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IN THE CIRCUIT COURT OF THE TWELFTH JUDICIAL CIRCUIT
IN AND FOR MANATEE COUNTY, FLORIDA

JOSEPH ZAREMBA,
Plaintiffs,

vs. **CASE NO. 2014 CA 001932 NC**

ORTHOPEDICS, INC., JAMES
H. BARR, et al,
Defendants,

COPY

ORDER ADOPTING RECOMMENDED ORDER

THIS CAUSE came before the Court on the Recommended Order of Magistrate, filed by Magistrate Deborah A. Bailey, and the undersigned, having considered the findings and recommendation contained therein, it is hereby,

ORDERED AND ADJUDGED that:

1. The Recommended Order of Magistrate, entered on OCTOBER 21, 2015 a copy of which is attached hereto, is ratified and approved.

2. The parties are ordered to abide by all of the findings and recommendations contained in the Recommended Order of Magistrate, and the Court hereby adopts each and every finding and recommendation therein as the Order of this Court.

DONE AND ORDERED in Chambers at Sarasota, Sarasota County, Florida on this 12 day of Nov 2015.

Peter Dubensky

PETER A. DUBENSKY
Circuit Judge

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IN THE CIRCUIT COURT OF THE TWELFTH JUDICIAL CIRCUIT
IN AND FOR SARASOTA COUNTY, FLORIDA

JOSEPH ZAREMBA,
Plaintiff,

CONSOLIDATED CASES

vs. CASE NO. 2014 CA 01932 NC

ORTHOPEDICS, INC.,; JAMES H. BARR; BIOMET INC.; BIOMET ORTHOPEDICS, et al.,
Defendants.
_______________________________________/

LILLIAN SILBERG,
Plaintiff,

vs. CASE NO. 2014 CA 01934 NC

ORTHODYNAMICS, INC.; PAUL HABER; et al.,
Defendants.
_______________________________________/

BETTE PALUZZI,
Plaintiff,

vs. CASE NO. 2014 CA 01936 NC

ORTHOPEDICS, INC.; JAMES H. BARR, et al.,
Defendants.
_______________________________________/

RECOMMENDED ORDER OF MAGISTRATE

This matter came on for hearing before the Magistrate on October 8, 2015, on the **Plaintiff's Motion to Compel**. The Magistrate has jurisdiction pursuant to Fla. R. Civ. P. 1.490. Upon further consideration of the parties' arguments and authorities, the Magistrate recommends the Court **GRANT** the Plaintiff's Motion for the reasons set forth below.

In these consolidated actions, Plaintiffs seek damages associated with alleged defects in hip implant components manufactured by Defendant Biomet. Plaintiffs seek discovery about Biomet's M2a38 System although they were all implanted with Biomet's M2a Magnum System. Biomet introduced the M2a38 System in 2001 and introduced the M2a Magnum System in 2004.

Specifically, Plaintiffs served a Request for Production on July 2, 2015, seeking two specific categories of documents: (1) medical device report complaint files for both the M2a38 and M2a Magnum components from the time the products were introduced until present; and (2) compilations of complaints about M2a38 and M2a Magnum components from the time the products were introduced until the present.[1] Biomet objected to each Request contending that it was overly broad and unduly burdensome, was not reasonably likely to lead to the discovery of admissible information, and that the time, expense, and burden in producing the discovery was not proportional to the amount in controversy in these consolidated cases.

In between the filing of the Motion to Compel and the hearing, the parties have agreed that Biomet will produce the documents relating to the M2a Magnum components. Left for this court's determination is the discoverability of documents regarding the M2a38 components.

Rule 1.280(b)(1) governs the scope of discovery and permits discovery of information "reasonably calculated to lead to the discovery of admissible evidence." In a products liability action, a plaintiff seeking discovery of other products manufactured by a defendant bears the burden to demonstrate the other products are "substantially similar" to the subject product. *See e.g., Alvarez v. Cooper Tire & Rubber Co.*, 75 So. 3d 789, 794 (Fla. 4th DCA 2011); *American Medical Systems v. Osborne*, 651 So. 2d 209, 211 (Fla. 2d DCA 1995).

Plaintiffs initially provided the Magistrate with a page from a 510(k) Summary of Safety and Effectiveness provided by Biomet to the FDA at the time Biomet sought approval to market the M2a Magnum System. In that Summary, Biomet claimed that the M2a Magnum System was substantially equivalent[2] to the M2a38 System. In its "Summary of Technologies," Biomet asserted: "The M2a Magnum Hip System technological characteristics (materials and design) are similar to predicate devices." The Summary also states that mechanical testing "was performed to establish substantial equivalence[3] to the predicate devices," but no clinical testing was used.

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[1] Biomet has already produced some discovery regarding the M2a38 System as part of its document production in these cases, tracking what was produced in federal multidistrict litigation pending in Indiana, which involves plaintiffs who were implanted with both the M2a38 and M2a Magnum Systems.

[2] When the Magistrate inquired of Biomet's counsel as to the meaning of the term "substantially equivalent," counsel stated that it was a term of art used in the FDA regulatory scheme and the Plaintiffs should have to explain what it meant in order to carry their burden. Counsel argued that it was not the same as substantial similarity for purposes of determining whether the M2a38 System was within the scope of discovery under Florida law.

[3] The terms "substantially equivalent" and "substantial equivalence" are defined by statute. *See* 21 U.S.C. § 360c(i)(1). In relevant part, the term means "with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and the Secretary by order has found that the device has the same technological characteristics as the predicate device …." *See* 21 U.S.C. § 360c(i)(1)(A)(i). As noted above, Biomet asserted in its 510(k) Summary that the "technological characteristics (material and design) are similar to predicate devices."

