IN THE UNITED STATES DISTRICT COURT WESTERN DISTRICT OF TENNESSEE WESTERN DIVISION

AVANOS MEDICAL SALES, LLC,)
Plaintiff,)) No. 2:19-cv-02754-JPM-tmp
V.	
MEDTRONIC SOFAMOR DANEK USA,)
INC., MEDTRONIC, INC., and	
MEDTRONIC USA, INC.,)
Defendants.)

ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT AND DENYING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Before the Court is Plaintiff Avanos Medical Sales, LLC's ("Avanos") Motion for Partial Summary Judgment, filed on July 21, 2021. (ECF No. 205.) Also before the Court is Defendants Medtronic Sofamor Danek USA, Inc., Medtronic, Inc., and Medtronic USA, Inc.'s (collectively "Medtronic") Motion for Summary Judgment, filed on July 21, 2021. (ECF No. 207.)

For the reasons stated below, the Court **GRANTS** Plaintiff's Motion for Partial Summary Judgment on the Defense of Unclean Hands and **DENIES AS MOOT** Plaintiff's Motion for Partial Summary Judgment as to all other defenses. The Court **DENIES** Defendants' Motion for Summary Judgment on Non-Infringement and Willful Infringement. The Court **DENIES AS MOOT** Defendants' Motion for Summary Judgment on Non-Infringement of Claim 21; Non-Infringement under Doctrine of Equivalents; Pre-Suit Damages;

and Lost Profits Prior to November 1, 2019. The issues of infringement and willful infringement remain before the trier of fact.

I. BACKGROUND

a. Procedural Background

On July 21, 2021, Avanos filed its Motion for Partial Summary Judgment (ECF No. 205), and Medtronic filed its Motion for Summary Judgment (ECF No. 207). On August 18, 2021, Medtronic filed its Response in Opposition to Avanos's Motion. (ECF No. 218.) Avanos filed its Response in Opposition to Medtronic's Motion on August 20, 2021. (ECF No. 223.) Avanos filed its Reply to Medtronic's Response on September 1, 2021. (ECF No. 237.) Medtronic filed a Supplement to its Memorandum in Support of its Motion for Summary Judgment on September 9, 2021. (ECF No. 252.) On September 10, Avanos filed a Supplement to its Opposition to Medtronic's Motion for Summary Judgment. (ECF No. 256.) On September 17, 2021, Medtronic filed its Reply to Avanos's Response. (ECF No. 274.) Avanos then filed a Sur-Reply to Medtronic's Reply on September 17, 2021. (ECF No. 276.)

b. Factual Background

Avanos "is a company organized and existing under the laws of the state of North Carolina," and its principal place of business is in Alpharetta, Georgia. (First Amended Complaint, ECF No. 99 ¶ 2.) Medtronic Sofamor Danek USA, Inc. is incorporated in Tennessee, with its principal office located in Memphis, Tennessee. (Id. ¶ 3.) Medtronic, Inc. and Medtronic USA, Inc. are incorporated in Minnesota and each has a "regular and established"

place of business" in Memphis, Tennessee. (<u>Id.</u> $\P\P$ 4–5.) Avanos and Medtronic are medical device companies. (<u>Id.</u> $\P\P$ 6, 12.)

This is a patent infringement case. The technology involves medical devices used to treat chronic pain with radiofrequency ablation ("RFA"). (Id. ¶¶ 6–13.) RFA prevents nerves from sending pain signals to the brain by ablating them; ablation is the process by which the probes used in an RFA procedure create a lesion in the nervous tissue of the patient. (Id. ¶ 8.) Cooled RFA involves internally cooling the ablating probe by the internal circulation of cooling fluid so that more RF energy can be delivered without an increase in temperature; the increase in RF energy creates legions that are larger in volume and that thus better treat chronic pain. (Id. ¶ 10.)

