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10	MMAS Research LLC and Dr. Donald E. Mori	lsky	
11	IN THE UNITED ST	ATES DISTRICT COURT	
12	FOR THE CENTRAL DISTRICT OF CALIFORNIA		
13			
14	MMAS RESEARCH LLC and DR.	Case No.: 2:21-cv-3139	
15	DONALD E. MORISKY;	COMPLAINT FOR DAMAGES	
16	Plaintiff(s),	1. Copyright Infringement Under 17	
17	VS.	U.S.C. §§ 101, et seq.	
18	UNIVERSITY OF MASSACHUSETTS; DR. DAVID D.	2. False Designation of Origin/Federal Unfair Competition Under 15 U.S.C.	
19	MCMANUS; DR. TIMOTHY FITZGIBBONS; DR. JULIET	§ 1125(a) 3. Trade Secret Misappropriation	
20	FARRELL; DR. ARACELI CARRERA;	Under 18 U.S.C. § 1836, et seq. 4. Trade Secret Misappropriation	
21	DR. CHRISTINA TORRES; DR. SUSAN SHAW; and DOES 1-50;	Under Cal. Civ. Code § 3426 et seq. 5. Unfair Competition under Business	
22		and Professions Code §17200, et seq.	
23	Defendant(s).	JURY TRIAL DEMANDED	
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- 18. Plaintiffs are informed, believe, and thereon allege defendants, and each of them, did at all material times foresee the nature and extent of the probable consequences of their acts in proximately causing said damages to Plaintiffs, and acted within the course and scope of such service, agency, employment, and joint venture, and with the knowledge, permission, and authority, actual and apparent, express and implied, direct and vicarious, of the remaining defendants, and each of them.
- 19. Plaintiffs are informed, believe, and thereon allege that at all relevant times each of the defendants was the agent, employee, representative, co-conspirator, affiliate, alter-ego, and/or successor-in-interest of each of them, and of each other, and has, in such capacity or capacities, participated in the acts or conduct alleged herein. All allegations made herein shall apply to each of the Defendants, as applicable.
- 20. The true names and capacities, whether individual, corporate, associate or otherwise, of defendants DOES 1-50, inclusive, are unknown to Plaintiffs, who therefore sue said Defendants by such fictitious names. Plaintiffs are informed and believe and based thereon allege, that each of the Defendants herein designated as a DOE, is responsible in some manner for the events and happenings herein referred to, and caused injuries and damages proximately thereby. Plaintiffs will amend this complaint and insert the true names and capacities of said DOE Defendants when the same has been ascertained.

JURISDICTION AND VENUE

21. This action arises, in part, under the Copyright Act of 1976, 17 U.S.C. §§ 101, et. seq., and the Lanham Trademark Act of 1946, 15 U.S.C. § 1051, et seq., conferring Federal question jurisdiction under 28 U.S.C. § 1331, and supplemental jurisdiction on Plaintiffs' state law claims

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

GENERAL ALLEGATIONS

MORISKY MEDICATION ADHERENCE SCALES

- 23. As early as 2002, Plaintiff MORISKY, a Professor Emeritus at UCLA, independently developed a distinctive diagnostic tool which determines a patient's adherence to his or her prescribed medication. The tool is known as the Morisky Medication Adherence Scale ("MMAS").
- 24. The MMAS measures a person/patient's adherence to their prescribed medication, and the results lead to specific diagnosis, medication reconciliation, and interventions to optimize treatment, as well as form the basis for conclusions/assertions in scientific papers, all covering a wide variety of chronic and infectious diseases and medical conditions. The MMAS is most commonly administered electronically in questionnaire form by individuals/entities who are licensees of Plaintiff MORISKY.
- 25. The MMAS is currently utilized in two (2) forms: the MMAS-4 (consisting of 4 specifically-tailored questions) and the MMAS-8 (consisting of 8 specifically-tailored questions).

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- 27. The MMAS-8 is a diagnostic adherence assessment instrument which contains a total of eight (8) items measuring two dimensions of non-adherence, namely intentional and unintentional non-adherence. Furthermore, the MMAS-8 is more than a number defining the magnitude of non-adherence as it also tells the physician "Why" the patient is non-adherent.
- 28. The MMAS-8 is the only diagnostic adherence assessment instrument in the scientific literature that has one of the highest measures of reliability (stability of the measure over time) and validity. It has been validated in over eighty (80) different languages in the world using many levels of validation.
- 29. The Morisky Widget is an electronic derivative of the Morisky Medication Adherence Scales (the MMAS-4 and MMAS-8). The Morisky Widget administers, scores, and reports MMAS-4 and MMAS-8 test results.
- 30. Plaintiff MMAS RESEARCH licenses, and since January 2017 has licensed, use of the Morisky Widget to score and code the MMAS-4 and MMAS-8 tests. Prior to 2017, individual licenses to the MMAS-4 and MMAS-8 were granted and sold by Plaintiff MORISKY.

