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10 Attorneys for Plaintiff
AVATION MEDICAL, INC.

11 UNITED STATES DISTRICT COURT
12 NORTHERN DISTRICT OF CALIFORNIA

13
14 AVATION MEDICAL, INC.,
15 Plaintiff,
16 vs.
17 EMKINETICS, INC.,
18 Defendant.

Case No. 3:24-cv-01702

**COMPLAINT FOR DECLARATORY
JUDGMENT OF NONINFRINGEMENT
OF U.S. PATENT NOS. 9,002,477,
11,224,742, AND 11,844,943**

JURY TRIAL DEMANDED

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21 Plaintiff Avation Medical, Inc. (“Avation” or “Plaintiff”), by and through the
22 undersigned counsel, files this Complaint for Declaratory Judgment of Noninfringement
23 against Defendant EMKinetics, Inc. (“EMKinetics” or “Defendant”) and in support of its
24 Complaint alleges as follows:

25 **NATURE OF THE ACTION**

26 1. This is an action for a declaratory judgment of noninfringement arising under
27 the patent laws of the United States, Title 35 of the United States Code. Avation requests
28 this relief because Defendant has alleged and continues to allege that Avation’s Vivally®

1 System (“Vivally”) infringes U.S. Patent Nos. 9,002,477 (the “477 patent”), 11,224,742
2 (the “742 patent”), and 11,844,943 (the “943 patent”) (collectively, the “Challenged
3 Patents”).

4 2. Defendant’s affirmative allegations of infringement of the Challenged
5 Patents against Avation have created an immediate, real, and justiciable controversy
6 between Avation and Defendant.

7 3. Neither Avation nor its products practice the Challenged Patents. Avation
8 has not induced or contributed to any third-party product or technology that practices the
9 Challenged Patents.

10 **PARTIES**

11 4. Avation is a Delaware corporation with its headquarters at 1375 Perry Street,
12 Columbus, OH 43201.

13 5. Avation is an innovative neuromodulation and digital health company with a
14 mission to make wearable peripheral neuromodulation accessible to patients across a
15 variety of clinical conditions. Avation’s Vivally is an FDA-cleared, closed-loop, at-home
16 wearable neuromodulation device system for patients suffering from urge urinary
17 incontinence and urinary urgency caused by overactive bladder syndrome. Vivally is the
18 first and only such device that is cleared by FDA to be marketed in the United States that
19 applies closed-loop, adaptive and non-invasive at-home neuromodulation to treat these
20 bladder conditions.

21 6. On information and belief, Defendant is a Delaware corporation with its
22 principal place of business located at 1800 Gateway Drive, Suite 300, San Mateo,
23 California 94404, which is in San Mateo County.

24 **JURISDICTION AND VENUE**

25 7. This action arises under the Declaratory Judgment Act, 28 U.S.C. § 2201 *et*
26 *seq.*, and under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*

27 8. This Court has subject matter jurisdiction over this action under 28 U.S.C.
28 §§ 1331, 1338(a), and 2201, and 2202. As detailed below, Defendant’s infringement

1 allegations give rise to an immediate, real, and justiciable controversy between Avation
2 and Defendant as to whether Avation is infringing or has infringed any claims of the
3 Challenged Patents.

4 9. This Court has personal jurisdiction over Defendant because Defendant's
5 principal place of business is in California and more particularly in this District, rendering
6 it essentially at home in California.

7 10. Venue is proper in this District under 28 U.S.C. §§ 1400(b) because
8 Defendant resides in the Northern District of California.

9 **INTRADISTRICT ASSIGNMENT**

10 11. For purposes of intradistrict assignment under Civil Local Rules 3-2(c) and
11 3-5(b), this Intellectual Property Action will be assigned on a district-wide basis.

12 **BACKGROUND**

13 12. On April 7, 2015, the USPTO issued the '477 patent, entitled "Methods and
14 Devices for Performing Electrical Stimulation to Treat Various Conditions," to Daniel R.
15 Burnett. The face of the '477 patent lists EMKinetics, Inc. as the assignee. A true and
16 correct copy of the '477 patent is attached hereto as **Exhibit A**.

