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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

RECOR MEDICAL, INC.,

Plaintiff,

v.

MEDTRONIC IRELAND MANUFACTURING UNLIMITED CO. and MEDTRONIC VASCULAR, INC.,

Defendants.

CASE NO.

COMPLAINT FOR DECLARATORY JUDGMENT

JURY TRIAL DEMANDED

Plaintiff ReCor Medical, Inc. ("ReCor") seeks declaratory judgment that it does not infringe U.S. Patent No. 8,845,629 ("'629 Patent") and that the '629 Patent is invalid. Defendants Medtronic Ireland Manufacturing Unlimited Co. ("Medtronic Ireland") and Medtronic Vascular, Inc. ("Medtronic Vascular") (collectively and including their predecessors-in-interest, "Medtronic") created a controversy regarding the '629 Patent by threatening to enforce its patent rights against ReCor's Paradise Renal Denervation System ("the Paradise System"), including filing a suit against ReCor in Germany on the related European Patent No. EP 2 561 905 B1 ("EP '905 Patent"). This action seeks to clear the air and resolve that controversy.

NATURE OF THE ACTION

1. This is an action for a declaratory judgment arising under the patent laws of the United States, Title 35 of the United States Code. ReCor seeks declaratory judgment that it does not infringe the '629 Patent, literally or under the doctrine of equivalents, and that the '629 Patent is invalid. The action arises from a real and immediate controversy between ReCor and Medtronic regarding whether ReCor infringes any claims of the '629 Patent.

2. This action is related to an earlier-filed case: *ReCor Medical, Inc. v. Medtronic Ardian Luxembourg S.à.r.l. and Medtronic Vascular, Inc.*, No. 4:22-cv-00236-KAW (N.D. Cal.).

THE PARTIES

3. ReCor is a Delaware corporation with a principal place of business in Palo Alto, California. ReCor is focused on transforming the management of hypertension (high blood pressure), the leading cardiovascular risk factor in the world.

4. On information and belief, Medtronic Ireland is an Irish corporation with a principal place of business in Dublin, Ireland.

5. On information and belief, Medtronic Vascular is a Delaware corporation with a principal place of business in Santa Rosa, California.

6. On information and belief, Medtronic Ireland has licensed rights to the '629 Patent and related patents within California and this judicial district to Medtronic Vascular and/or other affiliated companies. Medtronic Vascular prosecuted the '629 Patent on behalf of Medtronic Ireland (including its predecessors-in-interest) and is listed as its representative with respect to the

'629 Patent. On information and belief, Medtronic Vascular is responsible for enforcing the '629 Patent and related patents on behalf of Medtronic Ireland.

7. On information and belief, Medtronic regularly conducts business activities in California and this judicial district.

FACTUAL BACKGROUND

8. ReCor developed and manufactures the Paradise System for treating hypertension. The kidneys, a component of the renal system, impact blood pressure by controlling salt and water retention. Signaling from overactive nerves leading to the kidneys can be a causative factor in hypertension. The Paradise System provides for a minimally invasive procedure to treat overactive nerves leading to the kidney to reduce hypertension. The Paradise System is inserted through a small incision in the groin and placed in the renal artery so that it is in proximity to nerves leading to the kidney. The Paradise System delivers heat to the tissue surrounding the artery using pulses of unfocused ultrasound energy (sound waves). The heat reduces activity of the nearby nerves. Circulating water within the Paradise System cools the surrounding arterial tissue to protect it from the heat generated by the ultrasound pulses.

9. ReCor manufactures the Paradise System at its facility in Palo Alto, California.

10. The Paradise System is an investigational medical device in the United States. ReCor has completed RADIANCE-HTN clinical trials using the Paradise System and announced that the Paradise System achieved blood pressure reductions in patients with mild-moderate and resistant hypertension in the absence of and presence of anti-hypertensive medication. The RADIANCE-HTN trials were conducted across seven countries, including the United States and Germany.

11. ReCor is currently conducting a clinical study known as RADIANCE-II for the Paradise System. Upon successful completion, ReCor will submit an application for premarket approval with the U.S. Food and Drug Administration ("FDA"). RADIANCE-II recruited participants across the United States and Europe, including Germany. In March 2022, ReCor announced that it completed enrollment of RADIANCE-II and that it plans to present results to the scientific and medical communities in publications and conferences later this year. ("ReCor

Medical Announces Completion of Enrollment in RADIANCE-II Pivotal Trial of the Paradise™ Ultrasound Renal Denervation System for the Treatment of Uncontrolled Hypertension," March 29, 2022, https://www.recormedical.com/blog/2022/03/29/recor-medical-announces-completion-of-enrollment-in-radiance-ii-pivotal-trial-of-the-paradise-ultrasound-renal-denervation-system-for-the-treatment-of-uncontrolled-hypertension/.)