Avanos asserts that the Accurian system manufactured and sold by Medtronic ("Accused Product") infringes claims 1–5, 7, 8, 13, and 17–21 in U.S. Patent No. 8,882,755 ("the '755 Patent"). (ECF No. 207-1 at PageID 7642.) The '755 Patent describes an RF device that uses cooled probes and temperature monitoring to improve upon existing RF systems. See '755 Patent at Abstract. It is undisputed that each claim in the '755 Patent "requires that 'cooling fluid does not flow into' the claimed 'protrusion.'" (ECF No. 222 at PageID 10680.)

II. LEGAL STANDARD

A party is entitled to 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). "A fact is 'material' for purposes of summary judgment if proof of that fact would establish or refute an essential element of the cause of action or defense." <u>Bruederle v. Louisville Metro Gov't</u>, 687 F.3d 771, 776 (6th Cir. 2012).

"In considering a motion for summary judgment, [the] court construes all reasonable inferences in favor of the nonmoving party." <u>Robertson v. Lucas</u>, 753 F.3d 606, 614 (6th Cir.

2014) (citing Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986)). "The moving party bears the initial burden of demonstrating the absence of any genuine issue of material fact." Mosholder v. Barnhardt, 679 F.3d 443, 448 (6th Cir. 2012) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986)).

"Once the moving party satisfies its initial burden, the burden shifts to the nonmoving party to set forth specific facts showing a triable issue of material fact." Mosholder, 679 F.3d at 448–49; see also Fed. R. Civ. P. 56(e); Matsushita, 475 U.S. at 587. "When the non-moving party fails to make a sufficient showing of an essential element of his case on which he bears the burden of proof, the moving parties are entitled to judgment as a matter of law and summary judgment is proper." Martinez v. Cracker Barrel Old Country Store, Inc., 703 F.3d 911, 914 (6th Cir. 2013) (quoting Chapman v. UAW Local 1005, 670 F.3d 677, 680 (6th Cir. 2012) (en banc)); see also Kalich v. AT & T Mobility, LLC, 679 F.3d 464, 469 (6th Cir. 2012).

To "show that a fact is, or is not, genuinely disputed," both parties must do so by "citing to particular parts of materials in the record," "showing that the materials cited do not establish the absence or presence of a genuine dispute," or showing "that an adverse party cannot produce admissible evidence to support the fact." Bruederle, 687 F.3d at 776 (alterations in original) (quoting Fed. R. Civ. P. 56(c)(1)); see also Mosholder, 679 F.3d at 448 ("To support its motion, the moving party may show 'that there is an absence of evidence to support the nonmoving party's case." (quoting Celotex Corp., 477 U.S. at 325)). "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge[.]" Martinez, 703 F.3d at 914 (alteration in original) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986)).

"The court need consider only the cited materials, but it may consider other materials in the record." Fed. R. Civ. P. 56(c)(3). "[T]he district court has no 'duty to search the entire record to establish that it is bereft of a genuine issue of material fact." Pharos Capital Partners, L.P. v. Deloitte & Touche, 535 F. App'x 522, 523 (6th Cir. 2013) (per curiam) (quoting Tucker v. Tennessee, 539 F.3d 526, 531 (6th Cir. 2008), abrogation recognized by Anderson v. City of Blue Ash, 798 F.3d 338 (6th Cir. 2015)). "[J]udges are not like pigs, hunting for truffles' that might be buried in the record." Emerson v. Novartis Pharm. Corp., 446 F. App'x 733, 736 (6th Cir. 2011) (alteration in original) (quoting United States v. Dunkel, 927 F.2d 955, 956 (7th Cir. 1991)).

