UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

LIFE SPINE, INC.,)
	Plaintiff,) No. 19 CV 7092
	i iaiiitiii,)
v.) Magistrate Judge Young B. Kim
AEGIS SPINE, INC.,))
) February 13, 2023
	Defendant.)

MEMORANDUM OPINION and ORDER

Plaintiff Life Spine, Inc. ("Life Spine") alleges in this diversity action that Defendant Aegis Spine, Inc. ("Aegis") stole confidential information and breached contractual obligations in order to develop and market the AccelFix-XT ("XT"), a medical device that directly competes with Life Spine's "flagship device," ProLift Expandable Spacer System ("ProLift"). During expert discovery, Life Spine disclosed Daniel Roffman and Robert Minkin as expert witnesses. Life Spine describes Roffman as a forensic expert who is expected to testify at trial about the reliability of XT related documents Aegis produced in discovery. Minkin is described as an expert in hospital operations, accreditation guidelines, and industry standards who is expected to testify about controls in the hospital setting precluding the public from accessing medical devices such as the ProLift. Aegis now moves to bar Roffman's and Minkin's expert opinions under Federal Rule of Evidence 702. For the following reasons, Aegis's motion is granted as to Roffman, but denied as to Minkin:

Background

The parties are both medical-device companies that develop and market "expandable cage" spinal implants, among other products.¹ (R. 494, Mem. Op. and Order at 2.) Aegis is a subsidiary of L&K Biomed Co., Ltd. ("L&K"), a South Koreabased medical device company, and several current and former high-ranking Aegis employees have worked for L&K. (Id.) Life Spine's ProLift features two key components—an implant inserted into a patient's spine during surgery and an installer used to insert and expand the implant once installed. (Id.) Aegis also distributes and sells expandable cage products, including of relevance here the XT, which it distributed and sold from September 2019 until this court enjoined its sale in March 2021. (Id.) The XT is manufactured by L&K, but Aegis claims intellectual property rights in it. (Id.) Aegis also distributes other L&K expandable cages manufactured—the AccelFix-XL ("XL") and AccelFix-XTP ("XTP"). (Id.)

During fact discovery, Aegis produced the design history file ("design file") for the XT, but the file did not explain how Aegis developed the XT's dovetail feature, which appears to be nearly identical to the ProLift's dovetail. (R. 456, Pl.'s Opp. Br. at 2.) Life Spine then moved to compel Aegis to produce the design files for the XL and XTP, (R. 292, Pl.'s Mot. to Compel), and the court granted the motion, finding that Life Spine's "need for more information to investigate whether its technology was used in the designs of XL and XTP outweighs the burden of production on Aegis

¹ The court issued a memorandum opinion and order addressing the parties' cross motions for partial summary judgment, which sets forth in greater detail the facts of this case. (R. 494, Mem. Op. and Order.)

and L&K," (R. 330, Mem. Op. and Order at 12). Thereafter, Aegis produced the design files "as a single PDF," (see R. 416, Order (internal quotations and citation omitted)), and Life Spine moved to compel Aegis to produce forensic images and native files for the design files, (R. 400, Pl.'s Mot. to Compel). The court denied the motion as untimely because fact discovery closed before Life Spine filed its motion. (R. 416, Order.) But the court ordered Aegis "to re-produce the files 'as they are kept in the usual course of business" to ensure that if the design files "include separate PDF documents and not one single PDF document," Life Spine would have access to the "unique properties, including the creation date" for the documents. (Id.)

Aegis responded by producing files that included pages showing how an L&K engineer purportedly "inferred' the precise designs and dimensions of the [XT] dovetail in one day from two Opticage patent drawings." (R. 456, Pl.'s Opp. Br. at 2.) Life Spine contests the authenticity of the pages, which it refers to as the "Suspect Documents" (referred to here as "XL/XTP Pages"). (Id.) To address this authenticity issue at trial, Life Spine retained Roffman, "an expert in investigating suspect documents produced in litigation," to testify regarding the reliability of the XL/XTP Pages. (Id.)