12. On or about December 10, 2020, ReCor announced that the Paradise System received FDA Breakthrough Device Designation, which is intended to help patients receive more timely access to breakthrough medical technologies that have the potential to provide more effective treatment for life-threatening or irreversibly debilitating diseases or conditions. ("ReCor Medical Announces Positive Results in RADIANCE-HTN TRIO Study and Breakthrough Device Designation for Paradise™ Ultrasound Renal Denervation System," Dec. 10, 2020, https://www.recormedical.com/blog/2020/12/10/recor-medical-announces-positive-results-in-radiance-htn-trio-study-and-breakthrough-device-designation-for-paradise-ultrasound-renal-denervation-system/.)

13. ReCor has received European conformity (CE) marking approval for the Paradise System, indicating that it meets European safety, health, and environmental protection requirements. This CE mark allows the Paradise System to be sold in member states of the European Economic Area, including Germany.

14. ReCor has concrete plans to release the Paradise System in the United States upon receiving premarket approval from the FDA.

15. On information and belief, Medtronic has a developed a competing renal denervation device, the Symplicity Spyral Renal Denervation System ("the Symplicity System"). On information and belief, the Symplicity System uses radiofrequency energy, rather than ultrasound, to deliver heat to nerves leading to the kidney.

16. On information and belief, the Symplicity System is an investigational medical device, and Medtronic is seeking or intends to seek approval to market the Symplicity System in the United States. In or about March 2020, Medtronic announced that its Symplicity Catheter received FDA Breakthrough Device Designation.

17. Trade publications have noted that "with two unique devices now having received FDA Breakthrough Device Designation, GlobalData predicts that the renal denervation market will begin to gain traction more quickly in the US" and have observed a "sense of competition has come to the renal denervation market." (Medical Device Network, "Renal denervation market moves forward with FDA nod to ReCor Medical's Paradise Ultrasound Renal Denervation system," Jan. 5, 2021, https://www.medicaldevice-network.com/comment/recor-medical-renal-denervation-fda/.)

THE PATENT-IN-SUIT

18. The '629 Patent is entitled "Ultrasound apparatuses for thermally-induced renal neuromodulation," and issued on September 30, 2014. The face of the '629 Patent indicates that it is assigned to Medtronic Ardian Luxembourg S.à.r.l. ("Medtronic Ardian"). On information and belief, at some time after February 3, 2022, Medtronic Ardian assigned all of its right, title, and interest in the '629 Patent to Medtronic Ireland. On information and belief, Medtronic Ireland is the successor-in-interest to all rights and liabilities with respect to the '629 Patent previously held by Medtronic Ardian. A true and correct copy of the '629 Patent is attached as Exhibit 1.

19. The '629 Patent has a single independent claim and eleven dependent claims. Independent claim 1 recites:

> 1. An ultrasound apparatus for thermally-induced renal neuromodulation, the apparatus comprising:
>
> a catheter sized and shaped for delivery within a blood vessel to a vicinity of neural fibers that contribute to renal function;
>
> an ultrasound transducer carried by the catheter, wherein the ultrasound transducer is configured to transmit ultrasound energy waves to target renal neural fibers outside of the blood vessel to thermally induce modulation of target neural fibers while protecting non-target tissue in the blood vessel wall from thermal injury; and
>
> an expandable member carried by a distal region of the catheter,

> wherein the expandable member is configured to vary between a reduced configuration for delivery and retrieval and an expanded deployed configuration, and wherein the ultrasound transducer is positioned on a shaft of the catheter and within the expandable member.

20. On or about November 22, 2021, Medtronic filed an action against ReCor in the Mannheim District Court, Germany ("the German Action"), asserting that the Paradise System infringes claims of the EP '905 Patent. A copy of the EP '905 Patent is attached as Exhibit 2.

21. The EP '905 Patent has a single independent claim and ten dependent claims. Independent claim 1 of the EP '905 Patent recites:

> 1. An apparatus (220, 230, 240, 250, 260, 280, 290, 310, 320) configured for renal neuromodulation, e.g. renal denervation, wherein the apparatus is configured for employing focused or unfocused ultrasound to reduce or control neural signaling, the apparatus comprising:
>
> a catheter (210, 222, 232, 242, 252, 262, 282, 292, 312, 322) configured for being positioned within a renal artery (RA) and for delivering ultrasound to the target nerve or target neurons (RN), to reduce or control neural signaling.

