

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

IN RE: ETHICON, INC.
PELVIC REPAIR SYSTEMS
PRODUCT LIABILITY LITIGATION

MDL No. 2327

THIS DOCUMENT RELATES TO ALL CASES

PRETRIAL ORDER # 47

(Plaintiffs' Motion to Compel Discovery and for Expedited Hearing)

Pending before the Court is Plaintiffs' Motion to Compel Discovery and for Expedited Hearing. (ECF No. 584). Plaintiffs seek an order from the court overruling objections lodged by Defendant Ethicon, Inc. ("Ethicon") to certain topics of inquiry (a, b, c, i, s, and kk) contained in five Notices of Rule 30(b)(6) deposition. The Notices all contain the same topics of inquiry, but each Notice is specific to one of the five Tension Free Vaginal Tape ("TVT") products sold by Ethicon. Given that Ethicon identified the same corporate designee for all five products and his deposition is scheduled to begin on May 15, 2013, Plaintiffs also requested an expedited hearing on the motion. The court **GRANTED** Plaintiffs' request for an expedited hearing and instructed Ethicon to respond to the Motion, which it did. (ECF No. 594).

After considering the parties' written memoranda, the court conducted a telephonic hearing on May 14, 2013. Having fully considered the arguments of counsel, the court **GRANTS**, in part, and **DENIES**, in part, Plaintiffs' motion and **ORDERS** as follows:

1. The subject matter of Topic “a” is the “Standard Operating Procedures (SOP) associated with design and development” of each of the five products. Ethicon objects to the scope and breadth of the topic, but agrees to make a witness available to testify about the most recent SOPs. Plaintiffs argue that they are entitled to discover all versions of the SOPs and obtain testimony regarding them. According to Plaintiffs, the different versions of the SOPs are relevant to their claim that Ethicon’s products were not substantially similar to a predicate device as required by FDA 510(k) clearance. Moreover, the products were implanted in Plaintiffs over a span of years; therefore, they need to know which SOPs were in place at various points in time. Finally, Plaintiffs complain that they requested all versions of the SOPs many months ago and only recently learned that they have not received all of them. Ethicon did provide additional SOPs within the last few days, but Plaintiffs have not had an opportunity to review them.

The court agrees with Plaintiffs that all versions of the SOPs are relevant, and Plaintiffs are entitled to collect them. However, for purposes of a Rule 30(b)(6) deposition, the court agrees with Defendant that requiring a witness to be knowledgeable about all aspects of the SOPs and their revisions is an overly demanding request. As Ethicon emphasizes, it has provided Plaintiffs with 181 SOPs that cover the fifteen years that the TVT products have been sold. Some of the SOPs have been revised numerous times. Without more direction from the Plaintiffs as to what issues and which particular procedures will be the subject of inquiry, Ethicon is hard-pressed to properly prepare a corporate designee.

Accordingly, the court sustains Ethicon’s objection to the breadth of the topic, as currently stated. However, Ethicon is **ORDERED** to provide the remaining relevant

SOPs to Plaintiffs. After review of the SOPs by Plaintiffs and completion of the initial Rule 30(b)(6) deposition (in which Plaintiffs may explore the issue of the SOPs), the parties are **ORDERED** to meet and confer to determine how this topic can be stated with greater particularity for a follow-up deposition.

2. Topic “b” asks for testimony on the “complete design history file ... including each component part of the file, the custodian responsible for the file and the maintenance of the file.” Once again Ethicon objects that the topic is overly broad, stating that the design history file “encompasses multiple volumes, and each file can comprise thousands of pages.” In response, Plaintiffs argue that Ethicon is required by the FDA to establish and maintain a design history file for each device, and the file must be readily available for FDA audit. Consequently, the files should already exist in manageable forms. The parties did meet and confer and reached a compromise regarding certain aspects of this topic to be addressed at the May 15 deposition. However, the parties did not agree on whether the Rule 30(b)(6) witness should be required to testify as to the Bates-stamp range of documents that comprises each design history file and confirm that the documents contained in the Bates-stamp range constitute the complete and accurate design history file. Ethicon argues that this is not a proper topic for a Rule 30(b)(6) deposition inasmuch as the corporate designee did not review, collect, and Bates-stamp the documents himself. Therefore, Ethicon should be permitted to supply this information in response to an interrogatory.