The parties also dispute the extent to which Life Spine has maintained the confidentiality of the ProLift. Life Spine alleges that it has "tightly controlled and concealed from the general public" technical details related to the ProLift—and that this confidential information constitutes trade secrets. (Id. at 9.) Conversely, Aegis argues that key details regarding the ProLift were publicly available and, therefore,

not protectable. (R. 127, Def.'s Resp. to Prelim. Inj. Mot. at 10-11.) Life Spine retained Minkin, "an expert in the operation of acute hospitals," (R. 420, Def.'s Mot. Ex. 3 at 2), to opine on whether the type of information allegedly taken by Aegis was "closely held, controlled, and not readily available to the public in hospital settings," (R. 456, Pl.'s Opp. Br. at 9).

Analysis

Aegis seeks to exclude Roffman's and Minkin's opinions, arguing that neither expert performed work that applies sound principles or methodology to facts of this case, rendering their "bottom line" opinions inadmissible under Rule 702. (R. 420, Def.'s Mot. at 2.) A district court enjoys "broad latitude" in determining the admissibility of expert opinions, *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 142 (1999), provided that the court applies the legal framework set forth in Federal Rule of Evidence 702, *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 430-31 (7th Cir. 2013). Rule 702 permits testimony from a qualified expert if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

See Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 589-91 (1993). In short, a proposed expert must be qualified, and the expert's testimony must be "relevant and reliable." Kumho Tire, 526 U.S. at 141. The expert's proponent bears the burden of

showing that the expert's opinions satisfy Rule 702. See Lewis v. Citgo Petroleum Corp., 561 F.3d 698, 705 (7th Cir. 2009).

To meet the relevance requirement, the expert's testimony must "assist the trier of fact with its analysis of any of the issues involved in the case." Smith v. Ford Motor Co., 215 F.3d 713, 718 (7th Cir. 2000). To establish reliability, the expert's opinion must be based in the knowledge and experience of the applicable discipline. See Kumho Tire, 526 U.S. at 149. In this regard, courts may consider whether the theory: "can be (and has been) tested"; "has been subjected to peer review and publication"; "has a known potential rate of error"; and is "generally accepted in the relevant scientific community." Schultz, 721 F.3d at 431 (citing Daubert, 509 U.S. at 593-94). "[T]he key to the gate [for expert testimony] is not the ultimate correctness of the expert's conclusions." Id. Rather, "it is the soundness and care with which the expert arrived at her opinion," focusing "solely on principles and methodology, not on the conclusions they generate." *Id.* (quoting *Daubert*, 509 U.S. at 595). If the expert's methodology is reliable, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Daubert, 509 U.S. at 596).

A. Roffman

Although Roffman is an expert in digital forensic examinations, Aegis moves to bar his testimony because he has not performed any such analysis in this case. (R. 420, Def.'s Mot. at 2.) Aegis represents that Life Spine had planned to use Roffman

to perform a forensic examination of the XL/XTP design files stored on computer systems at L&K but did not do so because the court denied Life Spine's request for forensic images and native files. (Id. at 3 (citing R. 416, Order).) Without any forensic analysis relating to facts or data at issue, Aegis argues that Roffman "has no relevant expert testimony to offer at trial," and his report amounts to nothing more than "rank speculation." (Id.) Life Spine responds that should Aegis seek to introduce the XL/XTP Pages as evidence at trial, Roffman can offer expert testimony to guide the jury in assessing the reliability of and weight that should be accorded to those pages. (R. 456, Pl.'s Opp. Br. at 2.)

In his June 17, 2022 expert report, Roffman opines that based on his forensics experience and review of certain documents, "there are legitimate reasons to question the authenticity of" the XL/XTP Pages and, therefore, "it is not possible to say that the documents are what they purport to be or were created on the dates reflected on the face of the documents." (R. 420, Def.'s Mot. Ex. 1 at 4, 11.) In forming his opinions, Roffman reviewed certain Aegis and L&K documents, court orders, correspondence between the parties' attorneys, and reports from Life Spine's medical device expert, John Ashley. (Id. at 23.) Roffman supports his opinions with the following observations: (1) Aegis did not produce the XL/XTP Pages until after the court remarked at the preliminary injunction hearing that the XT design file did not explain how the design team created the device's dovetail; (2) Ashley questioned the authenticity of the XL/XTP Pages; (3) Aegis could not explain why the XL/XTP Pages refer to a Life Spine device that had not been publicly disclosed; (4) Aegis disclosed

that it deleted some information in the XL/XTP design files while this action was pending; and (5) Aegis declined Life Spine's request for a forensic examination of the relevant data. (Id. at 4-11; see also R. 456, Pl.'s Opp. Br. at 3.)

