* literature which may have colored an experts' opinion on a matter would *ipso facto* be relevant.

The Defendants also assert that the underlying information must be relevant because the FTC refuses to forego reliance on the studies at issue.[29] According to the Defendants, this suggests that even the FTC finds the underlying information to be relevant. This observation, however, does not constitute an affirmative showing that the information is relevant. Additionally, although the FTC refused to forego reliance on the studies altogether, it has stated that neither the studies nor the underlying information will be used as evidence to establish the elements of its claims.[30]

Finally, the Defendants appeal to the policies behind our broad discovery rules. They point out that discovery is meant to facilitate the search for truth, and that allowing discovery of the requested documents would result in a more thorough

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[29] Defs.' Mot. to Compel, at 9.

[30] To be clear, the FTC refused to forego reliance on the studies because its experts may refer to them before analyzing the facts of this case. But the FTC certainly did not concede that the studies, and the underlying information, are *relevant* to any claim or defense in this litigation.

analysis, and thus a more just resolution of the issues. However, although the discovery rules are broad, they are not limitless. As the U.S. Supreme Court stated:

> [D]iscovery rules are to be accorded a broad and liberal treatment to effect their purpose of adequately informing the litigants in civil trials. . . . But the discovery provisions, like all of the Federal Rules of Civil Procedure, are subject to the injunction of Rule 1 that they "be construed to secure the just, speedy, and inexpensive determination of every action." . . . To this end, the requirement of Rule 26(b)(1) that the material sought in discovery be "relevant" should be firmly applied . . . With this authority at hand, judges should not hesitate to exercise appropriate control over the discovery process.[31]

The Defendants have failed to satisfy their burden of showing that the information underlying the twenty-seven FTC studies at issue is relevant to the specific claims in this action.

B. Burdens of Production

The FTC argues that, even if the underlying information is relevant, the Court should limit its discovery under Federal Rule of Civil Procedure 26(b)(2)(C). Under this rule, "the court must limit the frequency or extent of discovery otherwise allowed by [the Federal Rules of Civil Procedure] . . . if it determines that . . . the burden or expense of the proposed discovery outweighs its likely benefit, considering the needs of the case . . . the importance of the issues at stake in the action, and the importance

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[31] Herbert v. Lando, 441 U.S. 153, 177 (1979).

of the discovery in resolving the issues."[32] When determining whether to limit discovery, "a district court is allowed a range of choice."[33]

Here, a significant burden would be placed on the FTC if it had to comply with the Defendants' discovery requests. For example, the studies deal with settlement agreements that pharmaceutical companies were required to file with the FTC under the Medicare Modernization Act ("MMA"). As of the end of fiscal year 2013, nearly *eight hundred* final brand-generic settlement agreements had been filed with the FTC.[34] The confidentiality of these submissions, as well as the information contained therein, is protected by both statute and regulation.[35] Thus, in order to comply with the Defendants' request, the FTC would have to redact an extraordinary number of documents. And even more, the Defendants want the FTC to justify each redaction by providing a statement "(1) identifying the type of information that it has withheld and the legal basis for the FTC's position that this information is protected by statute, and (2) explaining why the redactions will not deprive Defendants of a fair opportunity to

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[32] Fed. R. Civ. P. 26(b)(2)(C).

[33] Smith v. BP Am., Inc., 522 Fed. Appx. 859, 863 (11th Cir. 2013).

[34] See Pl.'s Resp. Br., Ex. 12.

[35] See 15 U.S.C. § 57b-2(c)(1); 16 C.F.R. § 4.10.

rebut the studies."[36] The parties may disagree as to whether certain excluded information is truly "confidential," or whether the redaction deprives the Defendants of a "fair opportunity to rebut the studies," and so the Court may become entangled in a series of further discovery disputes.[37] This burden outweighs any minimal benefit to be gained from disclosure. At this point, it is unclear whether the FTC's experts will use the studies, and even more unclear *how* they would use them. The Court is reluctant to place a significant burden on the FTC in order to ensure the production of information whose relevance to this litigation is questionable, at best.

III. Conclusion

For these reasons, the Court DENIES the Defendants' Motion to Compel [Doc. 333].

SO ORDERED, this 11 day of May, 2015.

/s/Thomas W. Thrash
THOMAS W. THRASH, JR.
United States District Judge

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[36] [Doc. 336].

[37] [Doc. 336] ("The parties shall in good faith meet and confer in an attempt to resolve the dispute; however, if the parties are unable to resolve the dispute, Defendants may apply to the Court for further relief.").