COPYRIGHTS

31. In an effort to protect the integrity of the MMAS-4 and protect against counterfeit, infringing, and/or unauthorized use, Plaintiff MORISKY filed for and obtained a Certificate of

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- 32. In an effort to protect the integrity of the MMAS-8 and protect against counterfeit, infringing, and/or unauthorized use, Plaintiff MORISKY filed for and obtained a Certificate of Registration for the Morisky MMAS-8 Copyright, which is comprised of the text of the MMAS-8 test.
- 33. In an effort to protect the integrity of the Morisky Widget and protect against counterfeit, infringing, and/or unauthorized use, Plaintiff MMAS RESEARCH filed for and obtained a Certificate of Registration for the Morisky Widget Copyright.
- 34. Plaintiff MORISKY has complied in all respects with the Copyright Act of 1976, 17 U.S.C. § 101, et. seq., and all other laws governing copyrights as to the MMAS-4, MMAS-8, and the MORISKY COPYRIGHTS.
- 35. Plaintiff MMAS RESEARCH has complied in all respects with the Copyright Act of 1976, 17 U.S.C. § 101 *et. seq.* and all other laws governing copyrights as to the Morisky Widget Copyright.
- 36. Since the MMAS-4 and MMAS-8 were created, Plaintiff MORISKY has been, and still is, the sole author and exclusive holder of all rights, title, and interest in and to the copyrights to the MMAS-4 and MMAS-8, including but not limited to the MORISKY COPYRIGHTS. Plaintiff MORISKY has not granted any license or right to any person or entity, including Defendants, to use the MORISKY COPYRIGHTS, except solely in association with the authorized use of the Morisky Medication Adherence Scales (MMAS-4 and/or MMAS-8).
- 37. The MMAS-4, MMAS-8, MORISKY COPYRIGHTS, and the Morisky Widget Copyright are vital to Plaintiffs' ongoing business and profession and, more specifically, Plaintiffs' efforts to ensure that third-party use of the Morisky Medication Adherence Scales (MMAS-4 and/or

MMAS-8) are authorized and utilized in compliance with Plaintiffs' strict coding and scoring which 2 are maintained by Plaintiffs as trade secrets. 3 Plaintiffs impose restrictions on the use and disclosure of the coding and scoring of 38. 4 the MMAS-4, MMAS-8, and the Morisky Widget not only to protect their federally registered rights, but also to protect patients and health care providers from counterfeit or scientifically incorrect 5 diagnostic assessments and inaccurate results. 6 7 **TRADEMARKS** 39. 8 Plaintiff MORISKY is the creator and owner of the trademarks "Morisky Medication 9 Adherence Scale," "MMAS," "MMAS-4," and "MMAS-8" (hereinafter the "MORISKY MARKS"). 10 40. The "MMAS" trademark is the subject of Federal Trademark Registration No. 11 5837273 and has been used in commerce since at least as early as February 2006. 12 41. As a result of the extensive, exclusive, and continued use of the MORISKY MARKS in commerce, medical institutions through, among others, their physicians, nurses, researchers, 13 14 clinicians, and/or medical students have come to recognize and identify the MORISKY MARKS 15 exclusively with the medication adherence scales developed by Plaintiff MORISKY. The MORISKY MARKS have become a valuable asset of Plaintiffs as well as a symbol of their goodwill and positive 17 reputations. LICENSES 18 19 42. 20 21 provided by Plaintiffs, are not permitted. 22 43. 23

- It is of critical importance the integrity of the MMAS be maintained. This is why a strict licensing regimen is used and disclosure of coding and scoring criteria, and translations not
- Plaintiffs have discovered that when someone obtains the MMAS coding and scoring criteria they often make changes that lead to erroneous results. Others obtaining the MMAS from counterfeiters often make further unauthorized revisions, further increasing the risk of harm to

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- 8 -**COMPLAINT** patients and misleading healthcare providers. Unlicensed translations are often divulged and used with the coding and scoring criteria which render the results invalid and misunderstood.

- 44. Plaintiffs have spent considerable time and money to develop, maintain, and advance the MMAS described herein and it now can be administered with regard to one hundred ten (110) medical conditions and thousands of specific medications as of this filing, and in more than eighty (80) languages. The MMAS is used by physicians, hospitals, clinicians, pharmaceutical companies, universities, medical researchers, and health ministries throughout the world, including National Institute of Health funded studies, all to measure medication adherence and identify the reasons for why patients do not take their prescribed medications. MMAS translations are provided by Plaintiffs for a small fee along with a translation certification. Translations of the MMAS without proper authorization are prohibited.
- 45. The various MMAS diagnostic assessments are validated and translated in over eighty (80) languages and utilized throughout the world. The MMAS is famous in the industry and is the number one patient-centered diagnostic medication adherence assessment of its kind. Plaintiffs make considerable efforts to maintain the secrecy of the coding and scoring of the scale and expressly forbid the disclosure of coding and scoring in their license agreements with licensees of all versions of the MMAS.
- 46. Plaintiffs permit the use of the MORISKY COPYRIGHTS, MORISKY MARKS, the MMAS, and the Morisky Widget only through a licensing program memorialized in a licensing agreement. This ensures uniformity of use in coding and scoring, as well as provides much needed support from Plaintiffs. Modifications of the MMAS, and disclosure of coding and scoring criteria and linguistically certified translations are not permitted.
- 47. Reasonable efforts are taken by Plaintiffs to protect and not to disseminate the MMAS, Morisky Widget, or translated versions to non-authorized users, as well as the coding and scoring.