In seeking to exclude Roffman's opinions, Aegis does not attack his qualifications as a forensic expert. Roffman has more than 20 years of experience in digital forensics and security consulting, having worked in digital forensics at FTI Consulting and the United States Department of Justice. (R. 420, Def.'s Mot. Ex. 1 at 2 & App. A at 20-21.) Aegis instead challenges Roffman's opinions on relevance and reliability grounds, arguing that he lacks sufficient facts or data or reliable methodology to opine on the authenticity of the XL/XTP Pages because he "has done no [forensic] examination or analysis" in this case. (Id. at 3.) For support Aegis cites Roffman's deposition testimony in which he concedes that he requested "electronic documents" but did not receive them, "[s]o there was no way that [he] could then authenticate or not these documents." (Id. Ex. 2 at 45.)

Starting with Aegis's relevance objection, the court examines whether Roffman's opinions will "assist the trier of fact with its analysis of any of the issues involved in the case." *Smith*, 215 F.3d at 718. In the court's view, it will not. For starters, Roffman observes that another Life Spine expert—Ashley—compared the ProLift's and XT's dovetails and concluded that Aegis's design team "copied the design and functionality of ProLift in creating [the XT]." (R. 420, Def.'s Mot. Ex. 1 at 4-5.) Roffman relies on that testimony, along with Ashley's finding that the XT design file does not describe how the dovetail was conceived for that device, to conclude that

Aegis attempted to explain the XT's dovetail design only after the court compelled the production of the XL/XTP design files. (Id.) Based on this "sequence" of events, Roffman opines that "[i]n [his] experience, parties in litigation sometimes fabricate or falsify documents to serve as evidence on issues they know to be in dispute." (Id. Ex. 1 at 4-6.) But in doing so, Roffman exceeds the scope of permissible testimony under Rule 702.

First, Roffman does not ground his testimony in any expertise relating to his relevant discipline of digital forensics. *See Kumho Tire*, 526 U.S. at 149. Although Life Spine tries to expand the breadth of Roffman's knowledge by referring to him as "an expert in investigating suspect documents produced in litigation," (R. 456, Pl.'s Opp. Br. at 2), here he did not apply any specialized knowledge to support his opinion that "there are legitimate reasons to question the authenticity" of the XL/XTP Pages, (R. 420, Def.'s Mot. Ex. 1 at 4). Life Spine nevertheless asserts that Roffman's opinions "would assist the trier of fact in determining whether to conclude that [the XL/XTP Pages] are reliable and/or how much weight to give them (if any) in reaching a verdict." (Id.) But that inquiry is reserved for the jury. To be sure, it is "the jury's function to weigh evidence and make credibility determinations." *Davis v. Duran*, 277 F.R.D. 362, 370 (N.D. Ill. 2011).

Second, to the extent Roffman seeks to bolster Ashley's findings, Roffman cannot "serve as the mouthpiece for another expert." *Zollicoffer v. Gold Standard Baking, Inc.*, 335 F.R.D. 126, 149 (N.D. Ill. 2020). Whereas Ashley exercised his professional judgment as a medical device developer in comparing the ProLift's and

XT's design and functionality and analyzing Aegis's attempt to explain the XT's dovetail, Roffman simply adopts those findings to contest the authenticity of the XL/XTP Pages. (R. 420, Def.'s Mot. Ex. 1 at 2-3.) Because Roffman has no expertise in engineering or design matters, he "lacks the necessary expertise to determine whether the techniques were appropriately chosen and applied" by Ashley. *Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 615 (7th Cir. 2002); see also Cnty. of Cook, Ill. v. Wells Fargo & Co., No. 14 CV 9548, 2022 WL 17752387, at *4 (N.D. Ill. Dec. 19, 2022). As such, Rule 702 precludes Roffman from testifying at trial about Ashley's opinions and how they purportedly shed light on the authenticity of the XL/XTP Pages.

