IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

JOSEPH D. STERN,	
Plaintiff, v.	Civil Action No. 1:16-cv-00091-RGA
GLOBUS MEDICAL, INC.,	
Defendant.	

MEMORANDUM OPINION

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Presently before the Court are Plaintiff's Motion for Summary Judgment of Infringement (D.I. 65) and Defendant's Motion for Summary Judgment of Non-Infringement Based on Offer for Sale (D.I. 69). The parties have fully briefed the issues. (D.I. 66, 70, 74, 75, 78, 79). The Court held oral argument on September 11, 2018. (D.I. 84 ("Tr.")). For the reasons set forth below, I grant Defendant's Motion for Summary Judgment of Non-Infringement Based on Offer for Sale and dismiss Plaintiff's Motion of Summary Judgment of Infringement as moot.

I. BACKGROUND

On February 17, 2016, Joseph D. Stern filed suit against Globus Medical, Inc. alleging infringement of U.S. Patent Nos. 8,556,895 (the "'895 Patent"), 8,858,556 (the "'556 Patent"), and 9,095,381 (the "'381 Patent"). (D.I. 1). On August 8, 2016, Defendant filed an Answer and Counterclaim for Declaratory Judgment of Non-Infringement and Invalidity. (D.I. 12). On March 27, 2017, Plaintiff stipulated to dismissal of the '381 Patent, leaving the '895 and '556 Patents in the case. (D.I. 40). This Court ordered briefing for early summary judgment on the issue of offer for sale on August 21, 2017. (D.I. 57). Claim construction was complete on August 29, 2017. (D.I. 61).

The remaining patents-in-suit share a common specification. They claim cervical plating systems and methods of cervical fusion using these systems. For purposes of infringement based on offer for sale, the following claim of the '895 Patent is representative:

1. An anterior cervical plating system comprising:

at least one pre-positioned cervical plate defining a cervical plate body having a lower horizontal face configured to be disposed adjacent a first vertebral body and an upper horizontal face opposite said fewer horizontal face, and having at least a first vertebral anchoring mechanism configured to attach to the first vertebral body and at least one interlocking portion arranged on the cervical plate body along a longitudinal axis thereof;

at least one revision cervical plate defining a revision plate body having at least a second vertebral anchoring mechanism configured to attach to a second vertebral body and at least one armature extending from the revision plate body along a longitudinal axis thereof, the at least one armature having a cooperative interlocking portion disposed thereon;

wherein the at least one cooperative interlocking portion of the revision plate is configured to cooperatively engage the at least one interlocking portion of the pre-positioned cervical plate to provide a stabilizing interconnection between adjacent pre-positioned cervical plate and the revision cervical plates, the stabilizing interconnection being capable of resisting movement of the adjacent cervical plates in at least one dimension;

wherein the cooperative interlocking portion of the revision cervical plate is configured such that it initially engages the interlocking portion of the pre-positioned cervical plate from above the upper horizontal face of the pre-positioned cervical plate;

wherein no threaded connector is inserted through or between any portion of the at least one armature in forming and permanently securing the stabilizing interconnection between the interlocking portion of the prepositioned cervical plate and the cooperative interlocking portion of the revision plate; and

wherein the cooperative interlocking portion of the revision plate does not directly anchor into the first vertebral body or the second vertebral body when the stabilizing interconnection is made.

('895 Patent, claim 1).

Defendant Globus markets and sells the component parts of the accused XTEND Anterior Cervical Plate System ("the System") for treatment of degenerative diseases of the spine. (D.I. 70 at 4). A surgeon implants the System in a patient's spine to immobilize two or more vertebral bodies. (*Id.*). Globus's marketing materials depict the System and provide instructions for its implantation. (*Id.*; *see also* D.I. 70-1, Exhs. F, G). Globus sells its product line, including the component parts of the System, to hospitals and surgical centers. (D.I. 70 at 5; *see also* D.I. 70-1, Exh. H). A patient in need of the System undergoes a first surgery to

implant an XTEND Primary plate and, when needed, a second "revision" surgery to implant an XTEND Extender plate. (See D.I. 70 at 5; Tr. at 24).

II. LEGAL STANDARD

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). Material facts are those "that could affect the outcome" of the proceeding, and "a dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party." *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). The moving party may discharge its burden pointing out to the district court that there is an absence of evidence supporting the non-moving party's case. *Celotex*, 477 U.S. at 323.

The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986); *Williams v. Borough of West Chester, Pa.*, 891 F.2d 458, 460-61 (3d Cir. 1989). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence . . . of a genuine dispute" Fed. R. Civ. P. 56(c)(1).

When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable

inferences in that party's favor. *Scott v. Harris*, 550 U.S. 372, 380 (2007); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). A dispute is "genuine" only if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson*, 477 U.S. at 247-49. If the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex*, 477 U.S. at 322.

