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Ca	se No.	2:17-cv-03178-CAS (KSx)	Date	December 3, 2018
Ca	.sc 110.	2:17-cv-03196-CAS (KSx)	Date	
Tit	·le	JOHN BOWER V. WRIGHT MED	ICAL TECHNO	DLOGY INC. ET AL.
110	.10	CATHERINE PRATER V. WRIGH	HT MEDICAL 7	ΓECHNOLOGY, INC.
		ET AL.		

CIVII MINIITES CENEDAL

Present: The Honorable CHRISTINA A. SNYDER N/A Catherine Jeang Lisa Gonzalez Court Reporter / Recorder Deputy Clerk Tape No. Attorneys Present for Plaintiffs: Attorneys Present for Defendants: Cherisse Cleoffe

Ryan O'Neil

602

Melanie Palmer

Proceedings: PLAINTIFFS' MOTION FOR REVIEW OF MAGISTRATE

JUDGE'S ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTION TO COMPEL FURTHER RESPONSES AND PRODUCTION OF DOCUMENTS (Filed

September 26, 2018, Dkt. 90)

I. INTRODUCTION

On April 27, 2017, plaintiffs John Bower ("Bower") and Catherine Prater ("Prater") filed separate but substantially similar complaints against defendants Wright Medical Technology, Inc. ("Wright") and MicroPort Orthopedics, Inc. ("MicroPort"). See Case No. 2:17-cv-03178-CAS, Dkt. 1 ("Bower Compl."); Case No. 2:17-cv-03196, Dkt. 1. ("Prater Compl."). Both plaintiffs assert seven claims against defendants: (1) strict products liability—manufacturing defect, (2) strict products liability—failure to warn, (3) negligence, (4) negligence—failure to recall/retrofit, (5) fraudulent misrepresentation, (6) fraudulent concealment, and (7) negligent misrepresentation. Id. In brief, plaintiffs allege that they received the same artificial hip devices manufactured by defendants and that the devices subsequently fractured causing them serious injury.

¹ For sake of clarity and convenience, the following references are to the record in the Bower action unless otherwise specified.

	CIVIL MINUIES - G	LNLNAL	U
Case No.	2:17-cv-03178-CAS (KSx)	Date	December 3, 2018
Case 110.	2:17-cv-03196-CAS (KSx)	Date	
Title	JOHN BOWER V. WRIGHT MEDICA	L TECHNO	DLOGY INC. ET AL.
11110	CATHERINE PRATER V. WRIGHT M	MEDICAL 7	TECHNOLOGY, INC.
	ET AL.		

CIVII MINIITES CENEDAL

609

<u>See id.</u> On January 3, 2018, the Court consolidated the Bower and Prater actions for all pre-trial purposes. Dkt. 48.

On September 22, 2018, Magistrate Judge Karen L. Stevenson ("the Magistrate Judge") granted in part and denied in part plaintiffs' motion to compel further discovery responses and production of documents. Dkt. 80 ("Order"). On September 26, 2018, plaintiffs filed the instant motion for review of the Order. Dkt. 90 ("Mot."). Defendants filed an opposition on November 12, 2018. Dkt. 94 ("Opp'n"). Plaintiffs filed a reply on November 19, 2018. Dkt. 95 ("Reply"). The Court held a hearing on December 3, 2018. Having carefully considered the parties' arguments, the Court finds and concludes as follows.

II. BACKGROUND

Plaintiffs allege the following facts. Both plaintiffs had hip replacement surgeries performed by Dr. Jason Snibbe ("Dr. Snibbe") at Cedars-Sinai Medical Center in Los Angeles, California. Bower Compl. ¶ 8; Prater Compl. ¶ 8. Prater underwent a right total hip arthroplasty on January 17, 2012. Prater Compl. ¶ 3. Bower underwent a left total hip arthroplasty on October 1, 2013. Bower Compl. ¶ 3. In both cases, Dr. Snibbe surgically implanted defendants' PROFEMUR® Total Hip System, specifically the "VV" Long neck, model PHAC-1254, made from cobalt chrome alloy. Bower Compl. ¶¶ 3, 66; Prater Compl. ¶¶ 3, 66. While Bower and Prater were performing normal and expected activities of daily living on December 4, 2016 and January 9, 2017 respectively, the modular neck of both devices suddenly and catastrophically failed. Plaintiffs were subsequently hospitalized and the devices were surgically removed. Bower Compl. ¶¶ 69–72; Prater Compl. ¶¶ 69–72.

