

UNITED STATES DISTRICT COURT  
DISTRICT OF CONNECTICUT

CHRISTINE NAPOLITANO                                 :  
   :  
   :  
v.   : CIV. NO. 3:09CV828 (TLM)  
   :  
SYNTHES, INC<sup>1</sup>   :  
   :  
   :  
   :

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 states that the LRP was designed in Europe by

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<sup>1</sup>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.

Mathys, Ltd. and Synthes was licensed to sell the LRP in the United States. One of the clinical indications for the LRP is 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.

Oral argument was held on the pending discovery motions on May 31, 2012.

Plaintiff's Motion for Extension of Time [Doc. #40]

On February 27, 2012, Judge Haight entered a scheduling order setting the following deadlines:

1. Depositions of plaintiff's rebuttal experts shall be completed by March 30, 2012.
2. All discovery will be completed by April 30, 2012.
3. Dispositive motions must be filed on or before May 30, 2012.
4. The Joint Trial Memorandum is due on or before July 31, 2012 or within thirty days after the Court rules on the last-filed dispositive motion, whichever is later.

5. The case will be trial ready on August 31, 2012.

On February 28, 2012, the case was transferred to Judge Melancon. On April 30, 2012, at the expiration of the discovery deadline, plaintiff filed this Motion for Extension of Time [doc. #40], to complete the following discrete discovery.

Depositions:

1. Dr. John Brunski. Plaintiff consents to defendant's continued deposition of Dr. Brunski, which was scheduled for April 30, 2012.
2. Mark Michels, former employee of Synthes. Defendant consents to the plaintiff's deposition of Mr. Michels, scheduled for May 24, 2012.
3. James K. McCracken, former employee of Synthes. Plaintiff does not state how much time he will need to depose Mr. McCracken or whether defendant objects to this deposition. Plaintiff will depose Mr. McCracken within thirty days. Plaintiff will endeavor to schedule this deposition first.
4. Ted Kompa, Synthes employee. Plaintiff does not state how much time he will need to depose Mr. Kompa or whether defendant objects to this deposition. Plaintiff will depose Mr. Kompa within thirty days.
5. Kim Coffey, Synthes employee. Plaintiff does not state how much time he will need to depose Ms. Coffey or whether

defendant objects to this deposition. Plaintiff will depose Ms. Coffey within thirty days.

6. Michael Huggins, former President of Synthes North America. Defendant objects to the deposition of Mr. Huggins, explaining that Mr. Huggins pleaded guilty to violations of federal law in connection with the marketing of a device by the Spine Division of Synthes. Defendant states that, "every single witness who has been deposed has stated that he or she had no contact with . . . Huggins about the plate at issue, . . . ." [Doc. #43 at 5]. Further, Mr. Huggins worked in the Spine Division, not the CMF division at issue in this lawsuit. On this record, plaintiff's request for leave to depose Mr. Huggins is denied without prejudice. Any renewal of the request must be made at the case management conference.

7. Richard Bohner, former President of Synthes US Operations. Defendant objects to the deposition of Mr. Bohner on the same grounds, explaining that Mr. Bohner also pleaded guilty to violations of federal law in connection with the marketing of a device by the Spine Division of Synthes. Defendant represents that, "every single witness who has been deposed has stated that he or she had no contact with Bohner . . . about the plate at issue, . . . ." [doc. #43 at

5], and that Mr. Bohner worked in the Spine Division, not the CMF division at issue in this lawsuit. On this record, plaintiff's request for leave to depose Mr. Bohner is denied without prejudice. Any renewal of the request must be made at the case management conference.

Accordingly, plaintiff's Motion for Extension of Time [Doc. #40 is **GRANTED** in part and **DENIED** in part. Plaintiff will depose Dr. Brunski, Mark Michels, James McCracken, Ted Kompa and Kim Coffey within thirty days. Plaintiff will endeavor to schedule the deposition of James McCracken first.

#### Outstanding Interrogatories and Requests for Production

Plaintiff seeks responses to four Requests for Production ("RFP") dated June 22, 2011, which are raised in a pending Motion to Compel [doc. #45] addressed below.

Plaintiff also seeks responses to Supplemental Interrogatories and Requests for Production served on December 8, 2011; February 22, and April 18, 2012. On June 6, 2012, defendant reported that it has served plaintiff with responses to the December 8, 2011 and February 22, 2012 discovery requests that were also a subject of plaintiff's Motion to Compel. [Doc. ##54, 61].