The decisive "question is whether 'the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." Johnson v. Memphis Light Gas & Water Div., 777 F.3d 838, 843 (6th Cir. 2015) (quoting Anderson, 477 U.S. at 251–52). Summary judgment "shall be entered' against the nonmoving party unless affidavits or other evidence 'set forth specific facts showing that there is a genuine issue for trial." Rachells v. Cingular Wireless Emp. Servs., LLC, No. 1:08CV02815, 2012 WL 3648835, at *2 (N.D. Ohio Aug. 23, 2012) (quoting Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 888, 110 S.Ct. 3177, 3188, 111 L.Ed.2d 695 (1990)). "[A] mere 'scintilla' of evidence in support of the non-moving party's position is insufficient to defeat summary judgment; rather, the non-moving party must present evidence upon which a reasonable jury could find in her favor." Tingle v. Arbors at Hilliard, 692 F.3d 523, 529 (6th Cir. 2012) (quoting Anderson, 477 U.S. at 251). "[I]n order to withstand a motion for summary judgment, the party opposing the motion must present 'affirmative evidence' to support his/her position." Mitchell v. Toledo Hosp., 964 F.2d 577, 584 (6th Cir. 1992) (citing Anderson v.

Liberty Lobby, 106 S. Ct. 2505, 2510, 2514 (1986); Street v. J.C. Bradford & Co., 886 F.2d 1472, 1479 (6th Cir. 1989)). "[C]onclusory assertions, unsupported by specific facts made in affidavits opposing a motion for summary judgment, are not sufficient to defeat a motion for summary judgment." Rachells, 2012 WL 3648835, at *2 (quoting Thomas v. Christ Hosp. and Med. Ctr., 328 F.3d 890, 894 (7th Cir. 2003)). Statements contained in an affidavit that are "nothing more than rumors, conclusory allegations and subjective beliefs" are insufficient. Mitchell, 964 F.2d at 584–85.

III. ANALYSIS AS TO AVANOS'S MOTION

a. Waiver, Estoppel, Government Sales, and Implied License

Avanos seeks summary judgment on Medtronic's asserted defenses of waiver, estoppel, government sales, and implied license. (ECF No. 205-1 at PageID 7174.) Medtronic has withdrawn these defenses. (ECF No. 218 at PageID 8848–49.) As a result, Avanos's Motion for Partial Summary Judgment with respect to these defenses is **DENIED AS MOOT**.

b. Unclean Hands

Avanos also seeks summary judgment on Medtronic's defense of unclean hands because Medtronic has failed to "show material facts necessary to support [it]." (ECF No. 205-1 at PageID 7174.) Medtronic, however, asserts that the document Bates stamped AVNS-00424241 ("Compelled Probe Analysis Document") "demonstrates that Avanos has knowingly made statements . . . in support of its infringement claim that contradict Avanos's pre-suit investigation and knowledge." (ECF No. 218 at PageID 8845.) Medtronic contends that this is sufficient to create "a genuine issue of fact as to Medtronic's defense of unclean hands." (Id.)

"[B]efore a complainant can have a standing in court, . . . he must come into court with clean hands." Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240, 244 (1933). "[A]

determination of unclean hands may be reached when 'misconduct' of a party seeking relief 'has immediate and necessary relation to the equity that he seeks in respect of the matter in litigation.'" <u>Gilead Scis. Inc. v. Merck & Co., Inc.</u>, 888 F.3d 1231, 1239 (Fed. Cir. 2018) (quoting <u>Keystone Driller</u>, 290 U.S. at 245). "[O]ne's misconduct need not necessarily have been of such a nature as to be punishable as a crime or as to justify legal proceedings" as the doctrine "gives wide range to the equity court's use of discretion[.]" <u>Precision Instrument Mfg.</u> Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 815 (1945).

