UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

| LIFE SPINE, INC., | |) |
|--------------------|------------|---------------------------------|
| , , | |) No. 19 CV 7092 |
| | Plaintiff, |) |
| | |) |
| V. | |) Magistrate Judge Young B. Kim |
| | |) |
| AEGIS SPINE, INC., | |) |
| | |) March 15, 2021 |
| | Defendant. |) |

MEMORANDUM OPINION and ORDER

Life Spine, Inc. ("Life Spine") brings this lawsuit pursuant to the court's diversity jurisdiction against Aegis Spine, Inc. ("Aegis"), a former distributor of one of its proprietary surgical devices, alleging that Aegis used its access to Life Spine's confidential and trade secret information to create knock-off surgical devices that compete directly with Life Spine's products in violation of its legal obligations. Before this court is Life Spine's motion for a preliminary injunction, in which it seeks an order preventing Aegis from developing, manufacturing, marketing, distributing, or selling its competing line of surgical devices pending trial. (R. 122.) For the following reasons, the motion is granted:

Procedural History

Life Spine brought this action on October 28, 2019, and six weeks later the parties consented to this court's jurisdiction. See 28 U.S.C. § 636(c); (R. 1; R. 43). Shortly thereafter Life Spine filed its amended complaint, alleging that Aegis had breached three separate contracts, violated federal and state trade secrets laws,



breached its fiduciary duties, engaged in acts of fraud and misrepresentation, and committed conversion. Life Spine also seeks a declaratory judgment holding that Aegis's line of competing surgical devices belongs to Life Spine. (R. 45.) Aegis moved to dismiss seven of the amended complaint's thirteen counts. (R. 46.)

On March 17, 2020, this court granted Aegis's motion to dismiss in part, dismissing two counts alleging breach of the parties' Loaner and Confidentiality Agreements, after concluding that the parties' subsequent Distribution and Billing Agreement ("DBA") replaced those agreements. (R. 70, Mem. Op. at 6-10.) The court also limited the scope of Counts VI (fraudulent misrepresentation) and VIII (fraudulent inducement) to the five alleged fraudulent statements identified in the opinion. (Id. at 18-21.) In all other respects, the court denied the motion to dismiss.

After engaging in several months of preliminary injunction discovery, Life Spine filed its motion for a preliminary injunction on August 28, 2020. (R. 114.) After the motion was fully briefed, the court held a nine-day hearing ending on November 3, 2020, at which eleven witnesses, including one expert witness, testified. The parties also submitted numerous exhibits in support of their positions, including designated deposition excerpts from an additional four witnesses, as well as dueling, post-hearing proposed findings of fact and conclusions of law. Based on the testimony and documentary evidence presented at the hearing, the court makes the following findings:

¹ Because of travel and facility restrictions related to the COVID-19 pandemic, the hearing took place by video.



Facts

"When a motion for preliminary injunction is presented to a court in advance of hearing on the merits, [the court] is called upon to exercise its discretion upon the basis of a series of estimates." *Arjo, Inc. v. Handicare USA, Inc.*, No. 18 CV 2554, 2018 WL 5298527, at *1 (N.D. Ill. Oct. 25, 2018) (internal quotation and citation omitted). The court's factual findings at this stage are inherently preliminary and may be modified after a trial on the merits. *Id.*; *see Tech. Pub. Co. v. Lebhar-Friedman, Inc.*, 729 F.2d 1136, 1139 (7th Cir. 1984) ("A factual finding made in connection with a preliminary injunction is not binding on the court in the trial on the merits[.]"). With that in mind, the court provides the following factual recitation pursuant to Federal Rules of Civil Procedure 52(a)(2) and 65. This statement of facts is based on the testimony and evidence presented at the hearing, and where necessary, the court's assessment of witnesses' credibility.

A. Life Spine's ProLift Expandable Cage

Life Spine is a company based in Huntley, Illinois, that designs, develops, and sells medical devices that are surgically implanted for the treatment of spine disorders. (Tr.² 54-56.) Life Spine's best-selling device is the ProLift Expandable Spacer System ("ProLift"), which is made up of a small implant—more commonly referred to as a "cage" in the industry—and an installer. (Tr. 55, 60-61, 64-66.) The ProLift cage is designed to be inserted into the spine of patients suffering from

² All citations to "Tr." in this opinion refer to the transcript from the preliminary injunction hearing or designated deposition transcripts that were entered into evidence. "PX" refers to Plaintiff's exhibits and "DX" refers to Defendant's exhibits.



degenerative disc disease. The ProLift installer attaches to the ProLift cage and is used to insert the cage into the patient's spine and then expand the cage to restore spinal disk height. (Tr. 64-66.) Expandable cages like the ProLift represent a significant advancement from static cages, which maintain a fixed height, because expandable cages reduce the amount of trauma in a patient's tissue, shorten the duration of surgery, and reduce the patient's recovery time. (Tr. 61-64, 262.)

Life Spine spent more than three years designing and developing the ProLift, beginning in late 2012 and ultimately receiving 510(k) clearance from the FDA to market the cage in March 2016.³ (Tr. 69, 88, 568-69; DX 14.) The development process took more than three years from design to regulatory clearance because expandable cages are complex devices comprised of multiple small components and requiring precise engineering to ensure that they maintain their strength and integrity over the course of potentially decades of intense spinal pressure. (Tr. 69-70, 1184.) Life Spine engineers started the ProLift design process by studying publicly available information about existing expandable cages through the internet. Life Spine engineers also studied existing patents, which typically include drawings showing a device's features and components. (Tr. 555, 558-59.) Several of the patents for expandable cages show devices that feature an upper endplate, lower endplate, base ramp, nose ramp, and screw that is used to expand the cage,

³ Before a company can introduce a new medical device into interstate commerce it must seek clearance from the FDA. The 510(k)-approval process allows a company to gain that clearance by showing that its device is "substantially equivalent" to an already-approved predicate device out in the market. See 21 U.S.C. § 360(k); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996).



and Life Spine included these same features in its design of the ProLift. (Tr. 557-58, 561-62.)

After reviewing public information about existing expandable cages, Life Spine's engineering team embarked on a process of trial and error to ensure the device could meet FDA-required performance standards. (Tr. 581-82; DX 86 at 17998.) The process resulted in multiple redesigns after failed testing to adjust the device's components and subcomponents, sometimes by mere fractions of millimeters, to ensure those components interacted in a way that produced a high-quality device that could meet FDA testing requirements. (Tr. 627-28, 1476-77.) The design history file⁴ for the ProLift includes about 30 sets of engineering drawings reflecting each modification made to the device over time. (Tr. 626.) In November 2015 Life Spine applied to the FDA for 510(k) approval for the ProLift, listing two predicate devices designed by other companies. (DX 92; DX 93.) The FDA approved its application in March 2016. (DX 14.)

Life Spine maintains protections to prevent what it considers to be trade secrets and confidential information related to the ProLift design from being discovered or made public. In particular, Life Spine considers the precise dimensions and measurements of the ProLift components and subcomponents and their interconnectivity to be trade secrets. Those specifications can only be discovered by a third party if that third party has unfettered access to both the ProLift and specialized measurement equipment. (Tr. 159-60, 1449, 1453-54, 1460-

⁴ A design history file captures and categorizes all changes made to a device over the course of the development process. (Tr. 626.)



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