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MMAS Research LLC and Dr. Donald E. Morisky

IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

MMAS RESEARCH LLC and
DR. DONALD E. MORISKY,

Plaintiff(s),

vs.

DUKE UNIVERSITY; DR. ALLISON
VORDERSTRASSE; DR. LUCY
PINER; DR. BRIAN D. DUSCHA; DR.
MAHESH PATEL; DR. KAREN P.
CRAIG; DR. ROBERT W.
MCGARRAH III; DR. WILLIAM E.
KRAUS; DR. DEEPAK VOORA; DR.
ASHLEY AULL DUNHAM; DR.
BRANDI GRANGER; and DOES 1-50,

Defendant(s).

Case No.: 2:21-cv-2569

COMPLAINT FOR DAMAGES

- 1. Copyright Infringement Under 17 U.S.C. §§ 101, *et seq.***
- 2. False Designation of Origin/Federal Unfair Competition Under 15 U.S.C. § 1125(a)**
- 3. Trade Secret Misappropriation Under 18 U.S.C. § 1836, *et seq.***
- 4. Trade Secret Misappropriation Under Cal. Civ. Code § 3426 *et seq.***

JURY TRIAL DEMANDED

Plaintiffs MMAS RESEARCH LLC and DR. DONALD MORISKY complain and allege as follows:

1 9. Defendant Dr. Lucy Piner (“PINER”) is or was a researcher at DUKE at all relevant
2 times.

3 10. Defendant Dr. Mahesh Patel (“PATEL”) is or was a researcher at DUKE at all relevant
4 times.

5 11. Defendant Dr. Karen M. Craig (“CRAIG”) is or was a researcher at DUKE at all
6 relevant times.

7 12. Defendant Dr. Robert W. McGarrah III (“MCGARRAH”) is or was a researcher at
8 DUKE at all relevant times.

9 13. Defendant Dr. William E. Kraus (“KRAUS”) is or was a researcher at DUKE at all
10 relevant times.

11 14. Defendant Dr. Deepak Voora (“VOORA”) is or was a researcher at DUKE at all relevant
12 times.

13 15. Defendant Dr. Ashley Aull Dunham (“DUNHAM”) is or was a researcher at DUKE at
14 all relevant times.

15 16. Defendant Dr. Brandi Granger (“GRANGER”) is or was a researcher at DUKE at all
16 relevant times.

17 17. Collectively, Defendants VORDERSTRASSE, DUSCHA, PINER, PATEL, CRAIG,
18 MCGARRAH, KRAUS, VOORA, DUNHAM, and GRANGER are the “DUKE RESEARCHERS,” or
19 individually, as a “DUKE RESEARCHER.”

20 18. Whenever appearing in this Complaint, each reference to Defendants or to any of
21 them, is intended to be and shall be a reference to all defendants hereto, including DUKE and
22 DUKE RESEARCHERS, and to each of them named and unnamed, including all fictitiously named
23 defendants, unless said reference is otherwise specifically qualified.

1 19. Plaintiffs are informed, believe, and thereupon allege that each RESEARCHER was
2 and is in some manner responsible for the actions, acts, and omissions herein alleged, and for the
3 damage caused by the defendant DUKE and is, therefore, jointly and severally liable for the damage
4 caused to Plaintiffs.

5 20. Plaintiffs are informed, believe, and thereon allege that each of the Defendants were, at
6 all times herein relevant, acting in concert with and in conspiracy with each one of the remaining
7 defendants.

8 21. Each defendant is sued both as principal and as the servant, agent, employee, co-
9 venturer, and co-tortfeasor of the remaining defendants, and each of them is liable in some manner for
10 the damages to Plaintiffs complained of herein.

11 22. Plaintiffs are informed, believe, and thereon allege defendants, and each of them, did at
12 all material times foresee the nature and extent of the probable consequences of their acts in proximately
13 causing said damages to Plaintiffs, and acted within the course and scope of such service, agency,
14 employment, and joint venture, and with the knowledge, permission, and authority, actual and apparent,
15 express and implied, direct and vicarious, of the remaining defendants, and each of them.

16 23. Plaintiffs are informed, believe, and thereon allege that at all relevant times each of the
17 defendants was the agent, employee, representative, co-conspirator, affiliate, alter-ego, and/or successor-
18 in-interest of each of them, and of each other, and has, in such capacity or capacities, participated in the
19 acts or conduct alleged herein. All allegations made herein shall apply to each of the Defendants, as
20 applicable.

21 24. The true names and capacities, whether individual, corporate, associate or otherwise,
22 of defendants DOES 1-50, inclusive, are unknown to Plaintiffs, who therefore sue said Defendants
23 by such fictitious names. Plaintiffs are informed and believe and based thereon allege, that each of
24 the Defendants herein designated as a DOE, is responsible in some manner for the events and
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1 happenings herein referred to, and caused injuries and damages proximately thereby. Plaintiffs will
2 amend this complaint and insert the true names and capacities of said DOE Defendants when the
3 same has been ascertained.

4 **JURISDICTION AND VENUE**

5 25. This action arises, in part, under the Copyright Act of 1976, 17 U.S.C. §§ 101, *et*.
6 *seq.*, and the Lanham Trademark Act of 1946, 15 U.S.C. § 1051, *et seq.*, conferring Federal
7 question jurisdiction under 28 U.S.C. § 1331, and supplemental jurisdiction on Plaintiffs' state law
8 claims under 28 U.S.C. § 1367. This Court has original jurisdiction over this controversy for
9 misappropriation of trade secrets claims pursuant to 18 U.S.C. § 1836(c).

10 26. Venue is proper in this District pursuant to 28 U.S. C. §§ 1391(b)(2) as: (a) a
11 substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in this District;
12 (b) Defendants conduct business in this District; (c) the unlawful acts of Defendants complained of
13 herein have been committed within this District and have had or will have had effect in this District;
14 (d) the written agreements/contracts as identified and described more thoroughly below were
15 entered into by the respective parties in this District; (e) the written agreements/contracts as
16 identified and described more thoroughly below conferred jurisdiction in this District; and (f)
17 Plaintiffs are residents of this District, has been and will continue to be damaged by Defendants'
18 unlawful acts.