III. DISCUSSION

A. Defendant's Motion for Summary Judgment

Defendant seeks summary judgment of non-infringement based on Defendant's alleged offer to sell Plaintiff's patented system. (D.I. 69). The motion is a limited one. It only concerns direct infringement. It does not address indirect infringement. The motion raises two issues: (1) there is no "offer for sale" because what Defendant offered does not directly infringe; and (2) there is no "offer for sale" because there is no price connected to the infringing system and thereby there is no "commercial offer for sale."

1. "Pre-Positioned Cervical Plate"

The relevant claims of the patents-in-suit require, among other things, a "pre-positioned cervical plate." The parties agreed to a construction of "pre-positioned" as "pre-installed." (D.I. 61 at 2). The parties do not agree, however, that the patent claim requires that the "pre-positioned" plate be affixed to a human spine. Plaintiff argues the "pre-positioned" language in the claim is merely to distinguish that plate from the "revision plate." (Tr. at 5). Defendant strongly disagrees, arguing, "What is . . . claimed . . . is installation into a person, into a vertebral body that's made of bone." (*Id.* at 26).

When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc).

The Patents' specification strongly supports Defendant's position that the claims require a pre-installed plate that is implanted on a vertebral body. Evidence that the inventor expected the system to build off an already implanted plate begins in the Patents' abstracts: "[A] new cervical plate can be interconnected with a pre-existing plate during revision surgery without removal of the pre-existing plate." ('895 Patent, Abstract (emphasis added)). This theme is carried throughout the specification. (See e.g., id. at 5:52-53 ("the pre-installed plate (10), which has previously been affixed to the anterior cervical spine"); Id. at 8:11-14 ("All these locking mechanisms have the advantage that they could be added after the new plate has been positioned, and do not need to be pre-installed on the old plate."); Id. at 12:31-33 ("[S]table revision of the plates may be undertaken without necessitating the removal of any pre-installed plates."); Id. at 13:21-23 ("it should be understood that the same system of providing a stable linkage without disturbing the fixation of the pre-positioned plate . . ."). Considering these repeated references to a previously implanted plate, the Inventor's understanding of his invention could hardly be clearer. Thus, I agree with Defendant and find that "pre-positioned cervical plate" means "cervical plate pre-installed on a vertebral body."

¹ Plaintiff stated at oral argument that the specification uses "pre-positioned plate," "pre-installed plate," "existing plate," "old plate," and "original plate" interchangeably. (Tr. at 5).

2. Infringement

A patent is infringed when a person "without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent" 35

U.S.C. § 271(a). "To prove direct infringement, the plaintiff must establish by a preponderance of the evidence that one or more claims of the patent read on the accused [system] literally or under the doctrine of equivalents." *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1310 (Fed. Cir. 2005). For a sale of a system to literally infringe, the accused infringer must sell each component of the system in accordance with the claims. *Id.* Moreover, the system "must meet all of the [claim's] structural limitations." *See id.* at 1311-12 (finding no infringement prior to installation of a medical device on a spine). If a completed sale would not infringe a patent, then an offer to make the same sale does not infringe. *See Rotec Indus., Inc. v. Mitsubishi Corp.*, 215 F.3d 1246, 1252 & n.2 (Fed. Cir. 2000) ("[O]ne may not be held liable under § 271(a) for . . . 'selling' less than a complete invention.").

Defendant did not make any infringing sales or offers. The undisputed record shows that Defendant sold only unaffixed XTEND Primary plates. There is no indication that Defendant sold pre-installed Primary plates. That is, there is no indication that defendant sold a Primary plate and the accompanying spine. Therefore, Defendant did not sell a "pre-installed cervical plate" within the meaning of the claims and did not infringe the Patents via a sale. Moreover, Defendants did not offer to sell all the components of an infringing system. A review of Defendant's advertising material quickly reveals that Defendant was not offering to sell plates pre-installed to human spines. The product list is equally clear—Defendant was offering to sell only the hardware. Therefore, even assuming Defendant offered to sell all the hardware necessary to make an infringing system and provided instructions on how to build an infringing

system, any completed sale would have fallen short of infringement. The items sold would not have included the spine, a structure required by the claims. *See Cross Med. Prods.*, 424 F.3d at 1311-12. Because a completed sale of Defendant's System did not and would not infringe Plaintiff's Patents, any offer to make that same sale did not infringe. Thus, I find that Defendant is not liable for infringement based on an offer to sell theory.

3. Commercial Offer for Sale

Because I find that Defendant's alleged offer does not infringe the '895 Patent or the '556 Patent, I need not address Defendant's second argument for summary judgment. Thus, I do not address whether Defendant made a commercial offer to sell the accused system.

B. Plaintiff's Motion for Summary Judgment

Because I have granted Defendant's motion for summary judgment of non-infringement,
Plaintiff's cross-motion for summary judgment on the same issue is moot. I therefore will
dismiss it as moot.

IV. CONCLUSION

Defendant's Motion for Summary Judgment is granted. Plaintiff's motion for summary judgment is dismissed as moot.

An order consistent with this opinion will follow.