22. The claimed subject matter of the EP '905 Patent is similar to that of the '629 Patent. The EP '905 Patent and the '629 Patent both claim priority to two provisional applications (Nos. 60/616,254 and 60/624,793) and one nonprovisional application (No. 11/129,765).

23. On or about December 8, 2021, Medtronic Vascular notified ReCor by letter of the German Action ("Medtronic Letter"). A copy of the Medtronic Letter is attached as Exhibit 3. The letter was sent on Medtronic letterhead from Medtronic Vascular's headquarters in Santa Rosa, California. The letter references "Medtronic and Ardian" and, on information and belief, was sent on behalf of Medtronic Vascular and Medtronic Ardian. On information and belief, Medtronic Ireland currently stands in the shoes of Medtronic Ardian with respect to the Medtronic

Letter. The Medtronic Letter states that Medtronic "takes intellectual property seriously and seeks to enforce its patent rights when and where appropriate to protect their value and Medtronic's ability compete fairly in the marketplace." On information and belief, the "intellectual property" and "patent rights" referenced in the Medtronic Letter includes the '629 Patent. On information and belief, Medtronic Ireland has adopted the threats contained in the Medtronic Letter on its own behalf. Medtronic Ireland has failed to take any action to dispel the threats contained in the Medtronic Letter following the assignment of Medtronic Ardian's right, title, and interest in the '629 Patent to Medtronic Ireland.

24. The Medtronic Letter was addressed to the General Managers of Otsuka Medical Devices Europe GmbH in Germany (the co-defendant that Medtronic sued in Germany together with ReCor) and the President & Chief Executive Officer of ReCor in Palo Alto, California.

25. When ReCor's President and CEO reached out to Medtronic to discuss the dispute, Medtronic did not respond that there was no dispute. Rather, Medtronic's Senior Vice President and President located in Santa Rosa, California forwarded an email from its lawyer and said that it would be more productive "to connect in a couple of months." In response, ReCor reiterated that it had reviewed the patent and does not infringe any valid claims, but was still interested in discussing a resolution to avoid the legal costs of litigation.

26. Medtronic then reaffirmed in its response to ReCor's President and CEO that it was "very confident in the merits" of its position and "the only benefit [it] could see to a conversation … is if you'd like to offer adequate compensation package for ReCor's infringement of [Medtronic's] patent."

27. ReCor faces a substantial risk that Medtronic will assert the '629 Patent in an infringement suit targeting the Paradise System. Medtronic has done nothing to dispel the risk that ReCor will face such a lawsuit.

JURISDICTION AND VENUE

28. This action arises under the Declaratory Judgement Act, Title 28 of the United States Code, Chapter 151, for the purpose of determining an actual and justiciable controversy

between the parties. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

29. ReCor brings this declaratory judgment action based on an actual, substantial and continuing justiciable controversy existing between ReCor and Medtronic. The controversy arises out of the Medtronic Letter addressed to the General Managers of Otsuka Medical Devices Europe GmbH in Germany and the President & Chief Executive Officer of ReCor in Palo Alto, California. The letter threatens that Medtronic "takes intellectual property seriously and seeks to enforce its patent rights when and where appropriate to protect their value and Medtronic's ability compete fairly in the marketplace." Medtronic also started making good on this threat by accusing ReCor's Paradise System of infringing the EP '905 Patent in Germany.

30. The accused Paradise System is made by ReCor in Palo Alto, California. Medtronic's '629 Patent has claims similar to the EP '905 Patent and claims priority to three of the same applications as the EP '905 Patent. Medtronic's threats to enforce its patent rights and the German Action establish that there is a case and controversy to support this declaratory judgment action.

31. ReCor has made meaningful preparations to undertake activity that, on information and belief, Medtronic views as infringing. ReCor manufactures the Paradise System in the United States and in this judicial district. ReCor is conducting clinical trials on the Paradise System in the United States and abroad. ReCor is in the process of seeking FDA approval and has received CE mark approval in Europe. The design of the Paradise System is finalized.

32. This Court has personal jurisdiction over Medtronic by virtue of its contacts with this forum. This action arises out of and relates to activities that Medtronic has purposefully directed at California and this judicial district.