19 **GENERAL ALLEGATIONS**

20 **MORISKY MEDICATION ADHERENCE SCALES**

21 27. As early as 2002, Plaintiff MORISKY, a Professor Emeritus at UCLA,
22 independently developed a distinctive diagnostic tool which determines a patient's adherence to his
23 or her prescribed medication. The tool is known as the Morisky Medication Adherence Scale
24 ("MMAS").

1 exclusively with the medication adherence scales developed by Plaintiff MORISKY. The
2 MORISKY MARKS have become a valuable asset of Plaintiffs as well as a symbol of their
3 goodwill and positive reputations.

4 **LICENSES**

5 46. It is of critical importance the integrity of the MMAS be maintained. This is why a
6 strict licensing regimen is used and disclosure of coding and scoring criteria, and translations not
7 provided by Plaintiffs, are not permitted.

8 47. Plaintiffs have discovered that when someone obtains the MMAS coding and scoring
9 criteria they often make changes that lead to erroneous results. Others obtaining the MMAS from
10 counterfeiters often make further unauthorized revisions, further increasing the risk of harm to
11 patients and misleading healthcare providers. Unlicensed translations are often divulged and used
12 with the coding and scoring criteria which render the results invalid and misunderstood.

13 48. Plaintiffs have spent considerable time and money to develop, maintain, and advance
14 the MMAS described herein and it now can be administered with regard to one hundred ten (110)
15 medical conditions and thousands of specific medications as of this filing, and in more than eighty
16 (80) languages. The MMAS is used by physicians, hospitals, clinicians, pharmaceutical companies,
17 universities, medical researchers, and health ministries throughout the world, including National
18 Institute of Health funded studies, all to measure medication adherence and identify the reasons for
19 why patients do not take their prescribed medications. MMAS translations are provided by
20 Plaintiffs for a small fee along with a translation certification. Translations of the MMAS without
21 proper authorization are prohibited.

22 49. The various MMAS diagnostic assessments are validated and translated in over
23 eighty (80) languages and utilized throughout the world. The MMAS is famous in the industry and
24 is the number one patient-centered diagnostic medication adherence assessment of its kind.

1 Plaintiffs make considerable efforts to maintain the secrecy of the coding and scoring of the scale
2 and expressly forbid the disclosure of coding and scoring in their license agreements with licensees
3 of all versions of the MMAS.

4 50. Plaintiffs permit the use of the MORISKY COPYRIGHTS, MORISKY MARKS, the
5 MMAS, and the Morisky Widget only through a licensing program memorialized in a licensing
6 agreement. This ensures uniformity of use in coding and scoring, as well as provides much needed
7 support from Plaintiffs. Modifications of the MMAS, and disclosure of coding and scoring criteria
8 and linguistically certified translations are not permitted.

9 51. Reasonable efforts are taken by Plaintiffs to protect and not to disseminate the
10 MMAS, Morisky Widget, or translated versions to non-authorized users, as well as the coding and
11 scoring. These restrictions not only protect patients and health care providers from counterfeit
12 diagnostic assessments and inaccurate coding and scoring, but also protect the economic interests of
13 Plaintiffs in the MORISKY COPYRIGHTS, MORISKY MARKS, the MMAS itself, along with the
14 Morisky Widget diagnostic assessment, as they receive licensing fees and are paid per test
15 administered, unless such fees are waived. In fact, the license agreement expressly provides that
16 coding and scoring may not be disclosed.

17 52. Licenses are typically provided at no cost for federally-funded studies, and to
18 educational institutions that are not receiving funding for the research/study for which the MMAS
19 and Morisky Widget is to be used. Others are charged a fee for a fixed term or for a perpetual
20 license sold as the Morisky Widget. Plaintiffs also charge fees for training and certification in use of
21 the Morisky Widget, and there is a charge for each test administered by a licensee, in addition to
22 those included in the cost of the license.

23 53. The MORISKY COPYRIGHTS, MORISKY MARKS, and the MMAS have been
24 cited in over eight thousand (8,000) academic journals throughout the world.

1 54. Due to Plaintiffs' exclusive and extensive use, through a strict regimen of licensing
2 and supervision, the MORISKY COPYRIGHTS, MORISKY MARKS, the MMAS, and the
3 Morisky Widget have enormous value both economically and for the promotion of health and
4 proper diagnosis of persons suffering from a wide range of chronic and infectious diseases and
5 mental health conditions worldwide.

6 **DEFENDANTS DUKE AND VORDERSTRASSE'S INFRINGING CONDUCT**

7 55. On or around August 19, 2013, Plaintiff MORISKY and Defendants DUKE and
8 VORDERSTRASSE entered into a license agreement (hereinafter the "Duke/Vorderstrasse License
9 Agreement") whereby said Defendants were permitted to administer MMAS-8 tests, and in so
10 doing, utilize the MORISKY COPYRIGHTS and MORISKY MARKS for a period of one year. A
11 copy of the Duke/Vorderstrasse License Agreement is attached hereto and incorporated herein as
12 Exhibit A.

13 56. Section (C)(2) of the Duke/Vorderstrasse License Agreement provides: "Coding and
14 scoring criteria of the MMAS-8 are trade secrets of [Plaintiff MORISKY] and as such cannot be
15 divulged in any publication or report without [Plaintiff MORISKY's] prior written permission."

16 57. Section (C)(5) of the Duke/Vorderstrasse License Agreement provides: "In case of
17 scientific, administrative or intellectual property misconduct using the MORISKY SCALE system
18 of questionnaires or the Morisky name or MMAS names, [Plaintiff MORISKY] reserves the right to
19 withdraw permission for use and to pursue all legal remedies. Licensee agrees to the jurisdiction in
20 and venue of the State and Federal Courts in Los Angeles County."

