

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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UNITED STATES OF AMERICA, EX REL.  
YOASH GOHIL

CIVIL ACTION NO. 02-2964 (LFS)

Plaintiff/Relator

v.

SANOFI U.S. SERVICES, INC. et al.,

Defendants.

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**PLAINTIFF/RELATOR YOASH GOHIL'S MOTION TO COMPEL DISCOVERY**

Plaintiff/Relator Yoash Gohil, by and through his undersigned counsel, respectfully moves the Court for an Order compelling Defendants (also referred to collectively as "Aventis") to produce certain documents, and prohibiting Aventis from withholding documents and testimony from Plaintiff on the basis that the documents and testimony pertain to drugs other than Taxotere in connection with these requests. In support of its motion, Plaintiff states as follows:

1. In its Answer to Relator's First Requests for Admission,<sup>1</sup> Aventis took the position that:

- a. it had no corporate policy, strategy, or program to direct sales representatives to market Taxotere off-label;
- b. it was not aware of any collective effort by the sales force to detail Taxotere off-label and it was not possible to know the actions of every Taxotere sales representative; and
- c. with respect to tracking "return on investment" for marketing expenses, it was not possible to know the actions of every sales representative, and it is not aware of any

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<sup>1</sup> Defendants' Responses to Relator's First Request for Admissions, dated October 25, 2016, Answers 1-38 and 64.

collective effort by the sales force to consider “return on investment” for marketing expenditures.<sup>2</sup>

2. Aventis also produced corporate policies that prohibited off-label marketing and providing things of value to healthcare providers to induce prescriptions.

3. To rebut these factual defenses, and prove that Aventis used an unpublished corporate policy and training program designed to instruct and educate the sales force to violate the FDA marketing laws (See TAC-134 ¶¶ 94-100), on January 6, 2017, Plaintiff served certain narrowly tailored requests in a Third Request for Production of Documents on Defendants consistent with the Court’s September 29, 2016 Crime-Fraud Order (D.E. 212).

4. These document requests at issue require:

Request No. 9: All documents and data showing [Aventis] management’s knowledge of the off-label marketing of Nasacort, including, but not limited to, complaints or reports of off-label marketing, investigations of complaints or reports of off-label marketing, audits of off-label marketing, compliance investigations of off-label marketing, and physician surveys or reports.

Request No. 10: All documents and data showing [Aventis] management’s knowledge of the off-label marketing of Lovenox, including, but not limited to, complaints or reports of off-label marketing, investigations of complaints or reports of off-label marketing, audits of off-label marketing, compliance investigations of off-label marketing, and physician surveys or reports.

Request No. 13: All documents related to any corporate compliance plan or program.

Request No. 14: All documents concerning Aventis’s compliance work plans, action plans, monitoring plans, or any other plan concerning compliance with laws or regulations.

Request No. 16: All documents concerning complaints of any Aventis employee made in connection with claims that Aventis was not complying with laws or regulations concerning the marketing and selling of any drug, including, but not limited to, Laurie Babb, Jane Chin, and Michael Ward.

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<sup>2</sup> Aventis maintains this position despite production of training documents directing sales representatives to use weekly prescription tracking documents to determine return on investment on various types of marketing programs, including advisory board meetings, roundtable meetings, and speaker programs.

Request No. 18: All documents concerning any investigations, audits, or reviews conducted by Aventis into any complaints of Aventis employees made in connection with claims that Aventis was not complying with laws or regulations, including, but not limited to, Laurie Babb, Jane Chin, and Michael Ward.<sup>3</sup>

5. On or about February 6, 2017, Defendants objected to these requests, asserting that information related to any product other than Taxotere is outside the scope of permissible discovery. With respect to Requests 13, 14, 16, and 18, Defendants have agreed to produce certain responsive documents, but will not procure compliance documents related to drugs other than Taxotere.

