UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

LESLEY KELLEY as Personal Representative of the Estate of John H. Kelley, Jr.,

Plaintiff,

-vs- Case No. 2:09-cv-351-FtM-99SPC

JOHNSON & JOHNSON COMPANY a New Jersey corporation for profit; JANSSEN PHARMACUTICA, INC. a New Jersey corporation for profit; ALZA CORPORATION a Delaware corporation for profit,

Defendants.

ORDER

This matter comes before the Court on the Plaintiff, Leslie Kelley's Motion to Compel Better Responses to the Plaintiff's First Request for Production and First Interrogatories (Doc. #36) filed on May 12, 2010, and the Plaintiff, Leslie Kelley's Motion for a Hearing on the Motion to Compel (Doc. # 37) filed on May 12, 2010. The Defendant filed its Response in Opposition to the Motion to Compel (Doc. # 28) on May 26, 2010. The Defendant joined in the Motion for a Hearing (Doc. # 39) on May 26, 2010. The Motions are now ripe for review.

The Federal Rules state that, "[t]he party upon whom the request [for production] is served shall serve a written response within 30 days after the service of the request." Fed. R. Civ. P. 34(b). Likewise a party upon whom interrogatories have been served has thirty days to respond either by filing answers or objections to the propounded interrogatories. Fed. R. Civ. P. 33(b). If the serving party does not receive a response to their interrogatories and request for production the serving party may request an order compelling disclosure. Fed. R. Civ. P. 37(a). Whether or not to grant the order

to compel is at the discretion of the trial court. Commercial Union Insurance Co. v. Westrope, 730 F.2d 729, 731 (11th Cir. 1984). The Plaintiff moves the Court to Compel requests for production numbers 1, 2, 7, 8, 14, and 15.

The Plaintiff moves the Court for better responses to requests for production numbers 1 and 2. Requests for production numbers 1 and 2 request the Defendant to produce all trial and deposition transcripts, including exhibits, from any pending or previously litigated cases involving the Sandoz patch or Duragesic. Request number 1 asks for:

> [a]ny and all documents produced by ALZA in any other pending or settled litigation where the plaintiff alleged personal injury or death resulting from use of the Sandoz patch and/or any other fentanyl pain patch manufactured, marketed, sold or distributed by ALZA, including copies of all interrogatories and responses and supplemental requests and responses.

Request number 2 asks for:

> Any and all trial or deposition transcripts, including exhibits, in any other pending or settled litigation where the plaintiff alleged personal injury or death resulting from use of the Sandoz patch and/or any other fentanyl pain patch manufactured, marketed, sold or distributed by ALZA.

After discussions with the Plaintiff, the Defendant has agreed to produce approximately two and a half million pages of documents that are responsive to request for production numbers 1 and 2. However, the Plaintiff states the information is insufficient because it does not relate to the past cases.

The Defendant withheld case specific information regarding individual plaintiffs' records and depositions arguing that the case specific materials are not relevant to this action and that the request are not specific nor do they describe with reasonable particularity each item or category of items to

be inspected. The Defendant also states that the discovery of individual plaintiffs' records violates the protective orders issued in those respective cases.

While some information from past cases may be relevant to the Plaintiff's negligence claims, the names and personal information from the previous plaintiffs that are confidential based upon prior court orders are not subject to being compelled in this particular action. Merely because a document was listed on a party's exhibit list does not mean the document was used in court. Typically an exhibit lists will contain all of the evidence the party has in its possession but that does not necessarily mean the documents will be or were used at trial. Thus, many of the documents and materials requested by request for production numbers 1 and 2 are still protected by the respective protective orders. The Plaintiff does not delineate between protected documents and documents that are not protected. Without more specifics the requests are simply too overbroad for the Court to compel the production.

Moreover, the Defendant has agreed to the production of an additional two and a half million pages of documents that have yet to be reviewed. Much of the requested information may already be produced in that additional production. Therefore, the Motion to Compel requests for production numbers 1 and 2 is due to be denied.

Request for production number 7 seeks:

> [a]ny and all documents which detail ALZA's standard operating procedures and/or protocols for the handling of complaints, adverse reactions or complications from healthcare providers, regulatory bodies, and/or consumers regarding the Sandoz patch and/or any other fentanyl pain patch manufactured, marketed, sold or distributed by ALZA.

The Defendant objects to request number 7 because it does not relate in time to the production of the Plaintiff's Sandoz patch. The Defendant continues the information sought is overbroad because it

is not limited to the Decedents use of the Sandoz patch. The Defendant also argues the rationale for demanding the operating procedures rest upon the Plaintiff's desire to see if those procedures were being followed by the Defendant regarding the Sandoz patch. The Defendant argues from Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001), that the use of adverse reports to determine if the policy and procedures were followed by the Defendant is preempted by the FDA. Under the regulations, the Defendant is required to keep a record of all adverse complaints they receive and then file those adverse reports with the FDA and thus the Defendant argues the policy and procedures manuals and materials are a matter of internal revue between the FDA and the Defendant.