21 58. Section (C)(6) of the Duke/Vorderstrasse License Agreement provides: "Rights
22 granted under this Agreement to use the Morisky scales terminate one-year from the date below or
23 on termination of Licensee's study, whichever is shorter. Licensee acknowledges understanding and
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1 agreeing [sic] to abide by the above requirements regarding use of any Morisky Medication
2 Adherence Scale or other Morisky intellectual property.”

3 59. Upon information and belief, Defendants DUKE and VORDERSTRASSE conducted
4 a medical study testing patient adherence to proscribed treatments, which is described on the
5 ClinicalTrials.gov website under the title, “Genetic Risk and Health Coaching for Type 2 Diabetes
6 and Coronary Heart Disease” (the “Vorderstrasse Study”). Attached as Exhibit B is a true and
7 correct copy of the ClinicalTrials.gov webpage containing the Vorderstrasse Study, hereby
8 incorporated by reference in its entirety.

9 60. On or around January 29, 2019, in response to Plaintiff MMAS RESEARCH’s
10 inquiry, Defendant VORDERSTRASSE stated that she administered MMAS tests between
11 December 20, 2013, and February 28, 2017. Attached as Exhibit C is a copy of Defendant
12 VORDERSTRASSE’s January 29, 2019 response.

13 61. In her January 29, 2019 response, Defendant VORDERSTRASSE attached the
14 following MMAS-8 Scale that she administered to patients (the “Duke/Vorderstrasse MMAS-8
15 Patient Questionnaire”). Attached as Exhibit D is a true and correct copy of the Duke/Vorderstrasse
16 MMAS-8 Patient Questionnaire, hereby incorporated by reference in its entirety.

17 62. Upon information and belief, between December 20, 2013, and February 28, 2017,
18 Defendants DUKE and VORDERSTRASSE administered MMAS-8 tests using the
19 Duke/Vorderstrasse MMAS-8 Patient Questionnaire.

20 63. Upon information and belief, at least some of the MMAS-8 tests administered by
21 Defendants DUKE and VORDERSTRASSE were administered after expiration of the
22 Duke/Vorderstrasse License Agreement.

23 64. To the extent it was administered after expiration of the Duke/Vorderstrasse License
24 Agreement expired, the Duke/Vorderstrasse MMAS-8 Patient Questionnaire both utilizes the
25

1 MORISKY COPYRIGHTS and/or displays the MORISKY MARKS without a valid license and
2 without authorization by Plaintiff MORISKY.

3 65. Further, the Duke/Vorderstrasse MMAS-8 Patient Questionnaire discloses trade
4 secret MMAS-8 coding and scoring criteria without a valid license and without authorization by
5 Plaintiff MORISKY.

6 **DEFENDANTS DUKE, PINER, DUSCHA, PATEL, CRAIG, MCGARRAH, and KRAUS 'S**
7 **INFRINGING CONDUCT**

8 66. On or around January 7, 2015, Plaintiff MORISKY and Defendants DUKE and
9 PINER entered into a license agreement (hereinafter the "Duke/Piner License Agreement") whereby
10 said Defendants were permitted to administer MMAS-8 test for one clinical study, and in so doing,
11 utilize the MORISKY COPYRIGHTS and MORISKY MARKS during the one-year period
12 commencing on January 7, 2015. A copy of the Duke/Piner License Agreement is attached hereto
13 and incorporated herein as Exhibit E.

14 67. Section (C)(2) of the Duke/Piner License Agreement provides: "Coding and scoring
15 criteria of the MMAS-8 are trade secrets of [Plaintiff MORISKY] and as such cannot be divulged in
16 any publication or report without [Plaintiff MORISKY's] prior written permission."

17 68. Section (C)(5) of the Duke/Piner License Agreement provides: "In case of scientific,
18 administrative or intellectual property misconduct using the MORISKY SCALE system of
19 questionnaires or the Morisky name or MMAS names, [Plaintiff MORISKY] reserves the right to
20 withdraw permission for use and to pursue all legal remedies. Licensee agrees to the jurisdiction in
21 and venue of the State and Federal Courts in Los Angeles County."

22 69. Section (C)(6) of the Duke/Piner License Agreement provides: "Rights granted
23 under this Agreement to use the Morisky scales terminate one-year from the date below or on
24 termination of Licensee's study, whichever is shorter. Licensee acknowledges understanding and
25

1 agreeing [sic] to abide by the above requirements regarding use of any Morisky Medication
2 Adherence Scale or other Morisky intellectual property.”

3 70. Page 2, paragraph 1, of the Duke/Piner License Agreement provides: “If your study
4 becomes funded following the waiver of license fee, you must inform the developer/owner of the
5 MMAS-8 and pay the license fee for continued use of the copyrighted intellectual property.”

6 71. Pursuant to the Duke/Piner License Agreement, Defendants DUKE, PINER,
7 DUSCHA, PATEL, CRAIG, MCGARRAH, and KRAUS conducted a clinical study, the results of
8 which were published in an article entitled, “A Lifestyle-Based Mobile Health Strategy for
9 Cardiovascular Disease Prevention in Graduates From Cardiac Rehabilitation: VIDA Pilot Study” (“Piner Study 1”). Attached hereto as Exhibit F is a true and correct copy of the ClinicalTrials.gov
10 webpage describing Piner Study 1 (“Piner Study 1 Webpage”), hereby incorporated by reference in
11 its entirety.
12

13 72. The Piner Study 1 Webpage lists the “Study Start Date” for Piner Study 1 as July
14 2015. The Piner Study 1 Webpage lists the “Actual Primary Completion Date” and “Actual Study
15 Completion Date for Piner Study 1 as March 20, 2017.

16 73. The Piner Study 1 Webpage provides: “Secondary Outcome Measures . . . 4. Change
17 in Medication Adherence as measured by Morisky Medication Adherence Scale (MMAS-8).”

18 74. Upon information and belief, between January 7, 2016 and March 20, 2017,
19 Defendants DUKE, PINER, DUSCHA, PATEL, CRAIG, MCGARRAH, and KRAUS administered
20 MMAS-8 tests in Piner Study 1, utilizing the MORISKY COPYRIGHTS and/or displaying the
21 MORISKY MARKS without a valid license and without authorization by Plaintiff MORISKY.