Biomet argues the Plaintiffs fail to meet their burden and relies primarily on the affidavit of Biomet Research Senior Director, David W. Schroeder. Schroeder attests that Biomet's metal on metal hip implants "are the result of incremental changes in metal on metal articulation technology." (Schroeder Affidavit at ¶ 9)[4] Additionally, Schroeder asserts that the M2a38 and M2a Magnum systems "differ from each other in terms of the bearing design, head design, head size, cup design, cup size, range of motion, neck lengths, diametrical clearance and materials." (Schroder Affidavit at ¶ 6) Schroeder attaches a chart to his Affidavit, however, that appears to reflect significant similarities between the two systems.[5]

Additionally, documents produced by Biomet to the Plaintiffs in discovery, which were reviewed *in camera*, support the Plaintiffs' position of substantial similarity between the M2a38 System and the M2a Magnum System. Specifically, a Table included in another Biomet FDA filing (BMT-MM01003885) demonstrates substantial similarity in the specifications and properties of both systems and significant overlap in the design specifications of both systems. BMT-MM01003886 references that the one-piece shells common to the M2a38 and M2aMagnum Systems are manufactured of the same material and according to the same ASTM standard. In addition, complaint reports (BMT-MM03118090 and BMT-MM00011562-63) note patient complaints with the M2a38 System that are similar to the complaints lodged by the Plaintiffs in these consolidated actions.

Biomet placed heavy reliance on the *Osborne* and *Alvarez* cases to support its argument that Plaintiffs failed to meet their burden. Biomet also argued that Plaintiff should have to produce expert testimony or an affidavit to overcome the Schroeder Affidavit. Quite simply, the Magistrate disagrees.

First, in *Osborne*, the Plaintiff relied on an argument that defense counsel had characterized an implant as "a later model within the series" and it worked in a substantially similar manner. *See Osborne*, 651 So. 2d at 210. The court found that this characterization was overcome by the defendant's later filing of sworn affidavits that described the product at issue "as significantly different in design and performance from other AMSI models." *Id.* at 211. Here, the Plaintiffs do not rely on generic argument alone but, rather, have relied on Biomet's own representations as to the similarity between the M2a38 and M2a Magnum Systems and the similarity in

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[4] In the Magistrate's opinion, Plaintiffs have recognized these "incremental" changes by asking for discovery on the predicate device on which Biomet relied in seeking approval of the M2aMagnum System, rather than asking for discovery of all of Biomet's metal on metal hip components without regard to substantial similarity. Although Biomet argues that giving Plaintiffs access to the M2a38 System documentation will "open the floodgates" to discovery on any and all metal on metal hip implant components, the Magistrate finds that argument unpersuasive in the context of the instant Motion.

[5] Again, these similarities, not differences, were relied on by Biomet in touting its similarity in material and design to the M2a38 System to the FDA when seeking approval of the M2a Magnum System.

complaints between patients that have been implanted with components of both systems. Importantly, the documents relied on by the Plaintiffs are Biomet documents.

Second, *Alvarez* actually supports the conclusion drawn by the Magistrate. In *Alvarez*, a tire tread separation case, the trial court limited document discovery from Cooper Tire to "those involving tires with the same or similar specifications." *See Alvarez*, 75 So. 3d at 790. The appellate court found no error in this limitation and affirmed, noting that "[w]hether another product is 'substantially similar' is a question for the trial court based upon all of the proofs presented." *Id.* at 794. Here, after reviewing all of the information provided by the Plaintiffs and Biomet in conjunction with the Motion to Compel, the Magistrate concludes that the M2a38 System is substantially similar to the M2a Magnum System, which was implanted in the Plaintiffs, thus rendering information about the M2a38 system discoverable.

Accordingly, the Magistrate recommends the Court rule as follows:

1. Plaintiffs' Motion to Compel is **GRANTED.**
2. Biomet's objections to Requests 1 and 2 of the Plaintiffs' July 2, 2015 Request for Production are overruled in their entirety as regards the M2a38 System components.[6]
3. Within 30 days of the date the Court adopts this Recommended Order, Biomet shall produce documents involving the M2a38 System components that are responsive to Requests 1 and 2 for the time period of 2001, when the M2a38 System was introduced, to the present.

IF YOU WISH TO SEEK REVIEW OF THE REPORT AND RECOMMENDATION MADE BY THE MAGISTRATE, YOU MUST FILE EXCEPTIONS IN ACCORDANCE WITH FLORIDA RULE OF CIVIL PROCEDURE 1.490(i). YOU WILL BE REQUIRED TO PROVIDE THE COURT WITH A RECORD SUFFICIENT TO SUPPORT YOUR EXCEPTIONS OR YOUR EXCEPTIONS WILL BE DENIED. A RECORD ORIDINARILY INCLUDES A WRITTEN TRANSCRIPT OF ALL RELEVANT PROCEEDINGS. THE PERSON SEEKING REVIEW MUST HAVE THE TRANSCRIPT PREPARED IF NECESSARY FOR THE COURT'S REVIEW.

Deborah A Bailey

10/21/2015

Magistrate Deborah Bailey

Copies furnished to: As per attached service list

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[6] Although the arguments at the hearing and the bulk of this Recommended Order focus on substantial similarity, Biomet produced no record evidence to support its objection that the burden of producing this discovery was somehow inordinate. *See In re: Commitment of Sutton*, 884 So. 2d 198, 203 (Fla. 2d DCA 2004) ("An objection claiming an undue burden in responding to discovery requests must be supported by record evidence, such as an affidavit detailing the basis for claiming that the onus of supplying the information or documents is inordinate."). In the absence of any such record evidence, the objection must be overruled.

2014 CA 1932

ZAREMBA V. ORTHOPEDICS

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