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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

RECOR MEDICAL, INC.,

Plaintiff,

v.

MEDTRONIC ARDIAN LUXEMBOURG
S.À.R.L. and MEDTRONIC VASCULAR,
INC.,

Defendants.

CASE NO.

**COMPLAINT FOR
DECLARATORY JUDGMENT**

JURY TRIAL DEMANDED

1 Plaintiff ReCor Medical, Inc. (“ReCor”) seeks declaratory judgment that it does not
2 infringe U.S. Patent No. 8,845,629 (“’629 Patent”) and that the ’629 patent is invalid. Defendants
3 Medtronic Ardian Luxembourg S.à.r.l. (“Medtronic Ardian”) and Medtronic Vascular, Inc.
4 (“Medtronic Vascular”) (collectively, “Medtronic”) created a controversy regarding the ’629
5 Patent by threatening to enforce its patent rights against ReCor’s Paradise Renal Denervation
6 System (“the Paradise System”), including filing a suit against ReCor in Germany on the related
7 European Patent No. EP 2 561 905 B1 (“EP ’905 Patent”). This action seeks to clear the air and
8 resolve that controversy.

9 **NATURE OF THE ACTION**

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

15 **THE PARTIES**

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

19 3. On information and belief, Medtronic Ardian is a Luxembourg corporation with a
20 principal place of business in Luxembourg.

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

23 5. On information and belief, Medtronic Ardian has licensed rights to the ’629 Patent
24 and related patents within California and this judicial district to Medtronic Vascular and/or other
25 affiliated companies. On information and belief, Medtronic Vascular is responsible for enforcing
26 the ’629 Patent and related patents on behalf of Medtronic Ardian.

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

1 **FACTUAL BACKGROUND**

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

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

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

19 10. ReCor is currently conducting a clinical study known as RADIANCE-II for the
20 Paradise System. Upon successful completion, ReCor will submit an application for premarket
21 approval with the U.S. Food and Drug Administration ("FDA"). RADIANCE-II is recruiting
22 participants across the United States and Europe, including Germany. Completion of enrollment
23 of RADIANCE-II is expected in 2022.

24 11. On or about December 10, 2020, ReCor announced that the Paradise System
25 received FDA Breakthrough Device Designation, which is intended to help patients receive more
26 timely access to breakthrough medical technologies that have the potential to provide more
27 effective treatment for life-threatening or irreversibly debilitating diseases or conditions. ("ReCor
28 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/>.)

12. 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.

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

14. On information and belief, Medtronic has 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.

15. 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.

16. 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

17. 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

1 it is assigned to Medtronic Ardian. A true and correct copy of the '629 Patent is attached as
2 Exhibit 1.

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

5 1. An ultrasound apparatus for thermally-induced renal
6 neuromodulation, the apparatus comprising:

7 a catheter sized and shaped for delivery within a blood vessel to
8 a vicinity of neural fibers that contribute to renal function;
9 an ultrasound transducer carried by the catheter, wherein the
10 ultrasound transducer is configured to transmit ultrasound
11 energy waves to target renal neural fibers outside of the
12 blood vessel to thermally induce modulation of target neural
13 fibers while protecting non-target tissue in the blood vessel
14 wall from thermal injury; and

15 an expandable member carried by a distal region of the catheter,
16 wherein the expandable member is configured to vary between
17 a reduced configuration for delivery and retrieval and an
18 expanded deployed configuration, and wherein the
19 ultrasound transducer is positioned on a shaft of the catheter
20 and within the expandable member.

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

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

26 1. An apparatus (220, 230, 240, 250, 260, 280, 290, 310, 320)
27 configured for renal neuromodulation, e.g. renal denervation,
28 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.

21. 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).

22. 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. 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." Upon information and belief, the "intellectual property" and "patent rights" referenced in the Medtronic Letter includes the '629 Patent.

23. 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.

24. 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.

25. 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.”

26. 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

27. 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.

28. 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.

29. 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.

30. 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

1 the United States and abroad. ReCor is in the process of seeking FDA approval and has received
2 CE mark approval in Europe. The design of the Paradise System is finalized.

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

6 32. Medtronic purposefully directed threats to “enforce its patent rights” in the
7 Medtronic Letter from Medtronic Vascular’s headquarters in Santa Rosa, California to ReCor’s
8 headquarters in Palo Alto, California.

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

12 34. ReCor’s Paradise System was developed and is manufactured in Palo Alto,
13 California, within this judicial district.

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

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

18 **DIVISIONAL ASSIGNMENT**

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

21 **FIRST CLAIM**

22 **Declaratory Judgment of Non-Infringement of ’629 Patent**

23 38. ReCor incorporates each of the allegations in paragraphs 1-37.

24 39. This is an actual and justiciable controversy between ReCor and Medtronic
25 concerning infringement of the ’629 Patent.

26 40. ReCor has not infringed and does not infringe any claim of the ’629 Patent, directly
27 or indirectly, literally or under the doctrine of equivalents.
28

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

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

11 **SECOND CLAIM**

12 **Declaratory Judgment of Invalidity of '629 Patent**

13 43. ReCor incorporates each of the allegations in paragraphs 1-42.

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

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

20 46. The claims of the '629 Patent are invalid as anticipated and obvious. For example,
21 at least claims 1-3 and 8-9 are anticipated by U.S. Patent No. 6,669,655 (“Acker”). To the extent
22 claims 1-3 and 8-9 are not anticipated by Acker, they would have been obvious over Acker in view
23 of the knowledge of a person of ordinary skill in the art, or in the alternative, over U.S. Pat. Pub.
24 2003/0216792 A1 (“Levin”) in view of Acker. At least claims 4 and 10-11 would have been
25 obvious over Acker in view of the knowledge of a person of ordinary skill in the art, or in the
26 alternative, over Levin in view of Acker. At least claim 12 would have been obvious over Levin,
27 Acker, and U.S. Patent No. 5,000,185. ReCor is not aware of any secondary considerations that
28 could rebut the prima facie case of obviousness.

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

ReCor respectfully requests a judgment that:

JURY DEMAND

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

LATHAM & WATKINS LLP

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