By e-mail dated June 29, 2012, plaintiff's counsel reported that the following requests dated December 8, 2011, have not been

resolved: Interrogatory No. 1 and Requests for Production 1, 3 and 4 (d-f). Plaintiff provides no explanation why, in light of defendant's May 25, answers, the requests remain unresolved.

Plaintiff's counsel also reported that the following requests from February 22, 2012, have not been resolved: Requests for Production Nos. 2, 6, 9, 10, 13, 14, 15, 18 & 19. Defendant asserts an attorney-client privilege in RFP Nos. 6 & 10 without providing a privilege log. Defendant will provide a privilege before the meet and confer with plaintiff or any privilege will be deemed waived. Defendant will provide a copy of the privilege log with copies of the documents for in camera review prior to the August 6, 2012 case management conference. As request for Production No. 14 asserts only a boilerplate objection, defendant will answer this request prior to the case management conference. To the extent that defendant has already produced responsive documents, it will provide a supplemental response which cites the Bates Stamp pages. See RFP Nos. 3, 4, 8, 9, 16, 17; Fed. R. Civ. P. 26(g)(1). Moreover, the parties should be prepared to discuss and/or brief RFP Nos. 13, 18 and 19, and any other requests to the extent they have not been resolved by defendant's letter dated June 28, 2012. To the extent that defendant represents that there are no responsive documents to a RFP, defendant will state this in writing and under oath in a

supplemental response to plaintiff. See Fed. R. Civ. P. 26(g)(1).

The parties will discuss the "unresolved" December 8, 2011 and February 22, 2012 requests at a meet and confer. If there are outstanding objections that cannot be resolved, the parties will provide the requests and outstanding objections to the Court and add this item to the agenda for the August 6, 2012 case management conference.

The parties do not state whether defendant has responded to the April 18, 2012 request. The parties will discuss the April 18, 2012 requests at the meet and confer. If there are outstanding objections that cannot be resolved, the parties will provide the requests and outstanding objections to the Court and add this item to the agenda for the August 6, 2012 case management conference.

Finally, plaintiff seeks responses to Requests for Admission dated April 30, 2012, addressed to evidentiary foundations. The parties will discuss the April 30, 2012 requests at the meet and confer. Each request for admission should be admitted or denied; if defendant cannot do so, the reason should be discussed with opposing counsel in an effort to clarify what evidence will require foundation testimony.

Defendant's Objection to Further Extensions of Time

The Court has carefully considered defendant's concerns regarding the age of the case and the significant delay attributed to plaintiff in completing discovery. The parties can be assured that the case will be closely managed going forward. Plaintiff has identified his outstanding discovery and a schedule for its completion is set and will be monitored by this Court. Plaintiff will not be permitted to propound additional discovery without good cause shown and without leave of Court. No extensions of time will be granted without good cause shown and any requests to extend the deadlines must be made prior to its expiration.

Plaintiff's Motion for Leave to Disclose One Additional Expert Beyond Scheduling Deadline [Doc. #41]

Plaintiff requests leave of Court to disclose a regulatory affairs/regulatory compliance expert three weeks after the conclusion of the deposition of James K. McCracken. Plaintiff contends that, since she recently received the Design History File for the subject device on February 10, 2012, she "only recently came to understand the manner in which this device was brought to the market." [Doc. #41]. Defendant legitimately objects that plaintiff could have and should have made this request years ago and that further delay is prejudicial and



creates undue expense. Plaintiff's request is **GRANTED** with the understanding that there will be no other requests to disclose experts and further delay will not be tolerated. Accordingly, plaintiff's Motion for Leave to Disclose One Additional Expert **[Doc. #41]** is **GRANTED** such that the expert will be disclosed three weeks after the deposition of James K. McCracken. Mr. McCracken will be deposed first among plaintiff's remaining witnesses.

Plaintiff's Motion to Compel **[Doc. #45]**

Plaintiff moves to compel responses to Requests for Production Nos. 22, 28, 30 and 40 from the June 11, 2011 discovery requests.

Request for Production No. 22: *Please produce a copy of the documents concerning the training or education of the Synthes sales force as to the biomechanics of plates or why plates fail.*

Defendant objects, stating that both Dr. David Shafer, the doctor who implanted the plate at issue, and Diane Healy, the Synthes sales consultant whose territory included Dr. Shafer's hospital, have been deposed.

Ms. Healy provided Dr. Shafer with the LRP Technique Guide, which has been produced to plaintiff, but did not provide any training to Dr. Shafer regarding the LRP, nor did Dr. Shafer ask her any specific questions about the LRP. Dr. Shafer testified that the

only communication he had with Ms. Healy regarding the LRP was with respect to sending the plate back to Synthes for analysis after the plate had broken, and that the decision as to which plate to use for a particular patient was his clinical decision as the patient's doctor.