22 75. Upon information and belief, Piner Study 1 was funded by Vida Health, a condition
23 which required Defendants DUKE and PINER to inform Plaintiff MORISKY pursuant to the
24 Duke/Piner License Agreement.
25

1 agreement, which is attached. [¶] However, this was for a different study [Piner Study 1], and not
2 the study listed below [Piner Study 2]. We thought the license provided us with a one-time site
3 license and was not needed for individual studies. Therefore, no agreement was signed for the study
4 cited below. Our apologies for this oversight.” A true and correct copy of Defendant DUSCHA’s
5 August 14, 2018 email is attached hereto as Exhibit H, hereby incorporated by reference in its
6 entirety.

7 82. The Piner Study 2 Webpage lists the “Study Start Date” for Piner Study 2 as July
8 2015. The Piner Study 2 Webpage lists the “Actual Primary Completion Date” and “Actual Study
9 Completion Date for Piner Study 2 as November 7, 2017.

10 83. The Piner Study 2 Webpage provides: “Secondary Outcome Measures . . . 6. Change
11 in Medication Adherence scores as measured by the Morisky Medication Adherence Scale
12 (MMAS-8).”

13 84. Upon information and belief, Defendants DUKE, PINER, DUSCHA, PATEL,
14 CRAIG, MCGARRAH, and KRAUS administered MMAS-8 tests for Piner Study 2 between July
15 2015 and November 7, 2017, utilizing the MORISKY COPYRIGHTS and/or displaying the
16 MORISKY MARKS.

17 85. Upon information and belief, Piner Study 2 was funded by Verizon.

18 86. Defendants DUKE, PINER, DUSCHA, PATEL, CRAIG, MCGARRAH, and
19 KRAUS never paid a license fee for the use of the MORISKY COPYRIGHTS, the MORISKY
20 MARKS, or the MMAS-8 for Piner Study 2.

21 87. Plaintiff MORISKY never licensed and never authorized the use of the MORISKY
22 COPYRIGHTS and/or the MORISKY MARKS by Defendants DUKE, PINER, DUSCHA, PATEL,
23 CRAIG, MCGARRAH, and KRAUS for Piner Study 2.

DEFENDANTS DUKE AND VOORA'S INFRINGING CONDUCT

88. In or around July 2013, Plaintiff MORISKY and Defendants DUKE and VOORA entered into a license agreement (hereinafter the "Duke/Voora License Agreement") whereby said Defendants were permitted to administer MMAS-8 test for one clinical study, and in so doing, utilize the MORISKY COPYRIGHTS and MORISKY MARKS for a one-year period. A copy of the Duke/Voora License Agreement is attached hereto and incorporated herein as Exhibit I.

89. Section (C)(2) of the Duke/Voora License Agreement provides: "Coding and scoring criteria of the MMAS-8 are trade secrets of [Plaintiff MORISKY] and as such cannot be divulged in any publication or report without [Plaintiff MORISKY's] prior written permission."

90. Section (C)(5) of the Duke/Voora License Agreement provides: "In case of scientific, administrative or intellectual property misconduct using the MORISKY SCALE system of questionnaires or the Morisky name or MMAS names, [Plaintiff MORISKY] reserves the right to withdraw permission for use and to pursue all legal remedies. Licensee agrees to the jurisdiction in and venue of the State and Federal Courts in Los Angeles County."

91. Section (C)(6) of the Duke/Voora License Agreement provides: "Rights granted under this Agreement to use the Morisky scales terminate one-year from the date below or on termination of Licensee's study, whichever is shorter. Licensee acknowledges understanding and agreeing [sic] to abide by the above requirements regarding use of any Morisky Medication Adherence Scale or other Morisky intellectual property."

92. The last paragraph on page 3 of the Duke/Voora License Agreement provides: "I understand that the licensure fee for use of the copyrights MMAS-8 will be waived, as I am a physician conducting adherence assessment with no private funding source. If this situation should change to private sources of funding, then the license is no longer in effect."

1 93. In February 2021, Plaintiffs became aware of two clinical studies conducted by
2 Defendants DUKE and VOORA. However, the Duke/Voora License Agreement only authorized
3 use of the MORISKY COPYRIGHTS and the MORISKY MARKS for one study.

4 94. On or around July 10, 2013, Defendants DUKE and VOORA published or caused to
5 be published the results of one study (“Voora Study 1”) entitled, “Statin Therapy to Improve
6 Medication Adherence.” Attached as Exhibit J is a true and correct copy of Voora Study 1 on the
7 ClinicalTrials.gov website (the “Voora Study 1 Webpage”), hereby incorporated by reference in its
8 entirety.

9 95. As of March 12, 2021, the Voora Study 1 Webpage remains publicly accessible on
10 the ClinicalTrials.gov website.

11 96. The Voora Study 1 Webpage provides: “Medication adherence is assessed by the 8-
12 item Morisky medication adherence scale (MMAS). The first 7 questions of the MMAS are scored
13 one point for 'yes' and zero points for a 'no' response; the last question is assessed using a 5-point
14 Likert-type responses ranging from "usually" to "all the time" (usually = 1; all the time = 5). Non-
15 adherence is defined as a score higher than zero. For the purposes of this pilot study, the MMAS is
16 adapted to focus on cholesterol lowering therapies.”

17 97. The Voora Study 1 Webpage, which remained publicly accessible as of March 12,
18 2021, discloses incorrect and trade secret coding and incorrect scoring criteria for the MMAS-8.

19 98. Upon information and belief, Defendants DUKE and VOORA entered into the
20 Duke/Voora License Agreement for the purpose of authorizing Defendants’ use of the MORISKY
21 COPYRIGHTS and the MORISKY MARKS during the term of the Duke/Voora License
22 Agreement and in connection with Voora Study 1, and no other study.

1 99. To the extent Defendants DUKE and VOORA used the MORISKY COPYRIGHTS
2 and/or the MORISKY MARKS in Voora Study 1 beyond the term of the Duke/Voora License
3 Agreement, such use was not authorized.