17 13. On January 18, 2022, the USPTO issued the '742 patent, entitled "Methods
18 and Devices for Performing Electrical Stimulation to Treat Various Conditions," to
19 Daniel R. Burnett. The face of the '742 patent lists EMKinetics, Inc. as the assignee. A
20 true and correct copy of the '742 patent is attached hereto as **Exhibit B**.

21 14. On December 19, 2023, the USPTO issued the '943 patent, entitled
22 "Methods and Apparatus for Transdermal Stimulation Over the Palmar and Plantar
23 Surfaces," to Amit Rajguru, Daniel R. Burnett, Alexander Vergara, and Michael Hemati.
24 The face of the '943 patent lists EMKinetics, Inc. as the assignee. A true and correct copy
25 of the '943 patent is attached hereto as **Exhibit C**.

26 15. On October 23, 2023, Defendant sent Avation a letter to "initiate licensing
27 discussions . . . concerning EMKinetics' patent portfolio." In the letter, Defendant stated
28 that "[w]e believe that the following assets may have particular interest and value to you"

1 and listed the ‘477 patent, the ‘742 patent, and U.S. Application No. 17/568,276, which
2 issued as the ‘943 patent.

3 16. On December 19, 2023, Defendant’s counsel David Gerasimow spoke via
4 phone to Avation’s litigation counsel Todd R. Tucker and communicated Defendant’s
5 belief that Avation requires a license to Defendant’s patent portfolio to market and sell the
6 Vivally System.

7 17. On February 23, 2024, Defendant sent Avation another letter, which
8 provided a “settlement offer” to “fully settle and resolve all claims of patent infringement
9 by EMKinetics against Avation.”

10 18. Defendant’s allegations of infringement by Avation’s Vivally and insistence
11 that Avation requires a license to Defendant’s patent portfolio to continue marketing and
12 selling the Vivally System demonstrate affirmative acts by Defendant to enforce its rights
13 in the Challenged Patents.

14 19. Defendant’s assertions of infringement by Avation’s Vivally allege current
15 infringement beyond meaningful preparation to conduct infringing activity. As a result of
16 Defendant’s assertions of infringement by Avation, Avation is under reasonable
17 apprehension and threat that Defendant will pursue claims that Avation infringes the
18 Challenged Patents.

19 20. The imminent threat to Avation is further underscored by the fact that on
20 February 23, 2024, Defendant filed a patent infringement lawsuit in the U.S. District Court
21 for the District of Delaware against a third-party medical company called Cala Health,
22 alleging Cala Health’s neuromodulation devices infringes several patents that are related to
23 the Challenged Patents. Defendant’s business strategy of suing companies in the
24 neuromodulation field that apparently refuse to license its patents make it highly likely that
25 Defendant will sue Avation for patent infringement of the Challenged Patents.

26 21. Accordingly, there is an immediate and existing case or controversy, and
27 declaratory judgment jurisdiction exists over the subject matter set forth in this complaint.

28 22. Neither Avation, nor any of its products, directly or indirectly infringe any of

1 the Challenged Patents.

2 23. Neither Avation, nor any of its products, perform each element of any claim
3 of the Challenged Patents, nor does Avation instruct third parties to perform each element
4 of any claim of the Challenged Patents.

5 **FIRST CAUSE OF ACTION**

6 **NONINFRINGEMENT OF U.S. PATENT NO. 9,002,477**

7 24. Avation repeats and realleges each and every allegation set forth in the above
8 paragraphs and incorporates them by reference herein.

9 25. In view of the facts as alleged above, there is an actual, substantial,
10 immediate, and justiciable controversy between Avation and Defendant regarding whether
11 Avation infringes any claim of the '477 patent.

12 26. According to the face of the '477 patent, Defendant is the assignee of the
13 '477 patent. On information and belief, Defendant owns all rights, title, and interest in and
14 under the '477 patent.

15 27. Defendant has alleged and continues to allege that Avation's Vivally is
16 covered by the claims of the '477 patent, and that Avation is infringing the '477 patent.
17 Defendant may bring suit on this matter at any time. In the meantime, Avation is harmed
18 by these false allegations.