Here, Medtronic contends that the Compelled Probe Analysis Document provides evidence that Avanos has taken inconsistent positions with the information in that Document, and that these inconsistent positions "raise[] a genuine dispute of material fact in support of Medtronic's unclean hands defense." (ECF No. 218 at PageID 8848.) Avanos contends that the Compelled Probe Analysis Document does not prove that any of Avanos's or its experts statements were inconsistent because all it shows is that there is a range of space between 6 and 20 microns in the Accurian probe that was scanned. (ECF No. 237 at PageID 12231–32.) The Compelled Probe Analysis Document does not prove that all Accurian probes have a gap size that "is consistently about 9 microns with the thermocouple hypotube flush against the wall" and as such, it does not prove that Avanos's or Avanos's experts' arguments are inconsistent, much less that there is any inconsistency that rises to the level of misconduct required for unclean hands. Because Medtronic's only argument for its unclean hands defense is this alleged inconsistency, Avanos's Motion for Summary Judgment with respect to Medtronic's defense of unclean hands is GRANTED.

IV. ANALYSIS AS TO MEDTRONIC'S MOTION

a. Non-Infringement

Medtronic seeks summary judgment as to non-infringement. (ECF No. 207-1 at PageID 7641.) "Evaluation of summary judgment of noninfringement is a two-part inquiry: first, a court construes the scope and meaning of the asserted patent claims, and then compares the construed claims to the accused product or process." Medgraph, Inc. v. Medtronic, Inc., 843 F.3d 942, 949 (Fed. Cir. 2016) (citing Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1288 (Fed. Cir. 2009)). To grant summary judgment on non-infringement, the Court must find that, "after resolving factual inferences in favor of the patentee," "no reasonable jury could find infringement." Brilliant Instruments, Inc. v. GuideTech, LLC, 707 F.3d 1342, 1344 (Fed. Cir. 2013) (internal citation omitted).

i. Non-Infringement Because Avanos Has Failed to Prove Water Does Not Flow into the Protrusion

Medtronic seeks summary judgment of non-infringement because it contends that Avanos "has failed to prove that water does not flow into the alleged protrusion of the Accurian probe," which is a limitation of all the asserted claims. (ECF No. 207-1 at PageID 7645.) Medtronic asserts that Avanos has failed to "test any accused products, and the absence of technical documents to support its position are glaring failures of proof." (Id. at PageID 7648.) In further support of its Motion, Medtronic contends in its Supplement to its Motion for Summary Judgment that the Compelled Probe Analysis Document proves that there is not a dispute of material fact that "a gap existed and cooling fluid could flow into this gap[.]" (ECF No. 252 at PageID 14503–04.)

In response, Avanos contends that "there is a genuine issue of material fact as to whether 'cooling fluid does not flow into' the 'protrusion.'" (ECF No. 223 at PageID 10728.) Avanos

provides testimony from its experts' reports and Medtronic's experts' reports in support of there being a dispute as to whether fluid flows into the gap. (Id. at PageID 10731.) ("But Dr. Yardimci himself calculated that if any water moves from the probe's main shaft into the entrance of the gap, the water's speed would drop precipitously from 5.740 m/s to 0.0005 m/s.

. . an 11,000-fold drop in velocity that does not permit 'circulation' or 'flow' of the water.") (emphasis omitted) ("Dr. Haemmerich and Dr. Hultmark explained that Medtronic's new testing only confirmed that cooling fluid would not reach the protrusion under Medtronic's experts' conditions.") (emphasis omitted). Additionally, Avanos contends that the Compelled Probe Analysis Document does not conclusively show that all Accurian probes would have the same gap dimensions and that the document does not show that water will flow into the protrusion. (ECF No. 256 at PageID 14623–27.)