4 100. Plaintiffs never authorized Defendants DUKE and VOORA's disclosure of the trade
5 secret coding criteria for the MMAS-8 on the Voora Study 1 Webpage.

6 101. From on or around August 22, 2013, to on or around October 16, 2015, Defendants
7 DUKE and VOORA conducted a second clinical study ("Voora Study 2").

8 102. Defendants DUKE and VOORA reported the results of Voora Study 2 in two
9 published articles. The first article, published in or around September 2018, was entitled, "Effects of
10 Delivering SLCO1B1 Pharmacogenetic Information in Randomized Trial and Observational
11 Settings," (the "Voora Effects Article"). Attached as Exhibit K is a true and correct copy of the
12 Voora Effects Article, hereby incorporated by reference in its entirety.

13 103. Page 1 of the Voora Effects Article provides: "METHODS: . . . The primary
14 outcome was statin adherence using the Morisky Medication Adherence Scale, which was assessed
15 in those patients who reinitiated statins."

16 104. Page 1 of the Voora Effects Article further states: "RESULTS: . . . Statin adherence
17 was similar between arms (Morisky Medication Adherence Scale in GIST versus UC, 6.8 ± 1.5
18 versus 6.9 ± 1.6 , $P=0.96$)."

19 105. Page 3 of the Voora Effects Article states: "At the 3-month follow-up time point, 62
20 out of 159 (39%) reported statin utilization and completed the Morisky Medication Adherence Scale
21 (MMAS)."

22 106. On or around March 2017, Defendants DUKE and VOORA published or caused to
23 be published a second article reporting the results of the Voora Study 2. This second article was
24 entitled, "Genetically Guided Statin Therapy" (the "Voora Guided Statins Article"). Attached as
25

1 Exhibit L is a true and correct copy of the Voora Guided Statins Article, hereby incorporated by
2 reference in its entirety.

3 107. Page 3 of the Voora Guided Statins Article provides: “The outcomes measured at 3
4 and 8 months were statin reinitiation, low-density lipoprotein cholesterol (LDLc), and statin
5 adherence using the validated Morisky Medication Adherence Scale.”

6 108. Page 11 of the Voora Guided Statins Article provides: “Survey Instruments. The
7 survey instruments administered to the patients in this study are described below. The primary
8 outcome of the study was the eight-item MMAS, which includes eight yes/no items that are
9 summed to create an overall adherence score ranging from 0 to 8, with higher scores indicating
10 better adherence.”

11 109. Upon information and belief, during the course of Voora Study 2, Defendants DUKE
12 and VOORA administered MMAS-8 tests which both utilize the MORISKY COPYRIGHTS and/or
13 display the MORISKY MARKS.

14 110. Plaintiff MORISKY never authorized use of the MORISKY COPYRIGHTS and/or
15 the MORISKY MARKS by Defendants DUKE and VOORA in Voora Study 2.

16 **DEFENDANT DUKE’S INFRINGING CONDUCT IN THE NORC EVALUATION**

17 111. Upon information and belief, the Southeastern Diabetes Initiative (“SEDI”) was “a
18 joint effort between several departments within Duke and external partners. The SEDI project is
19 funded by Centers for Medicare and Medicaid Health Care Innovations Award and a grant from the
20 Bristol Meyers Squibb Foundation.” Duke Center for Health Informatics, *Southeastern Diabetes*
21 *Initiative (SEDI) Data Mart: Phase 2 Completion*, [https://dukeinformatics.org/southeastern-](https://dukeinformatics.org/southeastern-diabetes-initiative-sedi-data-mart-phase-2-completion/)
22 [diabetes-initiative-sedi-data-mart-phase-2-completion/](https://dukeinformatics.org/southeastern-diabetes-initiative-sedi-data-mart-phase-2-completion/) (last modified Oct. 28, 2014).

23 112. On or around January 31, 2013, Plaintiff MORISKY and Defendants DUKE and
24 DUNHAM entered into a license agreement (hereinafter the “Duke/SEDI License Agreement”)

1 whereby said Defendants were permitted to administer MMAS-8 test for one research study,
2 entitled “CMS Innovation Award: Southeastern Diabetes Initiative [SEDI], and the Bristol Myers
3 Squibb Foundation Durham Diabetes Coalition” (hereinafter, the “Duke/SEDI Study”). A copy of
4 the Duke/SEDI License Agreement is attached hereto and incorporated herein as Exhibit M.

5 113. The Duke/SEDI License Agreement permitted Defendants DUKE and DUNHAM to
6 utilize the MORISKY COPYRIGHTS and MORISKY MARKS in connection with the Duke/SEDI
7 Study during the one-year period commencing on January 31, 2013.

8 114. Section (C)(2) of the Duke/SEDI License Agreement provides: “Coding and scoring
9 criteria of the MMAS-8 are trade secrets of [Plaintiff MORISKY] and as such cannot be divulged in
10 any publication or report without [Plaintiff MORISKY’s] prior written permission.”

11 115. Section (C)(5) of the Duke/SEDI License Agreement provides: “In case of scientific,
12 administrative or intellectual property misconduct using the MORISKY SCALE system of
13 questionnaires or the Morisky name or MMAS names, [Plaintiff MORISKY] reserves the right to
14 withdraw permission for use and to pursue all legal remedies. Licensee agrees to the jurisdiction in
15 and venue of the State and Federal Courts in Los Angeles County.”

16 116. Section (C)(6) of the Duke/SEDI License Agreement provides: “Rights granted
17 under this Agreement to use the Morisky scales terminate one-year from the date below or on
18 termination of Licensee’s study, whichever is shorter. Licensee acknowledges understanding and
19 agreeing [sic] to abide by the above requirements regarding use of any Morisky Medication
20 Adherence Scale or other Morisky intellectual property.”

21 117. On or around March 2016, NORC at the University of Chicago (“NORC”) released a
22 “Second Annual Report HCIA Disease Specific Evaluation” (the “NORC Evaluation”). Attached
23 hereto as Exhibit N is a true and correct copy of the NORC Evaluation, hereby incorporated by
24 reference in its entirety.

