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AVATION MEDICAL, INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

AVATION MEDICAL, INC.,
Plaintiff,
vs.
EMKINETICS, INC.,
Defendant.

Case No. 3:24-cv-01702

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

JURY TRIAL DEMANDED

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

NATURE OF THE ACTION

1. This is an action for a declaratory judgment of noninfringement arising under the patent laws of the United States, Title 35 of the United States Code. Avation requests

1 this relief because Defendant has alleged and continues to allege that Avation's Vivally®
 2 System ("Vivally") infringes U.S. Patent Nos. 9,002,477 (the "477 patent"), 11,224,742
 3 (the "742 patent"), and 11,844,943 (the "943 patent") (collectively, the "Challenged
 4 Patents").

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

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

11 **PARTIES**

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

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

22 6. On information and belief, Defendant is a Delaware corporation with its
 23 principal place of business located at 101 Mississippi Street, San Francisco, California
 24 94107, which is in San Francisco County.

25 **JURISDICTION AND VENUE**

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

8. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), and 2201, and 2202. As detailed below, Defendant's infringement allegations give rise to an immediate, real, and justiciable controversy between Avation and Defendant as to whether Avation is infringing or has infringed any claims of the Challenged Patents.

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

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

INTRADISTRICT ASSIGNMENT

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

BACKGROUND

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

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

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

1 15. On October 23, 2023, Defendant sent Avation a letter to “initiate licensing
2 discussions . . . concerning EMKinetics’ patent portfolio.” In the letter, Defendant stated
3 that “[w]e believe that the following assets may have particular interest and value to you”
4 and listed the ‘477 patent, the ‘742 patent, and U.S. Application No. 17/568,276, which
5 issued as the ‘943 patent.

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

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

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

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

22 20. The imminent threat to Avation is further underscored by the fact that on
23 February 23, 2024, Defendant filed a patent infringement lawsuit in the U.S. District Court
24 for the District of Delaware against a third-party medical company called Cala Health,
25 alleging Cala Health’s neuromodulation devices infringes several patents that are related to
26 the Challenged Patents. Defendant’s business strategy of suing companies in the
27 neuromodulation field that apparently refuse to license its patents make it highly likely that
28

1 Defendant will sue Avation for patent infringement of the Challenged Patents.

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

4 22. Neither Avation, nor any of its products, directly or indirectly infringe any of
5 the Challenged Patents.

6 23. Neither Avation, nor any of its products, perform each element of any claim
7 of the Challenged Patents, nor does Avation instruct third parties to perform each element
8 of any claim of the Challenged Patents.

9 **FIRST CAUSE OF ACTION**

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

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

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

16 26. According to the face of the '477 patent, Defendant is the assignee of the
17 '477 patent. On information and belief, Defendant owns all rights, title, and interest in and
18 under the '477 patent.

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

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

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

27 1. A method of performing electrical stimulation therapy,
28

1 comprising:
 2 non-invasively positioning a first portion of a patient's body
 3 relative to an electrical stimulator such that a posterior tibial
 4 nerve or branch thereof within the first portion of the body is in
 5 proximity to the electrical stimulator;
 6 passing a current through the electrical stimulator;
 7 delivering an electrical stimulus from the electrical stimulator
 8 to the posterior tibial nerve or branch thereof;
 9 detecting electrical conduction through the posterior tibial
 10 nerve or branch thereof or detecting a muscular response
 11 caused by an electrical conduction through the posterior tibial
 12 nerve or branch thereof via at least one sensor positioned along
 13 a second portion of the body;
 14 receiving a signal from the at least one sensor indicative of the
 15 detected electrical conduction or muscular response thereby
 16 providing feedback about the efficacy of the applied electrical
 17 stimulation therapy; and
 18 adjusting the current via a controller in communication with
 19 the electrical stimulator based on the feedback.

20 30. Avation's Vivally does not infringe Independent Claim 1 (or any of the
 21 dependent claims) because it does not include every limitation required by the claim. For
 22 instance, without limitation and by way of example only, Avation's Vivally does not meet
 23 or embody the limitation of "adjusting the current via a controller in communication with
 24 the electrical stimulator based on the feedback." Avation's Vivally does not "adjust[] the
 25 current" of an electrical stimulator "based on the feedback" of "at least one sensor" as
 26 those terms are used in the '477 patent. Avation's Vivally uses pulse-width modulation to
 27 apply stimulation energy, in which the electrical signal supplied via the stimulation
 28

1 electrodes is at a constant current. Therefore, at least these claim limitations are not
2 practiced by Avation.