33. Medtronic purposefully directed threats to "enforce its patent rights" in the Medtronic Letter from Medtronic Vascular's headquarters in Santa Rosa, California to ReCor's headquarters in Palo Alto, California.

34. Four named inventors of the '629 Patent are identified as having addresses within this judicial district and, on information and belief, their work leading to the '629 Patent was undertaken in this judicial district.

35. ReCor's Paradise System was developed and is manufactured in Palo Alto, California, within this judicial district.

36. Medtronic has the requisite minimum contacts with California and this judicial district for the Court to exercise personal jurisdiction under the California long-arm statute and consistent with traditional notions of fair play and substantial justice.

37. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391.

DIVISIONAL ASSIGNMENT

38. Pursuant to Civil Local Rule 3-2(c), this action is to be assigned on a district-wide basis.

FIRST CLAIM

Declaratory Judgment of Non-Infringement of '629 Patent

39. ReCor incorporates each of the allegations in paragraphs 1-38.

40. This is an actual and justiciable controversy between ReCor and Medtronic concerning infringement of the '629 Patent.

41. ReCor has not infringed and does not infringe any claim of the '629 Patent, directly or indirectly, literally or under the doctrine of equivalents.

42. The Paradise System does not infringe the claims of the '629 Patent because it does not include at least the following claim limitations, literally or under the doctrine of equivalents: "wherein the ultrasound transducer is configured to transmit ultrasound energy waves to target renal neural fibers outside of the blood vessel" and "the acoustically reflective portion and the acoustically transmissive portion are configured to transmit the first and second ultrasound energy waves to a focal distance point proximate to the target neural fibers." The Paradise System employs unfocused ultrasound that does not target renal neural fibers and does not transmit ultrasound energy waves to a focal distance point proximate to the target neural fibers.

43. ReCor is entitled to a declaratory judgment that it does not directly or indirectly infringe any claims of the '629 Patent, either literally or under the doctrine of equivalents.

SECOND CLAIM

Declaratory Judgment of Invalidity of '629 Patent

44. ReCor incorporates each of the allegations in paragraphs 1-43.

45. This is an actual and justiciable controversy between ReCor and Medtronic concerning validity of the '629 Patent.

46. The claims of the '629 Patent are invalid for failure to comply with one or more of the conditions of patentability under Title 35 of the United States Code and related judicial doctrines, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, and/or obviousness-type double patenting.

47. The claims of the '629 Patent are invalid as anticipated and obvious. For example, at least claims 1-3 and 8-9 are anticipated by U.S. Patent No. 6,669,655 ("Acker"). To the extent claims 1-3 and 8-9 are not anticipated by Acker, they would have been obvious over Acker in view of the knowledge of a person of ordinary skill in the art, or in the alternative, over U.S. Pat. Pub. 2003/0216792 A1 ("Levin") in view of Acker. At least claims 4 and 10-11 would have been obvious over Acker in view of the knowledge of a person of ordinary skill in the art, or in the alternative, over Levin in view of Acker. At least claim 12 would have been obvious over Levin, Acker, and U.S. Patent No. 5,000,185. ReCor is not aware of any secondary considerations that could rebut the prima facie case of obviousness.

48. The claims of the '629 Patent are invalid for lack of enablement. On information and belief, Medtronic has never developed a working device as claimed in the '629 Patent. Instead, Medtronic's Symplicity System uses radiofrequency energy to generate heat. Successful ultrasound renal denervation became possible through the extensive work undertaken by ReCor to develop the Paradise System, which is not disclosed in the '629 Patent. The specification of the '629 Patent fails to enable the claimed ultrasound apparatus for thermally-induced renal neuromodulation.

49. The claims of the '629 Patent are invalid under the judicially created doctrine of obviousness-type double patenting. The claims of the '629 Patent are not patentably distinct from the claims of at least U.S. Patent Nos. 9,186,198, 8,626,300, and/or 7,717,948, which are directed to obvious variants of the same alleged invention.

50. ReCor is entitled to a declaratory judgment that the claims of the '629 Patent are invalid.

PRAYER FOR RELIEF

ReCor respectfully requests a judgment that:

A. Declares that ReCor has not infringed and does not infringe the claims of the '629 Patent;

B. Declares that the claims of the '629 Patent are invalid;

C. Awards ReCor its costs and attorneys' fees; and

D. Awards ReCor such other relief as the Court may deem proper.

JURY DEMAND

ReCor hereby demands a jury trial on all issues and claims so triable.

Dated: May 25, 2022

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By: */s/ Roger J. Chin*

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