1 126. Again, contrary to the description provided by the Alabama Pharmacy Scoring PDF,
2 higher adherence equates to higher scores for both the MMAS-4 and the MMAS-8, while lower
3 adherence equates to lower scores for both the MMAS-4 and the MMAS-8.

4 127. Upon information and belief, neither the NORC Evaluation nor the Alabama
5 Pharmacy Scoring PDF are the Duke/SEDI Study. Consequently, neither the NORC Evaluation nor
6 the Alabama Pharmacy Scoring PDF were within the scope of the Duke/SEDI License Agreement.

7 128. Plaintiffs never authorized Defendants DUKE and DUNHAM to provide MMAS
8 scoring criteria to NORC. In addition, the MMAS scoring criteria provided by Defendants DUKE
9 and DUNHAM for publication in the NORC Evaluation is obviously incorrect.

10 **DEFENDANT DUKE AND GRANGER'S INFRINGING CONDUCT**

11 129. On or around October 2, 2013, Plaintiff MORISKY and Defendants DUKE and
12 GRANGER entered into a license agreement whereby said Defendants were permitted to administer
13 MMAS-8 test for one clinical study entitled, "Heart at Home (utilize the MMASTM as a core
14 assessment as standard of care)," and in so doing, utilize the MORISKY COPYRIGHTS and
15 MORISKY MARKS during a one-year period commencing on October 2, 2013 (hereinafter the
16 "Duke/Granger License Agreement"). A copy of the Duke/Granger License Agreement is attached
17 hereto and incorporated herein as Exhibit P.

18 130. Section (C)(2) of the Duke/Granger License Agreement provides: "Coding and
19 scoring criteria of the MMAS-8 are trade secrets of [Plaintiff MORISKY] and as such cannot be
20 divulged in any publication or report without [Plaintiff MORISKY's] prior written permission."
21

22 131. Section (C)(5) of the Duke/Granger License Agreement provides: "In case of
23 scientific, administrative or intellectual property misconduct using the MORISKY SCALE system
24 of questionnaires or the Morisky name or MMAS names, [Plaintiff MORISKY] reserves the right to
25

1 withdraw permission for use and to pursue all legal remedies. Licensee agrees to the jurisdiction in
2 and venue of the State and Federal Courts in Los Angeles County.”

3 132. Section (C)(6) of the Duke/Granger License Agreement provides: “Rights granted
4 under this Agreement to use the Morisky scales terminate one-year from the date below or on
5 termination of Licensee’s study, whichever is shorter. Licensee acknowledges understanding and
6 agreeing [sic] to abide by the above requirements regarding use of any Morisky Medication
7 Adherence Scale or other Morisky intellectual property.”

9 133. Upon information and belief, the Medication Adherence Alliance (“MAA”) is a
10 group of medication adherence experts whose mission is to “identify evidence-based resources to
11 educate and equip patients and their families, healthcare providers, industry partners, and academic
12 researchers about the field of medication adherence.” Medication Adherence Alliance, *About*,
13 <http://www.managingyourmeds.org/about/> (last visited Mar. 12, 2021).

14 134. Upon information and belief, and according to the MAA website itself, the MAA
15 website was developed by MAA members from Defendant DUKE and another organization named
16 PhRMA. *Id.*

17 135. On the MAA website, Defendant GRANGER is listed as the electronic health
18 records (EHR) Workgroup Director. On the MAA website’s “About” page, Defendant
19 GRANGER’s name is a hyperlink to her faculty profile on Defendant DUKE’s website:
20 <http://nursing.duke.edu/directories/faculty/bradi.granger>.

21 136. The MAA website provides a link ([http://managingyourmeds.org/wp-](http://managingyourmeds.org/wp-content/uploads/2016/02/Glossary-of-Terms-12_13_2015.pdf)
22 [content/uploads/2016/02/Glossary-of-Terms-12_13_2015.pdf](http://managingyourmeds.org/wp-content/uploads/2016/02/Glossary-of-Terms-12_13_2015.pdf)) to a downloadable PDF entitled,
23 “Duke University CRI - Medication Adherence Alliance -Adherence Measures Working Group”
24
25

1 (the “MAA PDF”). A true and correct copy of the MAA PDF is attached hereto as Exhibit Q, which
2 is hereby incorporated by reference in its entirety.

3 137. As of March 12, 2021, the MAA PDF remains available for download on the MAA
4 website.

5 138. The MAA PDF states as follows: “The Morisky Medication Adherence Scale
6 (MMAS) is a generic self-reported, medication-taking behavior scale, validated for hypertension but
7 used for a wide variety of medical conditions. The original version of the scale (MMAS-4) consists
8 of four items with a scoring scheme of “Yes” = 0 and “No” = 1. 1 The items are summed to give a
9 range of scores from low adherence to high adherence (Tables 1 and 2). The latest version of the
10 scale (MMAS-8) consists of eight items with a scoring scheme of “Yes” = 0 and “No” = 1 for the
11 first seven items and a 5-point Likert response for the last item. 2 The items are summed to give a
12 range of scores from low adherence to high adherence.”

13 139. Upon information and belief, Defendants DUKE and GRANGER published the
14 MAA PDF in reliance on the expired Duke/Granger License Agreement.

15 140. Upon information and belief, the MAA PDF is not the “Heart at Home” study
16 described in the Duke/Granger License Agreement. Consequently, Defendants DUKE and
17 GRANGER’s use of the MORISKY COPYRIGHTS and the MORISKY MARKS in the MAA PDF
18 was not within the scope of the Duke/Granger License Agreement.

19 141. Defendants DUKE and GRANGER used the MORISKY COPYRIGHTS and/or
20 displayed the MORISKY MARKS in the MAA PDF without a license and without authorization by
21 Plaintiff MORISKY.

22 142. In addition, the MAA PDF discloses incorrect and trade secret coding and incorrect
23 scoring criteria for the MMAS-4 and MMAS-8.