Third, Roffman makes further observations that run afoul of Rule 702. For example, Roffman disputes the authenticity of the XL/XTP Pages based on "evidence that Aegis deleted some of the files" related to the XL/XTP design files. (R. 420, Def.'s Mot. at 7 & Ex. 1 at 7.) In his deposition, however, Roffman testified that he had no knowledge as to what, if anything, was actually deleted. (Id. Ex. 2 at 78-79.) As a result, he lacks the proper foundation to form any opinions on the authenticity issue. Roffman likewise indicates his understanding that the XL design file included a document referring to a Life Spine product that had not been publicly cleared for marketing and sale. (Id. Ex. 1 at 6-7.) But as Aegis correctly points out, Roffman offers nothing "expert" on this issue, and "the jury can readily assess the facts for itself." (R. 467, Def.'s Reply at 4-5 (internal quotations omitted).)

Fourth, for Roffman's opinions to be reliable, they must be grounded in his area of expertise—digital forensics—but in this case he did not examine any digital files or native images. (Id. Ex. 1 at 2-3); see also Kumho Tire, 526 U.S. at 149. Further troubling is Aegis's contention that Roffman based his opinions on a select set of documents shared with him by Life Spine's attorneys, such as Ashley's reports and XL/XTP design files, without reviewing records reflecting contrary views, such as reports from Aegis's experts who disagreed with Ashley or testimony from the individual who authored the XL/XTP Pages. (R. 420, Def.'s Mot. at 5-6.) Under these circumstances, the court cannot say that Roffman arrived at his opinions based on a methodology of "soundness and care." Schultz, 721 F.3d at 431. Thus, even though Roffman "possesses the requisite qualifications" for forensic examination, Kirk v. Clark Equip. Co., 991 F.3d 865, 873 (7th Cir. 2021), he did not apply that expertise in formulating his opinions, and his methodology cannot withstand Rule 702 scrutiny, 2 see United States v. Hall, 93 F.3d 1337, 1343 (7th Cir. 1996).

B. Minkin

Aegis also seeks to exclude Minkin's opinions, arguing that like Roffman, Minkin does not rely on sufficient facts or reliable methodology. (R. 420, Def.'s Mot. at 8-13.) In support of its lack of relevance argument, Aegis contends that "[t]he

² Having so ruled, the court does not rule on the admissibility of the XL/XTP Pages at trial. As the court previously noted, "the question about the authenticity of [the XL/XTP Pages] may surface again in the context of admissibility of certain documents as evidence" and "[w]hether the issue of authenticity resurfaces will depend largely on who plans on offering [the XL/XTP Pages] into evidence." (R. 416, Order (inviting Life Spine to "raise its authenticity challenge" in motion in limine).)

policies and procedures that Minkin outlines are not created or enforced with the goal of protecting a company's property rights—the issue at the heart of this case." (Id. at 8.) And according to Aegis, Minkin's methodology fails the reliability standard because he has no personal experience with any processes or measures taken to secure ProLift. (Id. at 9-13.) Life Spine responds that Minkin's testimony counters Aegis's claims that details related to ProLift were "freely available." (R. 456, Pl.'s Opp. Br. at 9.)

Minkin offers the following opinions in his June 17, 2022 expert report:

Hospitals tightly control the process of handling, storing, and securing implantable medical devices in their facilities.

Any claim that open access exists to such devices in a hospital, especially in the OR, Implantable Device Secure Cabinet, or Central Processing areas, is uninformed and does not reflect the controls that are in place at hospitals as a matter of typical business operations.

A medical device manufacturer can be confident that protections and processes described above are in place and followed as a matter of business and clinical operation at a given acute care hospital or surgical center. Given the clinical, financial, and legal liability placed on a hospital while in possession of implantable devices, the processes I have described herein are industry standard.

(R. 420, Def.'s Mot. Ex. 3 at 8-9.)