Wright began manufacturing and selling the PROFEMUR® Total Hip System after December 13, 2000, when Wright received permission to distribute the device from the United States Food and Drug Administration ("FDA"). Bower Compl. ¶¶ 17, 20. The device the FDA approved contains a modular neck that was designed and had previously been distributed in Europe by Cremascoli Ortho ("Cremascoli"), which Wright acquired in December 1999. Id. ¶¶ 16, 18. The FDA never considered and approved the safety of the PROFEMUR® Total Hip System, but instead concluded it was substantially equivalent to an already legally marketed device manufactured by Cremascoli. Id. ¶ 19.

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Case No.	2:17-cv-03178-CAS (KSx) 2:17-cv-03196-CAS (KSx)	Date	December 3, 2018
Title	JOHN BOWER V. WRIGHT MEDI CATHERINE PRATER V. WRIGH ET AL.		

CIVIL MINUTES - GENERAL

·O'

On August 25, 2009, the FDA permitted Wright to distribute and market a PROFEMUR® device made from cobalt chrome alloy instead of the titanium-aluminum-vanadiam alloy used since 2000 without assessing the safety of the device but rather finding that the devices are substantially similar. <u>Id.</u> ¶¶ 21–22.

Plaintiffs allege that Wright made "representations, statements, claims, and guarantees about its PROFEMUR® modular necks" in "various marketing and promotional material published and distributed by Wright from approximately" 2002 to 2005. Id. ¶ 24. Specifically, Wright represented that the devices "have been successfully implanted in over 50,000 patients" and that "[n]one of the necks has experienced a clinical failure since their inception." Id. Wright represented that "[e]xtensive laboratory tests have proven that the coupling between the modular neck and femoral implant guarantees" "[s]tructural reliability," the "[a]bsence of significant micromovement," and the "[a]bsence of fretting corrosion." Id. Despite these representations, plaintiffs allege that defendants had in fact received notice of fractures of the modular necks that had been implanted in patients in Europe prior to 2001. Id. ¶ 28. However, defendants allegedly failed to disclose this history of fractures in European patients to the FDA until April 19, 2005. Id. ¶ 33.

Plaintiffs further allege that defendants did not inform surgeons known to have implanted the device of any fractures until December 1, 2008, when they issued a safety alert to medical professionals. <u>Id.</u> ¶ 40. This safety alert provided that defendants had "received reports of 43 modular neck failures as of November 21, 2008" and that "initial investigations have revealed several commonalities in these failures: heavyweight males, long modular necks and patient activities such as heavy lifting and impact sports." <u>Id.</u> Despite their investigations into these fractures, defendants allegedly did not issue warnings that the device should not be used in heavier patients or in patients who engage in heavy lifting or impact sports prior to August 2010. <u>Id.</u> ¶¶ 43–49. On August 25, 2009, Wright began distributing modular necks made from cobalt chrome alloy. <u>Id.</u> ¶ 50. Despite the change in materials, the devices remain "susceptible to micromotion and fretting corrosion at the neck-stem junction" and continue to fracture "from cyclic loading and metal fatigue." <u>Id.</u> ¶¶ 52–53. However, Wright did not inform patients that the device has a "higher than anticipated" rate of failure. Id. ¶ 54.

CIVIL MINUTES – GENERAL 'O'

2:17-cv-03178-CAS (KSx) Case No. Date December 3, 2018 2:17-cv-03196-CAS (KSx) JOHN BOWER V. WRIGHT MEDICAL TECHNOLOGY INC. ET AL. Title

CATHERINE PRATER V. WRIGHT MEDICAL TECHNOLOGY, INC. ET AL.

In 2014, MicroPort acquired the division of Wright responsible for designing and selling the device. Id. ¶ 59. On August 11, 2015, MicroPort announced a voluntary recall of the device implanted in Bower and Prater in the interest of "patient safety." Id. ¶¶ 60, 62. On September 28, 2015, the FDA issued a Class 1 recall of the device. Id. ¶ 64.

