UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

CHRISTINE NAPOLITANO	:	
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	:	
v.	:	CIV. NO. 3:09CV828 (TLM)
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SYNTHES, INC[1]	:	
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RULING ON PENDING DISCOVERY MOTIONS

This is a product liability case involving a medical implant device called a locking reconstruction plate ("LRP"), designed for use on the human jaw. [Compl. Doc. #1]. Plaintiff alleges that defendant negligently and recklessly manufactured and sold the plate; failed to provide adequate warnings/instructions; and breached an implied warranty of merchantability and express warranties. [Doc. #1]. As a result of a fractured plate, plaintiff alleges she suffered an exacerbation of her pre-existing mandibular condition, suffered and continues to suffer emotional distress, pain and suffering, and has incurred medical and hospital expenses for the replacement of this defective plate and the consequential medical care arising therefrom. [Doc. #1].

Defendant represents that the LRP was designed in Europe by Mathys, Ltd. and Synthes was licensed to sell the LRP in the United States. One of the clinical indications for the LRP is

1 Defendant represents that Synthes USA Sales, LLC, is the proper defendant and will accept liability if Synthes, Inc. is determined to be liable. [Doc. #9; #54 at 1]. The Court will refer to defendant as Synthes.

reconstruction of the jaw (mandible). The plate at issue was sold by Synthes on August 4, 2003. Plaintiff, who suffered from osteoradionecrosis of her mandible, underwent surgery in 2003 to resect (remove) approximately 5 centimeters of the right side of her mandible. The oral surgeon who performed her surgery, David Shafer, DDS, used a Synthes catalog no. 449.633 LRP and screws to hold the resected parts of the mandible in anatomic alignment. The subject plate was implanted in Ms. Napolitano on May 1, 2006, and fractured approximately six weeks later.

Joint Agenda Prepared for April 10, 2013 Conference

A status conference was held on April 10, 2013. Plaintiff provided an eight page agenda of outstanding discovery issues which were discussed on the record. Also pending are plaintiff's Motions to Compel. [Doc. ##91, 92, 93, 94].

Section 1

b. – RE: Request for Production #28 dated June 22, 2011. Defendant will provide copies of the surgeon surveys relating to the Matrix plates to the Court for in camera review by April 19, 2013.

- RE: Request for Production #40 dated June 22, 2011. Defendant will supplement its response and state under oath that, after a diligent search, the materials do not exist.

c. -RE: Interrogatory 1 and Request for Production No. 1, dated December 8, 2011. Defendant will supplement its response and state under oath that, after a diligent search, no other 2005 lawsuit exists.

-RE: Request for Production No. 3, dated December 8, 2011. Defendant will supplement its response and state under oath that, after a diligent search, all of the responsive documents have been produced.

-RE: Request for Production No. 4, dated December 8, 2011. In light of the ruling on plaintiff's Motion to Compel [Doc. #91], defendant will provide a supplemental response.

d. – RE: Requests for Production Nos. 6, 10, 13, dated February 22, 2012, Defendant will supplement its responses to these requests. Defendant will state under oath if no additional materials exist after a diligent search.

It is HEREBY ORDERED that, regarding Request for Production No. 6, dated February 22, 2012, defendant will provide litigation materials in the Casey case, subject to a protective order. Counsel will confer re whether additional measures must be taken to protect the Casey discovery materials and provide a draft protective order for entry by the Court.

- RE: Request for Production No. 15, dated February 22, 2012. In light of the ruling on plaintiff's Motion to Compel [Doc. #91], defendant will provide a supplemental response verifying that plaintiff has all the complaint files, explain why these are the only reports that are available, and identify the person on whom defendant is relying for this response.

-RE: Requests for Production Nos. 3 and 8. Defendant will provide a supplemental response.

e). RE: Agenda Items 1-38, Defendant agrees to provide supplemental responses to all of these requests as part of the master supplementation.

f). Defendant agrees to provide responses to plaintiff's Requests to Admit dated December 31, 2012, by May 10, 2013.

g). This issue will be deferred by agreement.