6. Aventis's objection is improper. In his Crime-Fraud Motion (D.E. 165-66 and 177), despite the official corporate policies, Relator presented extensive evidence of corporate goals to promote Taxotere and other drugs off-label; the use of corporate-wide kickbacks; systematic destruction of corporate records directed by the legal department to conceal off-label promotion and kickbacks, as well as obstruction of FDA inquiries. Relator therefore opposed Defendants motion to return documents and sought permission to use specific evidence obtained from a former employee relating to three drugs, Lovenox, Nasacort, and Taxotere, from the 1996-97 time frame in discovery. Indeed, in its response Aventis conceded that its predecessor, RPR Advanced Therapeutics Group, marketed both Taxotere and Lovenox. (D.E. 170-1 at 3, ¶ 12). Based on this and other evidence of off-label marketing and kickback payments, the Court found that such "documents offer evidence that the defendants violated" the FDCA, and that "the directives to market Nasacort, Lovenox, and Taxotere may have come from the same management." Crime-Fraud Order, (9/29/16 – D.E. 212 at 2 n.l.)<sup>4</sup> The Court held that the

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<sup>3</sup> In its Answers to Interrogatories, Aventis stated that these individuals made complaints about off-label marketing of Taxotere to management.

<sup>4</sup> Accordingly, the Court denied Aventis' cross-motion to compel the return of the Decembrino documents. *Id.*

documents related to Nasacort and Lovenox, were discoverable, as “relevant to the defendants’ state of mind, motive, corporate intent, and/or reckless disregard for the truth or falsity of claims related to the plaintiff’s action.” *Id.* See also *In re Pradaxa*, 2013 U.S. Dist. LEXIS 7979, at \*15 (S.D. Ill. Jan. 18, 2013) (“The fact that the [former] *qui tam* action involved drugs other than Pradaxa does not make the information irrelevant for purposes of discovery. It is entirely possible that the marketing policies and strategies at issue in the *qui tam* action extended to BIPI’s marketing of Pradaxa. Thus, the plaintiffs’ inquiry into those marketing practices and the individuals involved in those marketing practices appears to be reasonably calculated to lead to discovery of admissible evidence and is an appropriate subject of discovery.”)

7. The narrow categories of documents sought are relevant to the Defendants’ corporate intent as they are probative of a continuing informal corporate plan to promote multiple drugs off label and pay kickbacks even after 1997,<sup>5</sup> and establish the lack of effective compliance mechanisms that would have ensured that Aventis did “know the actions of every sales representative.”

8. On March 16, 2017, Plaintiff explained its position to Aventis and requested that these documents be produced.

9. Defendants responded on March 23, 2016 and took the position that the Crime-Fraud Order (D.E. 212) applied only to “a very limited set of documents pertaining to statements allegedly made by Elaine Decembrino.”

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<sup>5</sup> The evidence submitted by the Relator in the Crime Fraud Motion evidences that the nationwide off-label marketing and kickback scheme relating to Lovenox continued after 1997, specifically from 2000 to 2004 according to a *qui tam* complaint of two former Lovenox sales representatives. D.E. 177 at 3. In a related case, the District Court in the Northern District of Illinois found that the Aventis area manager knew and encouraged off-label marketing and misuse of company expense accounts to conceal kickback payments in connection with Lovenox. *Id.*

10. Defendants' position is unduly narrow, as there is no indication in the Crime-Fraud Order that the Court's relevancy determination is limited only to documents obtained by Ms. Decembrino.

11. For the foregoing reasons, Plaintiff's Requests 9, 10, 13, 14, 16, and 18 are all within the scope of permissible discovery and Defendants should be required to produce all responsive documents in their possession, regardless of whether those documents pertain to Taxotere or other drugs.

12. Further, for purposes of all future discovery conducted in this matter, Aventis should be prohibited from withholding any documents or testimony from Plaintiff on the basis that the documents or testimony pertain to drugs other than Taxotere in connection with these requests.

13. Pursuant to Local Rule 26.1(f), the parties have met and conferred, but are unable to resolve this discovery dispute. Plaintiff respectfully requests the Court's intervention.

Respectfully submitted,

*/s/ Stephen M. Orlofsky*

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Dated: April 5, 2017

**CERTIFICATE OF SERVICE**

I, STEPHEN M. ORLOFSKY, hereby certify that on April 5, 2017, I served via ECF the foregoing Plaintiff/Relator's Motion to Compel Discovery upon the following counsel of record:

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