As was the case with Roffman, Aegis does not contest Minkin's qualifications. Minkin was a former hospital executive and consultant on hospital policies, procedures, and standards relating to medical devices in the acute care hospital setting. (Id. at 8-13.) In his expert report, Minkin represents that he has served in various "senior leadership roles at multiple hospitals" and at "a national healthcare consulting firm." (Id. Ex. 3 at 2.) He also has earned the "Fellowship (FACHE)

distinction" from the American College of Healthcare Executives. (Id.) Based on this professional experience in healthcare management, along with training and education, Minkin states that he is qualified to opine on how acute care hospitals "manage, secure, store, handle, and . . . [maintain] the chain of custody of medical devices used in patient care, specifically regarding spinal implantable devices and accompanying instrumentation." (Id.)

Rather than challenging Minkin's qualifications, Aegis calls into question the relevance and reliability of his opinions. As to relevance, Aegis asserts that none of Minkin's opinions will assist the trier of fact with analyzing any issues because the applicable hospital policies and procedures "are not created or enforced with the goal of protecting a company's intellectual property rights," but rather to ensure "patient safety [and] sterility." (Id. at 8.) Maybe so. But the purpose of such policies and procedures does not negate their effect, which Minkin indicates is the "tight[] control" of medical devices in acute care hospitals. (Id. Ex. 3 at 3.) Here, the confidentiality of Life Spine's alleged trade secrets relating to ProLift is a key issue to be determined at trial. Minkin's expert testimony regarding hospital storage and handling measures, as well as incentives to restrict and track access to such devices, may help the jury understand typical hospital procedures and operations in this regard—and ultimately shed light on whether ProLift, or technical details relating to the same, were readily available to the public. (R. 456, Pl.'s Opp. Br. at 9-10); see also Fed. R. Evid. 702. As such, Minkin's testimony is relevant.

Aegis next contests the reliability of Minkin's methodology, arguing that "his own limited, personal experiences" in hospital management "at the few hospitals where he worked" do not make him an expert on how surgical assistants, operating room technicians, hospital storeroom workers, security personnel, or others within the hospital setting operate. (R. 420, Def.'s Mot. at 9-10.) Without personally experiencing each position within the chain of custody that a medical device may follow—or better yet "survey[ing]" these workers or Life Spine's own personnel, Minkin's testimony lacks the requisite soundness and care to satisfy Rule 702's reliability requirement, Aegis argues. (Id. at 10, 13.) In short, Aegis attacks Minkin's testimony on the basis that he lacks personal knowledge as to what actually occurred at the hospitals that use ProLift and whether those facilities ever deviate from standard practices and procedures and permitted public access to ProLift. (Id. at 10-13.)

As Life Spine notes in its opposition, in formulating his opinions, Minkin relied on "practices and procedures that are standard in hospitals across the United States," which in turn are "based on *national* accreditation guidelines and licensing standards." (R. 456, Pl.'s Opp. Br. at 11-15 (emphasis in original).) Because "all U.S. hospitals are required to seek accreditation and licensing," Minkin did not need to investigate each hospital that sold ProLift to ensure it controlled these devices. (Id. at 12.) And while "some variation" no doubt occurs in some hospital settings, (R. 420, Def.'s Mot. at 11), Life Spine contends that Minkin adequately explains why "slightly varying methods" do not undermine his opinions, (id. at 12 (citing id. Ex. 3 at 8).)

The court agrees with Life Spine. Whether Minkin's expert testimony is

"ultimate[ly] correct[]" is not "the key to the gate." Schultz, 721 F.3d at 431. What

matters is whether Minkin used "soundness and care" in reaching his opinions. *Id*.

The court finds that he did. To the extent that Aegis disagrees, it may engage in

"[v]igorous cross-examination, presentation of contrary evidence, and careful

instruction on the burden of proof' to challenge Minkin's conclusions. *Id.* It simply

is not this court's role as gatekeeper "to assess the evidence itself" or the correctness

of Minkin's assumptions or conclusions. Fletcher v. Doig, 196 F. Supp. 3d 817, 824

(N.D. Ill. 2016) (quoting Kawasaki Kisen Kaisha, Ltd. v. Plano Molding Co., 782 F.3d

353, 360 (7th Cir. 2015)). Accordingly, the court declines to exclude Minkin's

opinions.

Conclusion

For the foregoing reasons, Aegis's motion is granted as to Roffman, but denied

as to Minkin.

ENTER:

Yoyng B. Kim

United States Magistrate Judge

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