Section 2

a) This issue has been addressed.

b) Plaintiff will renew this request after an opportunity to review defendant's supplemental document production.

c) Plaintiff will renew this request at another time.

Sections 3 through 6

Plaintiff will serve Requests for Production by April 19, 2013. Defendant's response is due by May 6, 2013.

Plaintiff's Motion to Compel Information Regarding Similar Incidents [Doc. #91]

Plaintiff moves to compel production of information concerning failures of the non-locking version of the series 449 plates as set forth in Requests for Production Nos. 14 and 15, dated February 22, 2012.

Request for Production No. 14: Produce all complaint files for all complaints involving fracture or failure of the 449 series non-locking mandibular reconstruction plates. This is intended to include domestic (within the US) and foreign complaints. If complaint files were not maintained for these foreign complaints, then produce all documentation maintained regarding any such complaints.

Request for Production No. 15: Produce copies of all complaint trend data maintained for both the 449 series locking and non-

locking mandibular reconstruction plates from 1996 to the present. This request is intended to include the number of plates sold as well as the number of complaints received regarding fracture or failure of these plates.

Plaintiff contends that "[e]vidence of other similar incidents ("OSI") is frequently admitted in product liability litigation for a number of different purposes including notice, foreseeability, and the appropriateness of punitive damages." [Doc. #91 at 10]. Plaintiff argues that the locking and non-locking 449 series plates are very similar. [Doc. #91 at 11 (emphasis in original]. "The many shared characteristics of the locking and non-locking versions of the 449 series plates include: same dimensions, same shape, same material; same indications for use; same product insert/instructions for use." [Doc. #91 at 11]. Plaintiff states that the "only difference between the 2 plates is that the locking version has threaded holes for a locking screw while the non-locking version has holes that receive non-locking screws." [Doc. #91 at 11-12]. Moreover, plaintiff notes that "Synthes developed the non-locking version of the series 449 plates first." [Doc. #91 at 14]. "This is why the information concerning failures of the non-locking 449 plates are so important here on the issues of notice, foreseeability, and the appropriateness of punitive damages." Id.

Defendant's RFP responses raise boilerplate relevancy objections in addition to stating that the requests are overly broad and unduly burdensome. In response to plaintiff's motion to compel, defendant argues that this discovery "relates to a

model of product that is fundamentally different than the product at issue." [Doc. #89 at 6].

In Fine v. Facet Aerospace Products Co., the Court held that the party seeking the requested discovery must make a "threshold showing of relevance" before the opposing party is obligated to provide discovery on "a variety of designs not directly at issue in the litigation." 133 F.R.D. 439, 443 (S.D.N.Y. 1990)]. "[W]here there has been no suggestion that other models share pertinent characteristics with the products at issue, discovery relating to those models will be disallowed." Id. at 442.

Defendant argues that plaintiff cannot make the threshold relevancy showing that the different Synthes models, "share those characteristics pertinent to the legal issues raised in this litigation." Fine, 133 F.R.D. at 441. Defendant states that the locking reconstruction plate ("LRP") at issue in this case is a Synthes catalog no 449.633 locking reconstruction plate with angle. The Synthes LRP had 29 holes, six vertical holes before the angle, and 23 horizontal holes after the angle. The plate is 2.5 mm thick, and each hole is threaded to enable screws to be locked into the plate.[2] Here, defendant argues that

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[2]

Plate	**Catalog No.**	**Holes**	**Thickness**	**Locking Threads**	**Material**
LRP	449.633	29(6 x 23)	2.5mm	Yes	CP titanium
Non-locking Plate	449.87	18(5 x 13)	3.0mm	No	CP titanium

the non-locking plate is both thicker than the LRP and "the non-locking plate could not have been used in plaintiff's case because it was shorter than the LRP, and did not have locking technology." [Doc. #89 at 7]. In addition, the non-locking plate was not the device cited by Synthes as the predicate device in its 510(k) application to the FDA clearance for the LRP. [Doc. #105 at 77].