III. **LEGAL STANDARD**

Pursuant to Federal Rule of Civil Procedure 72(a), a party may file objections to a magistrate judge's non-dispositive order within fourteen days. The party shall file a motion for review by the assigned district judge "designating the specific portions of the ruling objected to and stating the grounds for the objection." Local Rule 72–2.1. Under this rule, the district judge will not modify or set aside a magistrate judge's ruling unless the objecting party shows that the ruling was "clearly erroneous or contrary to law." 28 U.S.C. § 626(b)(1)(A). "The 'clearly erroneous' standard applies to the magistrate judge's factual determinations and discretionary decisions, including orders imposing discovery sanctions." Computer Econ., Inc. v. Gartner Grp., Inc., 50 F. Supp. 2d 980, 983 (S.D. Cal. 1999). "A finding is 'clearly erroneous' when although there is evidence to support it, the reviewing [body] on the entire evidence is left with the definite and firm conviction that a mistake has been committed." Concrete Pipe & Prods. Of California, Inc. v. Constr. Laborers Pension Tr. for S. California, 508 U.S. 602, 623 (1993). The "contrary to law" standard allows "independent, plenary review of purely legal determinations" by the magistrate judge. Jadwin v. Cty. of Kern, No. CV-F-07-026 OWW/TAG, 2008 WL 4217742, at *1 (E.D. Cal. Sept. 11, 2008). An order is "contrary to law when it fails to apply or misapplies relevant statutes, case law, or rules of procedure." Id.

When reviewing a magistrate judge's decision concerning relevance, the standard of review is not the explicit statutory standard under § 626, but rather the "clearly implicit standard of abuse of discretion." Zakaria v. Gerber Prod. Co., No. CV 15-00200-JAK, 2016 WL 6871277, at *5 (C.D. Cal. July 1, 2016) (quoting Geophysical Sys. Corp. v. Raytheon Co., 117 F.R.D. 646, 647 (C.D. Cal. 1987)). "A magistrate abuses this discretion 'only when his decision is based on an erroneous conclusion of law or where the record contains no evidence on which he rationally could have based that decision."

CIVIL MINUTES – GENERAL 'O'

Case No.	2:17-cv-03178-CAS (KSx) 2:17-cv-03196-CAS (KSx)	Date	December 3, 2018
Title	JOHN BOWER V. WRIGHT MEDICAL T CATHERINE PRATER V. WRIGHT MED		
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Id. (quoting Premium Serv. Corp. v. Sperry & Hutchinson Co., 511 F.2d 225, 229 (9th Cir. 1975)).

IV. DISCUSSION

A. Plaintiffs' Discovery Requests

Plaintiffs moved to compel discovery related to the following five disputed issues:

- Issue #1: Documents related to fractures in the entire PROFEMUR® product line, including individual complaint files concerning all other [cobalt chrome] neck fractures, including other [cobalt chrome] long neck fractures, not just the PHAC-1254 component implanted in Plaintiffs;
- Issue # 2: Documents concerning PROFEMUR® TITANIUM LONG NECK implant device (Product No. PHAO-1254);
- Issue # 3: Documents evidencing failures in PROFEMUR® [cobalt chrome] devices, including evidence of corrosion present in any PROFEMUR® neck component, including long, short, and titanium models, including evidence related to adverse tissue reactions;
- Issue # 4: Documents relating to the failure rate of the PROFEMUR® neck line of products, including titanium and [cobalt chrome] necks, without limitation by time or specific model; and
- Issue # 5: Communications with the FDA regarding the PROFEMUR® line, including individual complaint files relating to titanium neck fracture incidents.

Order at 4 (citations omitted). The instant motion concerns the Magistrate Judge's ruling regarding the relevance and proportionality of discovery pertaining to fracture incidents occurring in the PHAO-1254 model—the titanium predecessor of the long neck device made from cobalt chrome alloy that is the subject of the instant actions. Mot. at 1. Plaintiffs contend that this discovery is relevant because the titanium and cobalt chrome long necks are substantially similar components that fractured in the same manner and in the same location, thus fractures in the titanium long neck bear on defendants' continuing duty to warn with respect to the substantially similar cobalt chrome long necks implanted

CIVIL MINUTES –	GENERAL	'O'

Case No. 2:17-cv-03178-CAS (KSx) 2:17-cv-03196-CAS (KSx) Date December 3, 2018

JOHN BOWER V. WRIGHT MEDICAL TECHNOLOGY INC. ET AL. CATHERINE PRATER V. WRIGHT MEDICAL TECHNOLOGY, INC. ET AL.

in plaintiffs, as well as defendants' alleged misrepresentations regarding the safety and efficacy of the cobalt chrome device. Mot. at 7–8. To support this theory, plaintiffs rely heavily on Dr. Snibbe's contention that he would not have implanted the cobalt chrome devices, or would have performed prophylactic revision surgeries to replace the cobalt chrome devices, if he had known that the titanium long necks were continuing to fracture at a high rate even after 2009. <u>Id.</u> at 8–9. Plaintiffs also contend that they require this discovery because they anticipate that defendants will try to introduce evidence showing that the overall fracture rate of the titanium long neck was within expected parameters through 2018. <u>Id.</u> at 9.