19 28. Avation has not infringed and does not infringe any claim of the '477 patent
20 either directly or indirectly, literally or under the doctrine of equivalents.

21 29. Independent Claim 1 of the '477 patent, which is the sole independent claim
22 of the '477 patent, recites as follows:

- 23 1. A method of performing electrical stimulation therapy,
24 comprising:
25 non-invasively positioning a first portion of a patient's body
26 relative to an electrical stimulator such that a posterior tibial
27 nerve or branch thereof within the first portion of the body is in
28 proximity to the electrical stimulator;

1 passing a current through the electrical stimulator;
2 delivering an electrical stimulus from the electrical stimulator
3 to the posterior tibial nerve or branch thereof;
4 detecting electrical conduction through the posterior tibial
5 nerve or branch thereof or detecting a muscular response
6 caused by an electrical conduction through the posterior tibial
7 nerve or branch thereof via at least one sensor positioned along
8 a second portion of the body;
9 receiving a signal from the at least one sensor indicative of the
10 detected electrical conduction or muscular response thereby
11 providing feedback about the efficacy of the applied electrical
12 stimulation therapy; and
13 adjusting the current via a controller in communication with
14 the electrical stimulator based on the feedback.

15 30. Avation's Vivally does not infringe Independent Claim 1 (or any of the
16 dependent claims) because it does not include every limitation required by the claim. For
17 instance, without limitation and by way of example only, Avation's Vivally does not meet
18 or embody the limitation of "adjusting the current via a controller in communication with
19 the electrical stimulator based on the feedback." Avation's Vivally does not "adjust[] the
20 current" of an electrical stimulator "based on the feedback" of "at least one sensor" as
21 those terms are used in the '477 patent. Avation's Vivally uses pulse-width modulation to
22 apply stimulation energy, in which the electrical signal supplied via the stimulation
23 electrodes is at a constant current. Therefore, at least these claim limitations are not
24 practiced by Avation.

25 31. Therefore, a substantial controversy exists between Avation and Defendant,
26 parties having adverse legal interests, of sufficient immediacy and reality to warrant the
27 issuance of a declaratory judgment that Avation has not infringed and does not infringe
28 any claim of the '477 patent.

1 32. A substantial, immediate, real, and justiciable controversy exists between
2 Avation and Defendant as to whether Avation’s products infringe the ‘477 patent. Avation
3 accordingly requests a judicial determination of its rights, duties, and obligations regarding
4 the ‘477 patent.

5 33. Avation seeks a judgment declaring that Avation does not directly or
6 indirectly infringe any claim of the ‘477 patent.

7 **SECOND CAUSE OF ACTION**

8 **NONINFRINGEMENT OF U.S. PATENT NO. 11,224,742**

9 34. Avation repeats and realleges each and every allegation set forth in the above
10 paragraphs and incorporates them by reference herein.

11 35. In view of the facts as alleged above, there is an actual, substantial,
12 immediate, and justiciable controversy between Avation and Defendant regarding whether
13 Avation infringes any claim of the ‘742 patent.

14 36. According to the face of the ‘742 patent, Defendant is the assignee of the
15 ‘742 patent. On information and belief, Defendant owns all rights, title, and interest in and
16 under the ‘742 patent.

17 37. Defendant has alleged and continues to allege that Avation’s Vivally is
18 covered by the claims of the ‘742 patent, and that Avation is infringing the ‘742 patent.
19 Defendant may bring suit on this matter at any time. In the meantime, Avation is harmed
20 by these false allegations.

21 38. Avation has not infringed and does not infringe any claim of the ‘742 patent
22 either directly or indirectly, literally or under the doctrine of equivalents.

23 39. Independent Claim 1 of the ‘742 patent, which is the sole independent claim
24 of the ‘742 patent, recites as follows:

- 25 1. A method of treating overactive bladder or incontinence,
26 comprising:
27 non-invasively positioning a first portion of a patient’s body
28 relative to an electrical stimulator such that a branch of a

1 posterior tibial nerve within the first portion of the body is
2 directly targeted by the electrical stimulator;
3 passing a current through the electrical stimulator; and
4 delivering an electrical stimulus from the electrical stimulator
5 to the branch of the posterior tibial nerve such that the branch
6 directly receives the electrical stimulation to treat overactive
7 bladder or incontinence.