> In order for the requested discovery to be relevant, then, it must be demonstrated that the designs are truly alternatives and that they are potentially safer. Of course, the party seeking discovery need not prove its case on the merits in order to obtain disclosure. It must however, make some threshold showing of relevance before the opposing party is obligated to open to discovery a variety of designs not directly at issue in the litigation.

Fine, 133 F.R.D. at 443. The Court finds that plaintiff has made a threshold relevancy showing under Rule 26. Fed. R. Civ. P. 26 (b)(1) ("Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence."); see Culligan v. Yamaha Motor Corp., 110 F.R.D. 122, 126 (S.D.N.Y. 1986 (finding "discovery of similar, if not identical, models is routinely permitted in product liability cases."); Fine, 133 F.R.D. at 442 ("there is support for the proposition that a plaintiff who raises a design defect claim is entitled to broader discovery that, for example, if the claim were solely one of negligent manufacture.").[3] This information will be subject to a

3 "Plaintiff has alleged that the Plate was defectively designed, was defectively manufactured, and caused an unreasonably

protective order. The Court defers the question of admissibility at trial until after the parties' experts have been disclosed and motions in limine are filed.

Plaintiff seeks information regarding the non-locking plate going back to 1996. If the parties are unable to agree, counsel will contact the Court to schedule a telephone status conference to discuss a reasonable time frame for the discovery and a schedule for production. In advance of the conference, defendant's counsel will confer with his client regarding a timeline for production as this information will assist the Court in setting a reasonable schedule for production of these materials.

Accordingly, plaintiff's Motion to Compel is **GRANTED. [Doc. #91].**

Plaintiff's Motion to Compel FDA Warning Letters and Form 483s [Doc. #92]

Plaintiff moves to compel production of Forms 483 or Warning Letters received from the FDA from June 26, 1996 to present, as set forth in plaintiff's Supplemental Request for Production No. 11, dated February 22, 2012.

Request for Production No. 11: Produce copies of any Form 483s or Warning Letters received from the FDA from June 26, 1996 to present that would encompass the manufacturing process and/or design process and/or complaint handling process for any 449 series LRP as referenced in part on page 194, line 5 [through] page 197, line 6 of Jodi Temple's transcript of 1/19/12.

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dangerous condition, i.e. in that the Plate was not sufficiently thick at the angle of the human jaw where the mechanical force of chewing is great, and in that the IFU [instructions for use] did not warn against using the plate for bridging large gaps without bone graft." [Doc. #91, n.5].

RESPONSE: Objection. The information requested is neither relevant to the claim or defense of any party nor reasonably calculated to lead to discovery of admissible evidence. Rule 26(b)(1). Without waiving this objection, Synthes has not received any FDA Form 483s or warning letters relating to the family of 2.4 mm locking reconstruction plate at issue, catalog nos. 449.632-449.655.

The Court finds the information sought in this RFP to be discoverable under a Rule 26 analysis. Fed. R. Civ. P. 26 (b)(1) ("Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence."). Defendant will produce copies of any Forms 483 or Warning Letters received from the FDA from June 26, 1996 to present that would relate to the manufacturing process and/or design process and/or complaint handling process for any 449 series LRP. If no Forms 483 and Warning Letters exist, defendant will state that under oath and in writing within fourteen (14) days. Accordingly, plaintiff's Motion to Compel is **GRANTED. [Doc. #92].**

Plaintiff's Motion to Compel Depositions of Huggins and Bohner [Doc. #93]

Plaintiff renews her request to depose Michael Huggins, former President of Synthes North America, and Richard Bohner, former President of Synthes U.S. Operations. On July 30, 2012, the Court denied her request without prejudice to renewal. Plaintiff renewed her request at the November status conference and by motion. [Doc. #93].