Defendants challenge the relevance of the titanium device because various experts, including plaintiffs' expert, have opined that the damage observed in the cobalt chrome devices is inconsistent with the damage observed in the titanium devices. Order at 7. Defendants also argue that complaints involving the titanium long neck are not relevant to plaintiffs' claims because "every modular neck failure, whether fracture-related or not, has distinguishing features that are vastly different than Plaintiffs' fracture failures with respect to causation, symptomology, and patient experiences, among other factors—particularly where those fractures involve a different modular neck component [] than the one which Plaintiffs received and is at issue in these cases []." Opp'n at 7. And despite plaintiffs' assertions to the contrary, defendants state that they do not intend to introduce evidence of the fracture rate of the titanium long neck at trial because, according to defendants, such evidence is not relevant. Id. at 12.

B. The Magistrate Judge's Order

After reviewing the parties' joint stipulation, holding a hearing that lasted over three hours, and holding an additional telephonic hearing, the Magistrate Judge granted plaintiffs' motion in part, but denied it in part, by limiting the scope of production related to the titanium device to the period of 1999 to 2009. Order at 8, 12, 13; Dkt. 85, August 22, 2018 Hearing Transcript ("Hearing"); Dkt. 87, September 7, 2018 Telephonic Conference Transcript ("Telephonic Conf."). In the Order, the Magistrate Judge applied the correct standards for relevance and proportionality under Federal Rule of Civil Procedure 26, and explained that information related to fractures of the titanium necks is relevant to plaintiffs' claims because the similarity (or dissimilarity) of the fracture patterns for the two products goes to the merits of plaintiffs' claims. Order at 7–8. The

CIVIL MINUTES – GENERAL 'O'

Case No.	2:17-cv-03178-CAS (KSx) 2:17-cv-03196-CAS (KSx)	Date	December 3, 2018	
Title	JOHN BOWER V. WRIGHT MEDICAL T	ECHNO	DLOGY INC. ET AL.	
11110	CATHERINE PRATER V. WRIGHT MEDICAL TECHNOLOGY. IN			

Court also found that production of this information would not be burdensome because the defendants had previously produced the design and regulatory files for the entire titanium neck product line and documents related to the fractures in the titanium long neck from 1999 to 2009 in <u>Sarafian v. Wright Medical Technology, Inc.</u>, Case No. CV 15-09397-CAS (KSx), and <u>Biorn v. Wright Medical Technology, Inc.</u>, Case No. CV 15-07102-CAS (KSx)—two separate but similar cases involving the same cobalt chrome device (collectively, the "Biorn/Sarafian Actions").

However, with respect to information relating to fractures in the titanium long necks that occurred *after* 2009—which the plaintiffs claimed was relevant to the issue of defendants' continuing duty to warn and representations regarding the safety of the cobalt chrome device—the Magistrate Judge found that this additional discovery was not relevant or proportional to the needs of these cases because it concerns a product that is not at issue in this case and incidents that "occurred years after the Cobalt Chrome Device replaced the Titanium Device." Order at 12–13. The Magistrate Judge similarly found that this information was not relevant or proportional with respect to plaintiffs' argument that they required this information because defendants might introduce the fracture rate of titanium long necks at trial. <u>Id.</u> at 12.