1 **FIRST CAUSE OF ACTION**

2 **COPYRIGHT INFRINGEMENT (17 U.S.C. §§ 101, *et seq.*)**

3 **(BY PLAINTIFF MORISKY AGAINST ALL DEFENDANTS)**

4 143. Plaintiff MORISKY realleges each allegation contained in the preceding paragraphs.

5 144. At all times relevant hereto, Plaintiff MORISKY was the owner of all copyright
6 rights or rights to assert copyright claims for the MORISKY COPYRIGHTS and all derivative
7 works. Plaintiff MORISKY has complied in all respects with the Copyright Act of 1976, 17 U.S.C.
8 §§ 101, *et seq.*, and all other laws governing copyright.

9 145. Plaintiff MORISKY is informed and believes and thereon alleges that Defendants
10 DUKE and VORDERSTRASSE without authorization, have infringed the MORISKY
11 COPYRIGHTS by using, copying, counterfeiting, distributing, or otherwise exploiting the same in
12 the Vorderstrasse Study after expiration of the Duke/Vorderstrasse License Agreement.

13 146. Plaintiff MORISKY is informed and believes and thereon alleges that Defendants
14 DUKE, PINER, DUSCHA, PATEL, CRAIG, MCGARRAH, and KRAUS without authorization,
15 have infringed the MORISKY COPYRIGHTS by using, copying, counterfeiting, distributing, or
16 otherwise exploiting the same from January 7, 2016 to March 20, 2017 in Piner Study 1, and at all
17 times in Piner Study 2.

18 147. Plaintiff MORISKY is informed and believes and thereon alleges that Defendants
19 DUKE and VOORA without authorization, have infringed the MORISKY COPYRIGHTS by using,
20 copying, counterfeiting, distributing, or otherwise exploiting the same in Voora Study 2.

21 148. Plaintiff MORISKY is informed and believes and thereon alleges that Defendants
22 DUKE and DUNHAM without authorization, have infringed the MORISKY COPYRIGHTS by
23 using, copying, counterfeiting, distributing, or otherwise exploiting the same in the NORC
24 Evaluation and the Alabama Pharmacy Scoring PDF.

1 149. Plaintiff MORISKY is informed and believes and thereon alleges that Defendants
2 DUKE and GRANGER without authorization, have infringed the MORISKY COPYRIGHTS by
3 using, copying, counterfeiting, distributing, or otherwise exploiting the same in the MAA PDF.

4 150. Plaintiff MORISKY is informed and believes and thereon alleges that the
5 aforementioned Defendants, by means of the actions complained of herein, without authorization,
6 have infringed and will continue to infringe the MORISKY COPYRIGHTS by using, copying,
7 counterfeiting, distributing, or otherwise exploiting the same without a license to do so.

8 151. Plaintiff MORISKY is entitled to an injunction restraining Defendants, and each of
9 the defendants, and all persons acting in concert with them, from engaging in further such acts in
10 violation of the copyright laws.

11 152. As a direct result of Defendants' infringement, Plaintiff MORISKY has sustained
12 damages in an amount to be determined at trial.

13 153. Pursuant to 17 U.S.C. §§ 502, 503, 504, and 505, Plaintiff MORISKY is entitled to
14 an award of actual damages, injunctive relief, the impoundment and destruction of the infringing
15 materials, and his attorneys' fees and costs against all Defendants.

16 154. In addition, Plaintiff MORISKY is further entitled to statutory damages for
17 Defendant DUKE's infringement and willful infringement of the Morisky MMAS-4 Copyright in
18 the NORC Evaluation and the accompanying Alabama Pharmacy Scoring PDF.

19
20 **SECOND CAUSE OF ACTION**

21 **FALSE DESIGNATION OF ORIGIN/FEDERAL UNFAIR COMPETITION**

22 **(15 U.S.C. § 1125(a))**

23 **(BY PLAINTIFF MORISKY AGAINST ALL DEFENDANTS)**

24 155. MORISKY realleges each allegation contained in the preceding paragraphs.

1 162. As a direct and legal result Defendants' unauthorized use of the MORISKY
2 MARKS, Defendants have damaged and will continue to damage MORISKY and MORISKY'S
3 goodwill and reputation; and have caused and are likely to continue to cause a loss of profits for
4 MORISKY. Defendants' actions have caused and will continue to cause irreparable harm to
5 MORISKY and to the public, who is confused by Defendants' unauthorized use of the MORISKY
6 MARKS, unless restrained and enjoined by this Court. MORISKY has no adequate remedy at law
7 to prevent Defendants from continuing their infringing actions and from injuring MORISKY.

8 163. As a further direct and legal result of Defendants' actions, MORISKY has been
9 damaged and will continue to sustain damage and are entitled to receive compensation arising from
10 MORISKY'S lost profits and efforts necessary to minimize and/or prevent customer and consumer
11 confusion, in an amount to be proven at the time of trial. In addition, MORISKY is entitled to
12 disgorge Defendants' profits, and are entitled to interest and to their attorney's fees and costs in
13 bringing this action, all in an amount to be proven at the time of Trial. MORISKY is further entitled
14 to injunctive relief as set forth above, and to all other and further forms of relief this Court deems
15 appropriate.

16
17 **THIRD CAUSE OF ACTION**

18 **TRADE SECRET MISAPPROPRIATION (18 U.S.C. § 1836, *et seq.*)**

19 **(BY PLAINTIFFS AGAINST DEFENDANTS DUKE , VORDERSTRASSE, VOORA, AND**
20 **GRANGER)**

21 164. Plaintiffs reallege each allegation contained in the preceding paragraphs.

22 165. Plaintiffs own confidential information, proprietary and trade secret information, as
23 alleged above, including but not limited to the MMAS coding and scoring criteria.
24
25

1 Defendants DUKE and VOORA's misappropriation of Plaintiffs' confidential, proprietary, and
2 trade secret information was intentional, knowing, willful, and malicious. Defendants DUKE and
3 VOORA have attempted and continue to attempt to conceal their misappropriation.