[Doc. #59 at 4]. On this record, plaintiff has 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 representation. Accordingly, plaintiff's RFP No. 22 is **DENIED** on this record. Plaintiff may renew her request at the case management conference. Any renewal of this RFP should be included on the Joint Agenda or the request will be deemed waived.

Request for Production No. 28: Please produce a copy of the survey or questionnaire results relating to both the Synthes 2.4 mm titanium locking reconstruction plate and the Matrix Mandible segment as identified by Brian Griffiths at his deposition. (Griffiths Tr. 100-101).

Defendant has produced responsive documents relating to surgeon comments about the LRP in the Design History file. Defendant argues that discovery of the Matrix system is not warranted as it was not on the market when the plate at issue was sold or implanted. The plate at issue was sold in August 2003 and

was implanted in May 2006. The Matrix system was not cleared by the FDA for sale in the United States until April of 2007. As such, defendant argues, the "Matrix system is a subsequent remedial measure under FRE 407 and is not admissible to prove a defect in a product or its design, negligence, culpable conduct, or the need for warnings or instruction." [Doc. #59]. Plaintiff contends that, a "surgeon might have said, 'I am glad that you made these design changes. I feel this will help avoid the early plate fractures I have been having and which I told you about in 2002.'" [Doc. #51 at 9]. Plaintiff does not address defendant's objection under FRE 407 or In re Joint Eastern District and Southern District Asbestos Litigation, 995 F.2d 343, 345 (2d Cir. 1993). Accordingly, RFP No. 28 is **DENIED** on this record. Plaintiff may renew her request at the case management conference. Any renewal of this RFP should be included on the Joint Agenda or this request will be deemed waived.

Request for Production No. 30: *Please produce a copy of Brian Griffiths' general file that he identified during his deposition.*

At his deposition Mr. Griffiths testified that he reviews articles/journals regarding mandible reconstruction plates on a periodic basis. When asked whether he keeps a file for all the articles concerning or referencing the 2.4mm LRP, Mr. Griffiths stated that he has "a general file with a bunch of articles of

interest, but nothing specific to just 24 LRP." [Griffiths Tr. 103-04]. Defendant objects to this request because Mr. Griffiths had "no involvement with the design of the LRP, and did not begin work at Synthes until eight years after the LRP was cleared for sale by the FDA. Accordingly, RFP No. 30 is **DENIED** on this record. Plaintiff may renew her request at the case management conference. Any renewal of this RFP should be included on the Joint Agenda or the request will be deemed waived.

*Request for Production No. 40: Please produce a copy of the educational materials created/published/promulgated by AO pertaining to the Synthes 2.4 titanium locking reconstruction plate, as identified by Brian Griffiths during his deposition.*

The AO (Association for the Study of Internal Fixation) is a European nonprofit organization dedicated to research, development, and education relating to trauma and musculoskeletal disorders. Defendant will contact Mr. Griffiths and ask him whether he has any AO materials pertaining to the Synthes 2.4 mm titanium locking reconstruction plate and the date(s) of the materials, and provide this information to plaintiff during the meet and confer. Accordingly, RFP No. 40 is **DENIED** on this record. Plaintiff may renew her request at the case management conference. Any renewal of this RFP should be included on the Joint Agenda or the request will be deemed waived.

## CONCLUSION

Accordingly, plaintiff's Motion for Extension of Time [**doc. #40**] is **GRANTED** as set forth in this opinion.

Plaintiff's Motion for Leave to Disclose One Additional Expert Beyond Scheduling Deadline [**doc. #41**] is **GRANTED** as set forth in this opinion.

Plaintiff's Motion to Compel [**doc. #45**] is **DENIED** on this record without prejudice. Plaintiff may renew her requests at the case management conference. Any renewal of RFP Nos. 22, 28, 30, or 40 should be included on the Joint Agenda or the requests will be deemed waived.

A telephone case management conference is scheduled for Monday, August 6, 2012 at 4:00PM. Five days prior to the conference, counsel will meet and confer to discuss the issues and set an agenda for the conference. Counsel will provide an email copy of the agenda by 9:00AM on Friday, August 3, to Judge Fitzsimmons assigned law clerk.

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 30th day of July 2012.

\_\_\_\_\_/s/\_\_\_\_\_  
HOLLY B. FITZSIMMONS  
UNITED STATES MAGISTRATE JUDGE