8 40. Avation's Vivally does not infringe Independent Claim 1 (or any of the
9 dependent claims) because it does not include every limitation required by the claim. For
10 instance, without limitation and by way of example only, Avation's Vivally does not meet
11 or embody the limitation of "positioning a first portion of a patient's body relative to an
12 electrical stimulator such that a branch of a posterior tibial nerve within the first portion of
13 the body is directly targeted by the electrical stimulator." Additionally, without limitation
14 and by way of example only, Avation's Vivally does not meet or embody the limitation of
15 "delivering an electrical stimulus from the electrical stimulator to the branch of the
16 posterior tibial nerve such that the branch directly receives the electrical stimulation to
17 treat overactive bladder or incontinence." Avation's Vivally does not "directly target[]" a
18 "branch of a posterior tibial nerve" or "deliver[] an electrical stimulus" to a "branch of the
19 posterior tibial nerve" so that the branch "directly receives the electrical stimulation," as
20 those terms are used in the '742 patent. Therefore, at least these claim limitations are not
21 practiced by Avation.

22 41. Therefore, a substantial controversy exists between Avation and Defendant,
23 parties having adverse legal interests, of sufficient immediacy and reality to warrant the
24 issuance of a declaratory judgment that Avation has not infringed and does not infringe
25 any claim of the '742 patent.

26 42. A substantial, immediate, real, and justiciable controversy exists between
27 Avation and Defendant as to whether Avation's products infringe the '742 patent. Avation
28 accordingly requests a judicial determination of its rights, duties, and obligations regarding

1 the '742 patent.

2 43. Avation seeks a judgment declaring that Avation does not directly or
3 indirectly infringe any claim of the '742 patent.

4 **THIRD CAUSE OF ACTION**

5 **NONINFRINGEMENT OF U.S. PATENT NO. 11,844,94**

6 44. Avation repeats and realleges each and every allegation set forth in the above
7 paragraphs and incorporates them by reference herein.

8 45. In view of the facts as alleged above, there is an actual, substantial,
9 immediate, and justiciable controversy between Avation and Defendant regarding whether
10 Avation infringes any claim of the '943 patent.

11 46. According to the face of the '943 patent, Defendant is the assignee of the
12 '943 patent. On information and belief, Defendant owns all rights, title, and interest in and
13 under the '943 patent.

14 47. Defendant has alleged and continues to allege that Avation's Vivally is
15 covered by the claims of the '943 patent, and that Avation is infringing the '943 patent.
16 Defendant may bring suit on this matter at any time. In the meantime, Avation is harmed
17 by these false allegations.

18 48. Avation has not infringed and does not infringe any claim of the '943 patent
19 either directly or indirectly, literally or under the doctrine of equivalents.

20 49. Independent Claims 1, 14, and 27 of the '943 patent recite as follows:

- 21 1. A method of treating overactive bladder or incontinence,
22 comprising:
23 non-invasively positioning a first portion of a patient's body
24 near an ankle relative to an electrical stimulator such that a
25 posterior tibial nerve within the first portion of the body is
26 directly targeted by the electrical stimulator;
27 passing a current through the electrical stimulator; and
28 delivering an electrical stimulus from the electrical stimulator

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to the posterior tibial nerve such that the posterior tibial nerve directly receives the electrical stimulation to treat overactive bladder or incontinence.

14. A method of treating overactive bladder or incontinence, comprising:
non-invasively positioning a first portion of a patient's body near an ankle relative to an electrical stimulator positioned within a sock worn upon a foot of the patient such that a posterior tibial nerve within the first portion of the body is directly targeted by the electrical stimulator;
passing a current through the electrical stimulator; and
delivering an electrical stimulus from the electrical stimulator to the posterior tibial nerve such that the posterior tibial nerve directly receives the electrical stimulation to treat overactive bladder or incontinence.