The court disagrees with Defendant. “Rule 30(b)(6) explicitly requires [the entity] to have persons testify on its behalf as to all matters known or reasonably available to it and, therefore, implicitly requires such persons to review all matters known or reasonably available to [the entity] in preparation for the Rule 30(b)(6)

deposition.” *United States v. Taylor*, 166 F.R.D. 356, 362 (M.D.N.C.1996). The designee should be prepared to give knowledgeable and binding answers on behalf of the entity, including answers regarding matters beyond those personally known to the designee and in which that designee was directly involved. *Id.* at 361. Plaintiffs are entitled to know Ethicon’s position on which documents comprise its design history files, and there is no basis for prohibiting Plaintiffs from obtaining that information through the testimony of a Rule 30(b)(6) witness. Accordingly, the court overrules Defendant’s objection on this issue. The court was advised by Ethicon that the corporate designee will not be prepared to provide this information on May 15. Accordingly, Defendant is **ORDERED** to prepare its designee to provide this information at a future deposition, and the court will entertain argument at a later date regarding the failure of Defendant to have its witness prepared to verify the design history files.

3. The subject matter of topic “c” is the “[m]embers and procedures of the Product Development Team” for each TVT product. Ethicon contends that to accurately provide this information, the corporate designee would have to “memorize the Design History Files,” which is an impossible burden. Moreover, Ethicon argues that the definition of “product development team” is unclear. While a core group of people may work on a project from start to finish, during the life of the project, many other employees may participate for shorter periods of time and for very specialized contributions. Thus, Ethicon claims that the topic is overly broad and unduly burdensome.

To the contrary, Plaintiffs assert that they are entitled to know the names of employees who participated in the development of the TVT products. They point out that preparing a Rule 30(b)(6) witness is often onerous, and that burden is not an

excuse to avoid providing relevant information. Finally, Plaintiffs indicate that they are entitled to know the corporation's position on who comprised the product teams.

After listening to the arguments of counsel, the court overruled Defendant's objection to the extent that Plaintiffs are permitted to question the corporate designee regarding the composition and structure of the product development teams. The parties are **ORDERED** to meet and confer thereafter to determine whether any additional information is required on this topic and, if so, how the subject matter can be narrowed.

4. Topic "i" involves all of the project names associated with the five TVT products. The parties met and conferred and agreed that Ethicon would provide a list of the names to Plaintiffs. In addition, Ethicon will have the corporate designee prepared to testify regarding the list of names. Therefore, Defendants' objection is denied as moot.

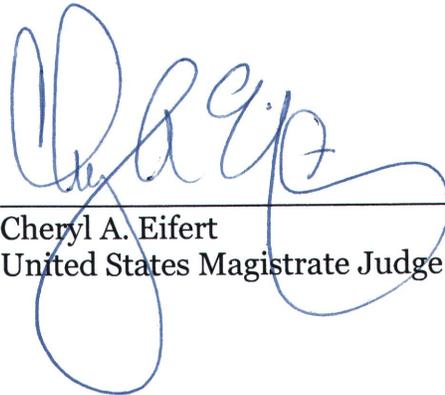
5. The subject matter of Topic "s" involves the patents related to each of the TVT products and to predecessor mesh products. The parties advised the court that they had reached a compromise on the subject matter for purposes of the Rule 30(b)(6) deposition. However, the parties indicated that they have remaining differences regarding the discovery of all patents and will attempt to resolve their differences before seeking judicial intervention.

6. Topic "kk" seeks testimony on the manufacturing processes as they relate to product design control and validation. Ethicon objects to the breadth of the topic, but indicates that it will have the Rule 30(b)(6) witness prepared to "speak at a high level of detail" regarding the processes and will supply additional witnesses if Plaintiffs require more information. The court agrees with Ethicon that the topic, as written in the Notice, is not sufficiently particularized; therefore, the court sustains Defendant's objection. In

light of defendant's proposal, the parties are **ORDERED** to meet and confer after the Rule 30(b)(6) deposition to determine if any issues remain on this topic that require judicial intervention.

The court **DIRECTS** the Clerk to file a copy of this order in 2:12-md-2327 and it shall apply to each member related case previously transferred to, removed to, or filed in this district, which includes counsel in all member cases up to and including civil action number 2:13-cv-111257. In cases subsequently filed in this district, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action at the time of filing of the complaint. In cases subsequently removed or transferred to this court, a copy of the most recent pretrial order will be provided by the Clerk to counsel appearing in each new action upon removal or transfer. It shall be the responsibility of the parties to review and abide by all pretrial orders previously entered by the court. The orders may be accessed through the CM/ECF system or the court's website at <http://www.wvsd.uscourts.gov>.

ENTERED: May 15, 2013.



Cheryl A. Eifert
United States Magistrate Judge