On renewal, plaintiff has not provided any evidence that Huggins or Bohner had personal knowledge of facts relevant to

this case. None of the employees listed by plaintiff reported to Huggins or Bohner or could say they were briefed on the issues in this case. Thus, plaintiff has not provided new information regarding Huggins' or Bohner's personal knowledge regarding this issues raised in this litigation. Plaintiff's argument that Huggins and Bohner "should have information" or that "it does not make sense that the deponents would not have knowledge of issues pertinent to this case . . . ." is not a sufficient basis for ordering their depositions. [Doc. #93 at 1, 7].

Plaintiff's request to reconsider the Court's July 30, 2012, ruling is GRANTED. Upon reconsideration and review of plaintiff's renewed motion and supplemented record, the Court affirms its prior ruling. Accordingly, plaintiff's Motion to Compel is **DENIED. [Doc. #93].**

Plaintiff's Motion to Compel Sales Training Materials [Doc. #94]

Plaintiff's Request for Production No. 21, dated April 19, 2012, seeks "all sales training/marketing documents, videos and slides referred to in [the document] bate stamped #01746-747 if not already produced."

Plaintiff's Request for Production No. 22, dated June 11, 2012, seeks "a copy of the documents concerning the training or education of the Synthes sales force as to the biomechanics of why plates fail."

On July 30, 2012, the Court ruled that plaintiff had "not

shown how the sales documentation would be helpful in proving the claims in her case, nor has she provided any citation to Dr. Schafer or Ms. Healy's depositions to counter defendant's representations." [Doc. #68 at 10]. Plaintiff renewed her request during the November status conference and by motion. [Doc. #94[. In her renewed motion, plaintiff has not provided evidence that Ms. Healy used or relied on training materials in her interactions with Dr. Shafer; rather, plaintiff argues that she is "entitled to discover everything Synthes said about its product, and especially what it told its own sales personnel." [Doc. #94 at 3]. Plaintiff contends that training materials are admissions, "likely to show what Synthes knew and when it knew it, and may also be evidence of recklessness." Id. The Court has reviewed the transcript excerpts of Ms. Healy and Dr. Schafer's depositions. The evidence does not show that Ms. Healy relied on training materials in her interactions with Dr. Shafer. [Doc. #94 at 3 (plaintiff admits that this fact is "besides the point."]. Moreover, there is no evidence to show there were communications between Ms. Healy and Dr. Shafer regarding the biomechanics of plate failure before the plate at issue was sold.

Plaintiff's request to reconsider the Court's July 30, 2012, ruling is GRANTED. Upon reconsideration and review of plaintiff's renewed motion and supplemental record, the Court affirms it prior ruling denying Requests for production No. 21 dated April 19, 2012, and No. 22 dated June 11, 2012. Accordingly, plaintiff's Motion to Compel is **DENIED. [Doc. #94].**

CONCLUSION

Accordingly, plaintiff's Motion to Compel **[doc. #91]** is **GRANTED** as set forth in this opinion.

Plaintiff's Motion to Compel **[doc. #92]** is **GRANTED** as set forth in this opinion.

Plaintiff's Motion to Compel **[doc. #93]** is **DENIED** as set forth in this opinion.

Plaintiff's Motion to Compel [**doc. #94]** is **DENIED** as set forth in this opinion.

This is not a recommended ruling. This is a discovery ruling and order which is reviewable pursuant to the "clearly erroneous" statutory standard of review. 28 U.S.C. §636 (b)(1)(A); Fed. R. Civ. P. 6(a), 6(e) and 72(a); and Rule 2 of the Local Rules for United States Magistrate Judges. As such, it is an order of the Court unless reversed or modified by the district judge upon motion timely made.

SO ORDERED at Bridgeport this 29th day of April 2013.

/s/
HOLLY B. FITZSIMMONS
UNITED STATES MAGISTRATE JUDGE