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

7 32. A substantial, immediate, real, and justiciable controversy exists between
8 Avation and Defendant as to whether Avation's products infringe the '477 patent. Avation
9 accordingly requests a judicial determination of its rights, duties, and obligations regarding
10 the '477 patent.

11 33. Avation seeks a judgment declaring that Avation does not directly or
12 indirectly infringe any claim of the '477 patent.

13 **SECOND CAUSE OF ACTION**

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

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

17 35. In view of the facts as alleged above, there is an actual, substantial,
18 immediate, and justiciable controversy between Avation and Defendant regarding whether
19 Avation infringes any claim of the '742 patent.

20 36. According to the face of the '742 patent, Defendant is the assignee of the
21 '742 patent. On information and belief, Defendant owns all rights, title, and interest in and
22 under the '742 patent.

23 37. Defendant has alleged and continues to allege that Avation's Vivally is
24 covered by the claims of the '742 patent, and that Avation is infringing the '742 patent.
25 Defendant may bring suit on this matter at any time. In the meantime, Avation is harmed
26 by these false allegations.

27 38. Avation has not infringed and does not infringe any claim of the '742 patent
28

1 either directly or indirectly, literally or under the doctrine of equivalents.

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

4 1. A method of treating overactive bladder or incontinence,
5 comprising:
6 non-invasively positioning a first portion of a patient’s body
7 relative to an electrical stimulator such that a branch of a
8 posterior tibial nerve within the first portion of the body is
9 directly targeted by the electrical stimulator;
10 passing a current through the electrical stimulator; and
11 delivering an electrical stimulus from the electrical stimulator
12 to the branch of the posterior tibial nerve such that the branch
13 directly receives the electrical stimulation to treat overactive
14 bladder or incontinence.

15 40. 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 “positioning a first portion of a patient’s body relative to an
19 electrical stimulator such that a branch of a posterior tibial nerve within the first portion of
20 the body is directly targeted by the electrical stimulator.” Additionally, without limitation
21 and by way of example only, Avation’s Vivally does not meet or embody the limitation of
22 “delivering an electrical stimulus from the electrical stimulator to the branch of the
23 posterior tibial nerve such that the branch directly receives the electrical stimulation to
24 treat overactive bladder or incontinence.” Avation’s Vivally does not “directly target[]” a
25 “branch of a posterior tibial nerve” or “deliver[] an electrical stimulus” to a “branch of the
26 posterior tibial nerve” so that the branch “directly receives the electrical stimulation,” as
27 those terms are used in the ‘742 patent. Therefore, at least these claim limitations are not
28

1 practiced by Avation.

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

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

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

12 **THIRD CAUSE OF ACTION**

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

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

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

19 46. According to the face of the '943 patent, Defendant is the assignee of the
20 '943 patent. On information and belief, Defendant owns all rights, title, and interest in and
21 under the '943 patent.

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

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

28

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

1. 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 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.

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
 bladder or incontinence.

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

51. Therefore, a substantial controversy exists between Avation and Defendant,

1 parties having adverse legal interests, of sufficient immediacy and reality to warrant the
 2 issuance of a declaratory judgment that Avation has not infringed and does not infringe
 3 any claim of the '943 patent.

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

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

10 **PRAYER FOR RELIEF**

11 WHEREFORE, Avation respectfully requests that judgment be entered in its favor
 12 and prays that the Court grant the following relief:

13 1. A judgment declaring that Avation has not infringed and is not infringing,
 14 either directly or indirectly, literally or under the doctrine of equivalents, any claims of the
 15 Challenged Patents, and declaring that the manufacture, use, sale, offer for sale, and/or
 16 importation of Avation's Vivally does not infringe, directly or indirectly, literally or under
 17 the doctrine of equivalents, any claims of the Challenged Patents;

18 2. A judgment that Defendant and each of its officers, directors, agents,
 19 counsel, servants, employees, and all persons in active concert or participation with any of
 20 them, be restrained and enjoined from alleging, representing, or otherwise stating that
 21 Avation or the manufacture, importation, use or sale of Avation's Vivally infringes the
 22 Challenged Patents, or from instituting or initiating any action or proceeding alleging
 23 infringement of the Challenged Patents against Avation or customers, manufacturers,
 24 users, importers, or sellers of Avation's Vivally;

25 3. A judgment declaring that Avation is the prevailing party and that this is an
 26 exceptional case under 35 U.S.C. § 285 and awarding Avation its reasonable attorneys'
 27 fees, expenses, and costs in connection with this case; and
 28

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

Respectfully submitted

By: /s/ Seth Jessee

Case No. _____
COMPLAINT FOR DECLARATORY JUDGMENT