C. Analysis

In the instant motion, plaintiffs argue that the "record provides no rational basis for permitting discovery concerning pre-2009 fractures but denying discovery of post-2009 fractures of the same component." Reply at 2. But it is apparent from the face of the Order that the Magistrate Judge did not abuse her discretion when she found that plaintiffs' discovery requests concerning post-2009 fractures in the titanium long neck are neither relevant nor proportional to the needs of these cases. The rationale of the Magistrate Judge's finding is further bolstered by the transcripts of the hearing and telephonic conference, which demonstrate that the Magistrate Judge carefully considered and rejected plaintiffs' arguments with respect to the relevance of the post-2009 discovery that they sought. In direct response to plaintiffs' argument regarding notice, the Magistrate Judge explained:

There had already been incidences of the titanium fracture well before [the cobalt chrome devices were implanted], which was one of the reasons why

Page 7 of 9

CIVIL MINUTES – GENERAL Case No. 2:17-cv-03178-CAS (KSx) 2:17-cv-03196-CAS (KSx) Date December 3, 2018 Title JOHN BOWER V. WRIGHT MEDICAL TECHNOLOGY INC. ET AL. CATHERINE PRATER V. WRIGHT MEDICAL TECHNOLOGY, INC. ET AL.

the manufacturer shifted to the cobalt chrome [] so, the notice has been established here, well-established for the predecessor product. . . I'm not seeing what the more notice adds once they've already shifted to a new product and the implanted product is the one that is squarely at issue here.

Telephonic Conf. at 8:20–24. With respect to plaintiffs' argument that Dr. Snibbe would have acted differently had he known that the titanium neck was continuing to fracture, the Magistrate Judge explained that she was "not following the inferential leap" that Dr. Snibbe would have acted differently based on fracture rates of a product that was not implanted in plaintiffs. <u>Id.</u> 9:19–10:3.

As to plaintiffs' argument regarding the defendants' potential introduction at trial of the fracture rate of the titanium long neck up until 2018, the Magistrate Judge explained that "[i]t seems highly tangential to the substantive issues in the case[,]" <u>id.</u> 62:1–11, and suggested that plaintiffs' concerns could be addressed with a motion *in limine*, <u>id.</u> 47:10–14.

The Magistrate Judge carefully considered plaintiffs' discovery requests and arguments and ultimately decided that discovery related to the fractures in the titanium long neck—after it was taken off the market and replaced by the cobalt chrome long neck in 2009—was not relevant to defendants' duty to warn. The Magistrate Judge did not abuse her discretion when she rejected plaintiffs' theory that such discovery was relevant because ongoing fractures in the titanium long neck would have influenced Dr. Snibbe's decision to use the cobalt chrome device, or to later perform a prophylactic revision surgery.

And although plaintiffs speculate that defendants may attempt to introduce the fracture rate for the titanium long neck through 2018, despite the defendants' contention that they do not plan to do so, the Magistrate Judge did not abuse her discretion by declining to find that plaintiffs' requested discovery was relevant or proportional. Relevance cannot be established solely on plaintiffs' speculation that defendants may introduce certain evidence at trial, especially when defendants repeatedly deny an intention to do so. Plaintiffs' concerns on this point can be addressed through a motion *in limine*.

	CIVIL MINUTES – G	ENERAL	· U
Case No.	2:17-cv-03178-CAS (KSx)	Date	December 3, 2018
Case 140.	2:17-cv-03196-CAS (KSx)	Date	December 3, 2016
Title	JOHN BOWER V. WRIGHT MEDICA	AL TECHNO	DLOGY INC. ET AL.
CATHERINE PRATER V. WRIGHT MEDICAL TECHNOLOG		TECHNOLOGY, INC.	
	ET AL.		

CIVII MINIITES CENEDAL

The Order also presents no misunderstanding of proportionality. Faced with a record consisting of extremely broad discovery requests, spanning decades and concerning multiple products that were not implanted in plaintiffs, the Magistrate Judge carefully determined that plaintiffs' requests were not proportional and that the <u>Biorn/Sarafian</u> production would be sufficiently comprehensive with respect to any relevant information concerning the titanium long neck. Telephonic Conf. at 14:3–8.

At hearing, the plaintiffs argued that the Magistrate Judge's findings on relevance would prevent plaintiffs from pursuing any discovery regarding post-2009 titanium long neck fractures. But plaintiffs' concerns are misplaced because the Magistrate Judge's findings are based on the voluminous, overbroad discovery requests that were before her. Nothing in the Order precludes plaintiffs from pursuing narrowly tailored discovery requests regarding the titanium long neck.

V. CONCLUSION

For the foregoing reasons, plaintiffs' motion for review of Magistrate Judge Karen Stevenson's order dated September 12, 2018 is **DENIED**.

IT IS SO ORDERED.

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60