The Defendant's objection is not well taken regarding the Plaintiff's request for the Defendant's policy and procedures manuals and guidelines detailing how it handles adverse reports. The Buckman decision would not prevent the discovery requested by the Plaintiff in this case. Instead, Buckman prevented the plaintiff from pursuing a state law fraud on a federal agency claim. The Buckman Court held that the relationship between a federal agency and the regulated entity is federal in nature because it originates from federal law. 531 U.S. at 341-342. The policy and procedurals documents are relevant here because it would tend to show whether or not the Defendant followed its own procedures in addressing problems with the Sandoz patch. As such, the Motion to Compel number 7 is due to be granted.

Request for production number 8 requests, "[a]ny and all documents relating to all adverse reaction reports for the Sandoz patch and/or any other fentanyl pain patch manufactured, marketed, sold or distributed by ALZA. While Court's have allowed the discovery of adverse reports, the nature of those reports has been limited in time and scope and subject matter. *See* Davidson v Orhto-

McNeil Pharmaceutical, Inc., 2006 WAL 1037072 * 1 (M.D. Fla. April 19, 2006) (limiting a request for all adverse reports to "adverse reports related to acute vision disturbances, ocular pain, elevated ocular pressure, redness, secondary angle closure glaucoma and the like. . . "). The Plaintiff requests all adverse reports for a period covering twenty (20) years and pertaining to all adverse reports for Duragesic and the Sandoz patch and not those that are closer in time and more specifically related to the Decedent's condition. Thus, the request is overbroad in its scope and reach and is due to be modified to the adverse reports beginning in 2005 when the Sandoz patch was first distributed in the United States.

The Defendant also objects to the production of the adverse reports arguing they are not relevant and will not be admitted into evidence because they are not supported by sufficient scientific methods. The adverse reports are based upon the calls and complaints of individuals who have or are currently using the product, thus the Defendant argues the adverse reports are not relevant to the Decedent's claim because each the adverse reports would not establish the Plaintiff's claim that his Sandoz patch leaked. However, to be discoverable the requested documents need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence. Fed. R. Civ. P. 26(b)(1). Whether or not the Defendant had adverse reports from users of the Sandoz patch complaining of leaky patches or leaking problems with the Sandoz patch goes directly to the heart of the Defendant's knowledge of the matter at issue in this case. Thus, its not the scientific method behind the adverse report but the knowledge gained by the Defendant from the warnings provided by the adverse reports. The request for production number 8 is due to be granted.

The Plaintiff seeks, in requests for production numbers 14 and 15, documents that relate to any warnings regarding the use of Sandoz patch and any press releases or public relations material for the Sandoz patch. Request for production number 14 requests:

> [a]ny and all documents relating to the issue of whether a warning about the risk or occurrence of fentanyl overdose should be mentioned in any advertisements for the Sandoz patch and/or any other fentanyl pain patch manufactured, marketed, sold or distributed by ALZA.

Request for production number 15 requests

> [a]ny and all documents relating to any press releases or public relations material for the Sandoz patch and/or any other fentanyl pain patch manufactured, marketed, sold or distributed by ALZA that relate or refer to the risk or occurrence of fentanyl overdose with the use of such products, including any drafts, discussions, FDA approvals or revisions of such information.

Regarding request for production number 15, the Defendant states that all of the requested information was produced citing to Bates stamped documents DUR0046910-0046911, DUR0294417-0294420, DUR0294593-0294601, DUR0429427-0429429, DUR1170126-1170127, and DUR1847906-1847927, and in an electronic searchable format KELLEY00016O-000166 and KELLEY000357-000358. Thus, request for production number 15 is due to be denied. As for request for production number 14, the Defendant states it has no documents in its custody or control responsive to the request. Therefore, the request for production number 14 is due to be denied.

The Plaintiff also filed an agreed upon Motion for a Hearing on the issues involved in the Motion to Compel. However, after a review of the Motion and the Response in Opposition, the Court finds it can rule on the Motion without holding a hearing at this time.

Accordingly, it is now

ORDERED:

(1) The Plaintiff, Leslie Kelley's Motion to Compel Better Responses to the Plaintiff's First Request for Production and First Interrogatories (Doc. #36) is **GRANTED in part and DENIED in part.**

- Request for production numbers 1, 2, 14, and 15 are **DENIED.**
- Request for production number 7 is **GRANTED**.
- Request for production number 8 is **GRANTED,** but limited in time from 2005 until the death of the Decedent.
- The Defendant has up to and including **July 6, 2010**, to produce the documents in accord with this Order.

(2) The Plaintiff, Leslie Kelley's Motion for a Hearing on the Motion to Compel (Doc. # 37) is **DENIED.**

DONE AND ORDERED at Fort Myers, Florida, this 15th day of June, 2010.

SHERI POLSTER CHAPPELL
UNITED STATES MAGISTRATE JUDGE

Copies: All Parties of Record