27. A method of treating overactive bladder or incontinence, comprising:
non-invasively positioning a first portion of a patient's body near an ankle relative to an electrical stimulator positioned upon a strap which is secured over a foot of the patient such that a posterior tibial nerve within the first portion of the body is directly targeted by the electrical stimulator;
passing a current through the electrical stimulator; and
delivering an electrical stimulus from the electrical stimulator to the posterior tibial nerve such that the posterior tibial nerve directly receives the electrical stimulation to treat overactive

1 bladder or incontinence.

2 50. Avation's Vivally does not infringe Independent Claims 1, 14, or 27 (or any
3 of the dependent claims) because it does not include every limitation required by the
4 claims. For instance, without limitation and by way of example only, Avation's Vivally
5 does not meet or embody the limitation of "non-invasively positioning a first portion of a
6 patient's body near an ankle relative to an electrical stimulator," which is required by each
7 of the independent claims. Avation's Vivally does not "position[]" the body "near an
8 ankle" "relative to an electrical stimulator" as those terms are used in the '943 patent. The
9 '943 patent disclosure clearly indicates that "delivering electrical stimulation . . . by
10 stimulating a site overlying a nerve near the medial malleolus [*i.e.*, ankle]. . . generates a
11 painful shock to the patient" and that such electrical stimulation "builds and quickly
12 becomes painful and intolerable." See **Exhibit C**, '943 patent at 50:62-51:3. The term
13 "near an ankle" as used in the claims of the '943 patent therefore cannot encompass
14 delivering electrical stimulation at a site overlying a nerve at the medial malleolus (*i.e.*,
15 ankle). Avation's Vivally provides stimulation energy to a site overlying a nerve at the
16 ankle. Therefore, at least these claim limitations are not practiced by Avation.

17 51. Therefore, a substantial controversy exists between Avation and Defendant,
18 parties having adverse legal interests, of sufficient immediacy and reality to warrant the
19 issuance of a declaratory judgment that Avation has not infringed and does not infringe
20 any claim of the '943 patent.

21 52. A substantial, immediate, real, and justiciable controversy exists between
22 Avation and Defendant as to whether Avation's products infringe the '943 patent. Avation
23 accordingly requests a judicial determination of its rights, duties, and obligations regarding
24 the '943 patent.

25 53. Avation seeks a judgment declaring that Avation does not directly or
26 indirectly infringe any claim of the '943 patent.

27 **PRAYER FOR RELIEF**

28 WHEREFORE, Avation respectfully requests that judgment be entered in its favor

1 and prays that the Court grant the following relief:

2 1. A judgment declaring that Avation has not infringed and is not infringing,
3 either directly or indirectly, literally or under the doctrine of equivalents, any claims of the
4 Challenged Patents, and declaring that the manufacture, use, sale, offer for sale, and/or
5 importation of Avation’s Vivally does not infringe, directly or indirectly, literally or under
6 the doctrine of equivalents, any claims of the Challenged Patents;

7 2. A judgment that Defendant and each of its officers, directors, agents,
8 counsel, servants, employees, and all persons in active concert or participation with any of
9 them, be restrained and enjoined from alleging, representing, or otherwise stating that
10 Avation or the manufacture, importation, use or sale of Avation’s Vivally infringes the
11 Challenged Patents, or from instituting or initiating any action or proceeding alleging
12 infringement of the Challenged Patents against Avation or customers, manufacturers,
13 users, importers, or sellers of Avation’s Vivally;

14 3. A judgment declaring that Avation is the prevailing party and that this is an
15 exceptional case under 35 U.S.C. § 285 and awarding Avation its reasonable attorneys’
16 fees, expenses, and costs in connection with this case; and

17 4. A judgment awarding Avation such other relief as the Court may deem just
18 and proper.

19 **JURY DEMAND**

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

21
22 Dated: March 19, 2024

Respectfully submitted

RUTAN & TUCKER, LLP

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24
25 By: /s/ Seth Jessee

Seth Jessee
Attorneys for Plaintiff
AVATION MEDICAL, INC.