In its Reply, Medtronic reiterates that there is no dispute of material fact. (ECF No. 274 at PageID 18588.) First, Medtronic raises an argument about how the Patent Trial and Appeal Board's Final Written Decision ("FWD") of the corresponding IPR proceeding for the '755 Patent requires finding that the entire steeple tip of the Accurian device is the "protrusion." (ECF No. 274 at PageID 18592.) As discussed in this Court's Order Denying Medtronic's Motion for Claim Construction, however, Avanos's positions in the IPR were not inconsistent with its infringement positions here, and the dispute over what portion of the Accurian probe is the "protrusion" is a "dispute of fact regarding infringement rather than claim construction." (ECF No. 271.) Medtronic also contends that even under Avanos's identification of the protrusion in the accused product, Avanos has failed to provide sufficient evidence to "establish the existence of a material dispute of fact that cooling fluid does not flow into the alleged

protrusion" due to the presence of a gap in the protrusion being undisputed. (ECF No. 274 at PageID 18597.)

Avanos, in its Sur-Reply, addresses Medtronic's claim that the presence of the gap does not indicate that water will flow through it: "[t]he same scientific principles that result in air stopping any water from flowing into the protrusion in a 9 micron gap would also stop water from flowing into the protrusion in a 20 micron gap." (ECF No. 276 at PageID 18852.) As such, Avanos reiterates that there is a material dispute of fact which precludes summary judgment of non-infringement. (Id. at PageID 18853.)

Here, Avanos has provided sufficient evidence in the record to show that there is a genuine dispute of material fact as to whether cooling fluid flows into the gap of the Accurian probe. (See ECF Nos. 223, 276.) (citing to both Parties' expert reports to show that this fact is disputed). Because there is a genuine dispute as to whether water flows into the gap, Medtronic's motion for summary judgment for non-infringement on this basis is **DENIED**.

ii. Non-Infringement of Claim 21

Medtronic also moves for summary judgment of non-infringement of Claim 21 of the '755 Patent. (ECF No. 207-1 at PageID 7650.) Medtronic contends that Claim 21 "requires that the temperature sensor is *not* thermally influenced by the cooling fluid," and as a result, the Medtronic Accurian probe does not infringe because it is undisputed that the temperature is "thermally influenced." (Id.) (emphasis in original). Avanos states in its Response that "it will not assert [its claim that] Medtronic infringes Claim 21 of the '755 Patent" at trial. (ECF No. 223 at PageID 10748.) As a result, Medtronic's motion for summary judgment for non-infringement of Claim 21 is **DENIED AS MOOT**.

iii. Non-Infringement Under Doctrine of Equivalents

Medtronic moves for summary judgment of non-infringement under the doctrine of equivalents ("DOE"). (ECF No. 207-1 at PageID 7652.) Medtronic contends that "Avanos has not offered any expert opinion concerning DOE, which is fatal to Avanos's claims." (Id.) Avanos, in its Response, "agrees that it will not assert . . . infringement under the Doctrine of Equivalents." (ECF No. 223 at PageID 10748.) Therefore, Medtronic's motion for summary judgment of non-infringement under the doctrine of equivalents is **DENIED AS MOOT**.

b. Pre-Suit Damages & Lost Profits Prior to Patent Ownership

Medtronic seeks summary judgment to preclude Avanos from seeking damages prior to the date Avanos filed suit, November 4, 2019, "because Avanos failed to comply with the notice requirements of 35 U.S.C. § 287(a)." (ECF No. 207-1 at PageID 7653.) Medtronic also seeks summary judgment to preclude Avanos from recovering lost profits prior to November 1, 2019, the date which Avanos acquired the '755 Patent. (Id. at PageID 7655.) In its Response, Avanos states that it "will not seek damages accruing before November 4, 2019, the date it filed the complaint, and Avanos has proposed an appropriate stipulation to that effect." (ECF No. 223 at PageID 10747.) As a result, Medtronic's motions for summary judgment related to pre-suit damages and lost profits prior to Avanos's patent ownership are **DENIED AS MOOT**.