4 172. Defendants DUKE and GRANGER misappropriated Plaintiffs' confidential,
5 proprietary, and trade secret information by disclosing MMAS-8 coding criteria in the MAA PDF,
6 in direct contravention of the terms of the Duke/Granger License Agreement. Defendants DUKE
7 and GRANGER's misappropriation of Plaintiffs' confidential, proprietary, and trade secret
8 information was intentional, knowing, willful, and malicious. Defendants DUKE and GRANGER
9 have attempted and continue to attempt to conceal their misappropriation.

10 173. As the direct and proximate result of Defendants DUKE, VORDERSTRASSE,
11 VOORA, and GRANGER's conduct, Plaintiffs have suffered and, if Defendants DUKE,
12 VORDERSTRASSE, VOORA, and GRANGER's conduct is not stopped, will continue to suffer,
13 severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at
14 trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages,
15 temporary, preliminary, and permanent injunctive relief to recover and protect their confidential,
16 proprietary, and trade secret information and to protect other legitimate business interests.
17 Plaintiffs' business operates in a competitive market and will continue suffering irreparable harm
18 absent injunctive relief.

19 174. Plaintiffs have been damaged by all of the foregoing and are entitled to an award of
20 exemplary damages and attorney's fees.

21
22 **FOURTH CAUSE OF ACTION**

23 **TRADE SECRET MISAPPROPRIATION (Cal. Civ. Code § 3426 *et seq.*)**

(BY PLAINTIFFS AGAINST DEFENDANTS DUKE, VORDERSTRASSE, VOORA, AND GRANGER)

175. Plaintiffs reallege each allegation contained in the preceding paragraphs.

176. Plaintiffs own confidential information, proprietary and trade secret information, as alleged above, including but not limited to the MMAS coding and scoring criteria, which constitute trade secrets as defined by California's Uniform Trade Secrets Act.

177. Plaintiffs have taken measures that are reasonable under the circumstances to maintain the secrecy of the trade secrets at issue. For example, Plaintiffs require any licensee of the MORISKY COPYRIGHTS to contractually agree to maintain the confidentiality of the coding and scoring criteria.

178. In fact, Plaintiffs required Defendants to contractually agree to maintain the confidentiality of the coding and scoring criteria of the MMAS in the Duke/Vorderstrasse License Agreement, the Duke/Piner License Agreement, the Duke/Voora License Agreement, the Duke/SEDI License Agreement, and the Duke/Granger License Agreement.

179. Defendants DUKE and VORDERSTRASSE knew or should have known under the circumstances that the MMAS-8 coding criteria misappropriated by them in the Duke/Vorderstrasse MMAS-8 Patient Questionnaire were trade secrets.

180. Defendants DUKE and VOORA knew or should have known under the circumstances that the MMAS-8 coding criteria misappropriated by them in the Voora Study 1 Webpage were trade secrets.

181. Defendants DUKE and GRANGER knew or should have known under the circumstances that the MMAS-8 coding criteria misappropriated by them in the MAA PDF were trade secrets.

1 182. Defendants DUKE, VORDERSTRASSE, VOORA, and GRANGER
2 misappropriated and threaten to further misappropriate trade secrets at least by acquiring trade
3 secrets with knowledge of or reason to know that the trade secrets were acquired by improper
4 means, and Defendants are using and threatening to use the trade secrets acquired by improper
5 means without Plaintiffs' knowledge or consent.

6 183. As the direct and proximate result of Defendants DUKE, VORDERSTRASSE,
7 VOORA, and GRANGER's conduct, Plaintiffs are threatened with injury and have been injured in
8 an amount in excess of the jurisdictional minimum of this Court and that will be proven at trial.
9 Plaintiffs have also incurred, and will continue to incur, additional damages, costs, and expenses,
10 including attorney's fees, as a result of the Defendants' misappropriation. As a further proximate
11 result of the misappropriation and use of Plaintiffs' trade secrets, Defendants DUKE,
12 VORDERSTRASSE, VOORA, and GRANGER were unjustly enriched.

13 184. Defendants DUKE, VORDERSTRASSE, VOORA, and GRANGER's acts were
14 willful, malicious, and fraudulent, and Plaintiffs are entitled to exemplary damages under California
15 Civil Code § 3426.3(c).

16 185. Defendants DUKE, VORDERSTRASSE, VOORA, and GRANGER's conduct
17 constitutes a transgression of a continuing nature for which Plaintiffs have no adequate remedy at
18 law. Unless this Court enjoins Defendants, they will continue to use Plaintiffs' trade secret
19 information to enrich themselves. Plaintiffs are entitled to an injunction against the
20 misappropriation and continued threatened misappropriation of trade secrets under California Civil
21 Code § 3426.2, and Plaintiffs ask this Court to restrain Defendants from using all trade secret
22 information misappropriated from Plaintiffs.

1 b. selling, offering to sell, advertising, promoting, or passing off, inducing, or
2 enabling others to sell, offer to sell, advertise, promote, or pass off any diagnostic
3 tools like the Morisky Widget provided by Plaintiffs under a name or mark the
4 same as the MORISKY MARKS;

5 c. otherwise unfairly competing with Plaintiffs in any manner, including but not
6 limited to, infringing usage of the MORISKY MARKS, or any confusingly
7 similar marks.

8 5. Order that Defendants file with this Court and serve upon Plaintiffs within thirty (30)
9 days after service on Defendants of an injunction in this action, a report by
10 Defendants, under oath, setting forth that Defendants have complied with the
11 injunction, as well as the steps they have taken to comply;

12 6. For costs of suit herein incurred;

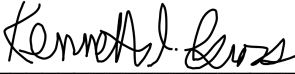
13 7. For attorneys' fees;

14 8. For prejudgment interest in the amount of ten percent (10%) per annum or the
15 maximum amount allowed by law; and

16 9. For such other and further relief the Court deems just and proper.

17
18
19 Dated: March 24, 2021

KENNETH I. GROSS & ASSOC.

20
21
22 By: 
23 Kenneth I. Gross, Esq.
24 Attorneys for Plaintiffs
25