

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
ABERDEEN DIVISION

ROCKY ESTES

PLAINTIFF

V.

CAUSE NO.: 1:14CV052-SA-DAS

LANX, INC., et al.

DEFENDANTS

ORDER ON OBJECTION

Plaintiff has filed an Objection to the Magistrate Judge's Order [68] denying his Motion to Compel. In particular, the Plaintiff requested that Lanx, Inc., be required to produce all 510(k) submissions to the FDA and all customer complaint records between 2007 and 2013. The Magistrate Judge, at a recorded hearing on the matter, held that the items requested were not relevant, and there was no bad faith or dishonesty casting doubt on the corporation's determination of what was relevant due to Lanx's willingness to produce discovery not required by the Federal Rules of Civil Procedure.

Factual and Procedural Background

Plaintiff brought this medical device products liability claim against Lanx for its allegedly "negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of the Lanx Pedicle Screw." *See* Complaint [1], Mar. 20, 2014.¹ After initial disclosures and the 30(b)(6) deposition of Lanx, Plaintiff filed a Motion to Compel seeking all 510(k) filings and Lanx's entire customer complaint file. After an in-person hearing on the issue, the Magistrate Judge denied the request.

Plaintiff filed an Objection to that ruling.

¹ Plaintiff has since filed an Amended Complaint [90] adding others claims against Lanx for its "Telluride System," of which the pedicle screw at issue here was part.

Standard of Review

“A party aggrieved by a magistrate judge’s ruling may appeal the ruling to the assigned district judge.” L.U.Civ.R. 72(a)(1)(A). The Local Rules provide:

No ruling of a magistrate judge in any matter which he or she is empowered to hear and determine will be reversed, vacated, or modified on appeal unless the district judge determines that the magistrate judge’s findings of fact are clearly erroneous, or that the magistrate judge’s ruling is clearly erroneous or contrary to law.

L.U.Civ.R. 72(a)(1)(B). Similarly, 28 U.S.C. § 636(b)(1)(A) provides that “[a] judge of the court may reconsider any pretrial matter under this subparagraph (A) where it has been shown that the magistrate judge’s order is clearly erroneous or contrary to law.”

Discussion and Analysis

The FDA employs a regulatory process known as a 510(k) submission for commercial distribution of products. A 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device. Plaintiff requested “[a]ll pre-market notification applications . . . for the specific implantable orthopaedic screws in question.” Lanx provided Plaintiff with the 510(k) submission that sought clearance for the pedicle screw at issue in this case. Plaintiff contends that Lanx failed to provide the 510(k) submission for the Lanx Telluride Spinal Fixation System. Lanx contends no such document exists as the 510(k) submissions are for component parts and not for a whole system or implant.

Lanx supplemented its initial disclosure and produced all Spinal Fixation System 510(k) submissions prior to December 2011 that listed clearance for any type of pedicle screw, not only the cannulated screw which is at issue here. In reviewing that larger disclosure, Plaintiff now claims he is entitled to three other 510(k) submissions that Lanx contends are not relevant as they

are submissions for components used in the “Aspen” fusion plate device, which was not used here. Plaintiff contends he is owed the 510(k) submissions for all component parts used with the Aspen system, as two customer complaints mention that pedicle screws were used with the Aspen system. Lanx contends that the Aspen system does not use pedicle screws, and that the customer complaints reference a situation in which multiple systems were used together at the discretion of the implanting surgeon. Lanx argued at the hearing on the motion to compel that the additional 510(k) submissions requested were not relevant to Plaintiff’s claim that the Lanx pedicle screws implanted during his spinal fusion surgery were defective. Judge Sanders agreed.

After reviewing the motion to compel, submissions by the parties, transcript of the hearing, and the objections raised thereto, the Court finds that the Magistrate Judge’s ruling that the additional 510(k) submissions were not relevant to this case is not clearly erroneous or contrary to law. There is no dispute that the requested 510(k)s are submissions related to components of the Aspen Spinous Process fixation system, a system not used here. Plaintiff failed to show either to the magistrate judge by motion, or the district judge on appeal, that those 510(k)s are relevant to this case.

Likewise, the Court finds that the Magistrate Judge, in holding that the customer complaint records were not relevant was not clearly erroneous or contrary to law. Plaintiff’s Complaint alleges that the Lanx pedicle screw implanted in Plaintiff was defective. Plaintiff believes he is entitled to all customer complaints lodged between 2007 and 2013, twenty-seven of which Lanx has already produced. Lanx contends that was all the customer complaints regarding broken pedicle screws, whether they were of the type at issue in this lawsuit or not, during that period. Judge Sanders denied Plaintiff’s request for full access to the customer complaint files. Indeed, disclosure of all those customer complaints, which based on the

numbers provided by Plaintiff could be as many as eight hundred, would be overly burdensome and unlikely to yield relevant matter. The Court finds that the magistrate judge's ruling was not clearly erroneous or contrary to law.

Conclusion

Because the Magistrate Judge's denial of the motion to compel was not clearly erroneous or contrary to law, the Court affirms that decision. The Motion to Appeal the Magistrate Judge Decision [69] is DENIED.

SO ORDERED, this the 11th day of December, 2015.

/s/ Sharion Aycock
U.S. DISTRICT JUDGE