c. Willful Infringement

Finally, Medtronic seeks summary judgment of no willful infringement. (ECF No. 207-1 at PageID 7656.) Medtronic contends that "Avanos's evidence fails to demonstrate deliberate or intentional infringement." (Id. at PageID 7657.) Avanos, in response, contends that "[t]he facts show more than mere awareness of the patent; they demonstrate 'deliberate and intentional' conduct." (ECF No. 223 at PageID 10739.) Specifically, Avanos points to the

following evidence in the record: an "August 2017 email identifying the '755 Patent;" "Baylis's October 2017 Disclosure Letter" in which "Baylis then identified to Medtronic 'over one hundred patents and patent applications, including the '755 patent, that Baylis states may be considered relevant to the Accurian system;" and "Baylis's February 2019 Certificate" that Avanos contends "specifically called out Avanos's IP and the risk of 'infringement." (Id. at PageID 10742–45.) In reply, Medtronic contends that "Avanos's characterization of Medtronic's communications with Baylis contradict the documents themselves and cannot serve as the basis for a dispute of material fact." (ECF No. 274 at PageID 18597.) Additionally, Medtronic asserts that "the fact that [Avanos] never provided Medtronic with presuit notice of its infringement allegations" is further support that "Avanos's willfulness claim fails" and also asserts that part of Avanos's willfulness argument is improper because Avanos uses a lack of opinion of counsel argument barred by 35 U.S.C. § 298. (Id. at PageID 18597–98.) In its Sur-Reply, Avanos contends that Medtronic "erroneously attacks the evidence Avanos presented . . . in isolation instead of acknowledging the totality of the circumstances." (ECF No. 276 at PageID 18855.)

For willful infringement, "the patentee must show the accused infringer had a specific intent to infringe at the time of the challenged conduct." <u>Bayer Healthcare LLC v. Baxalta Inc.</u>, 989 F.3d 964, 987 (Fed. Cir. 2021). The state of mind for willful infringement requires more than awareness of the asserted patent. <u>Id.</u> Specific intent includes showing "objective recklessness . . . that the risk of infringement 'was either known or so obvious that it should have been known to the accused infringer." <u>Halo Elecs., Inc. v. Pulse Elecs., Inc.</u>, 136 S. Ct. 1923, 1930 (2016) (quoting <u>In re Seagate Tech., LLC</u>, 497 F.3d 1360, 1368 (Fed. Cir. 2007)). "[T]he concept of willfulness requires a jury to find no more than deliberate or intentional

infringement." SRI Int'l, Inc. v. Cisco Sys., Inc., No. 2020-1685, 2021 WL 4434231, at *4

(Fed. Cir. Sept. 28, 2021) (internal quotations omitted).

Here, the Court finds that Avanos has pointed to sufficient evidence in the record that

Medtronic "acted despite a risk of infringement that was either known or so obvious that it

should have been known." See Deere & Co. v. AGCO Corp., No. 18-827-CFC, 2019 WL

668492, at *5 (D. Del. Feb. 19, 2019) (citing to Arctic Cat Inc. v. Bombardier Recreational

Prods., Inc., 876 F.3d 1350, 1371 (Fed. Cir. 2017)). Upon review of the documents that Avanos

has alleged support a finding of willful infringement (see ECF Nos. 207-33, 207-34, 207-35),

the Court finds that a reasonable juror could find that Medtronic willfully infringed by acting

despite an obvious risk, and it is a question of fact that shall be left to the jury to determine if

the evidence provided by Avanos proves that Medtronic willfully infringed. Medtronic's

motion for summary judgment of no willful infringement is **DENIED**.

IV. CONCLUSION

For the reasons stated above, the Court GRANTS Plaintiff's Motion for Partial

Summary Judgment on Unclean Hands and **DENIES AS MOOT** all of Plaintiff's other claims.

The Court **DENIES** Defendants' Motion for Summary Judgment on Non-Infringement and

Willful Infringement and **DENIES AS MOOT** all of Defendants' other claims.

IT IS SO ORDERED, this 4th day of October, 2021.

/s/ Jon P. McCalla

JON P. McCALLA

UNITED STATES DISTRICT COURT JUDGE

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