These restrictions not only protect patients and health care providers from counterfeit diagnostic assessments and inaccurate coding and scoring, but also protect the economic interests of Plaintiffs in the MORISKY COPYRIGHTS, MORISKY MARKS, the MMAS itself, along with the Morisky Widget diagnostic assessment, as they receive licensing fees and are paid per test administered, unless such fees are waived. In fact, the license agreement expressly provides that coding and scoring may not be disclosed.

- 48. Licenses are typically provided at no cost for federally-funded studies, and to educational institutions that are not receiving funding for the research/study for which the MMAS and Morisky Widget is to be used. Others are charged a fee for a fixed term or for a perpetual license sold as the Morisky Widget. Plaintiffs also charge fees for training and certification in use of the Morisky Widget, and there is a charge for each test administered by a licensee, in addition to those included in the cost of the license.
- 49. The MORISKY COPYRIGHTS, MORISKY MARKS, and the MMAS have been cited in over eight thousand (8,000) academic journals throughout the world.
- 50. Due to Plaintiffs' exclusive and extensive use, through a strict regimen of licensing and supervision, the MORISKY COPYRIGHTS, MORISKY MARKS, the MMAS, and the Morisky Widget have enormous value both economically and for the promotion of health and proper diagnosis of persons suffering from a wide range of chronic and infectious diseases and mental health conditions worldwide.

<u>DEFENDANTS UMASS, D. MCMANUS, AND FITZGIBBONS'</u> <u>INFRINGING CONDUCT</u>

51. Upon information and belief, from in or around April 2011 to January 2014,
Defendants UMASS and D. MCMANUS, among other UMASS researchers, conducted a clinical
study (the "TRACE-CORE Study"), the results of which were published in an article (the "TRACE-

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- 63. Section (C)(2) of the UMass/McManus License Agreement provides: "Coding and scoring criteria of the MORISKY are trade secrets of [Plaintiff MORISKY] and as such cannot be divulged in any publication or report without [Plaintiff MORISKY's] prior written permission."
- 64. Section (C)(5) of the UMass/McManus License Agreement provides: "In case of scientific, administrative or intellectual property misconduct in 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 for any infringement (if any at all) will take place in Los Angeles."
- 65. Section (C)(7) of the UMass/McManus 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 the use of any Morisky Medication Adherence Scale or other Morisky intellectual property."
- 66. Page 3 of the UMass/McManus License describes the title of the study: "Systemic Assessment of Geriatric Elements in Atrial Fibrillation (SAGE-AF) Grant ID: 1R01HL126911-01A1" (the "SAGE-AF Study").
- 67. Page 3 of the UMass/McManus License further states: "Start date for data collection: 06/21/2016 thru 2018. (You will be locked into a 2 year waiver of license fee, but the license contract has to be renewed each year)."
- 68. Defendants UMASS and D. MCMANUS never renewed the UMass/McManus License Agreement upon expiration of the initial one-year license term, which ended on October 20, 2017.

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1	69. Upon information and belief, between June 21, 2016 and 2018, Defendants UMASS	
2	and D. MCMANUS administered MMAS-8 tests in the SAGE-AF Study pursuant to the	
3	UMass/McManus License Agreement.	
4	70. Upon information and belief, at least some of the MMAS-8 tests administered by	
5	Defendants UMASS and D. MCMANUS in the SAGE-AF Study were administered after expiration	
6	of the UMass/McManus License Agreement.	
7	71. To the extent they administered MMAS-8 tests after expiration of the	
8	UMass/McManus License Agreement expired, Defendants UMASS and D. MCMANUS both	
9	utilized the MORISKY COPYRIGHTS and/or displayed the MORISKY MARKS without a valid	
10	license and without authorization by Plaintiff MORISKY.	
11	72. In or around November 30, 2018, Defendants UMASS, D. MCMANUS, and	
12	FITZGIBBONS published or caused to be published on the ClinicalTrials.gov website a study	
13	protocol (the "McManus Study Protocol") for a clinical study entitled, "Pulsewatch: Smartwatch	
14	Monitoring for Atrial Fibrillation after Stroke" (the "McManus/Pulsewatch Study"). A true and	
15	correct copy of the McManus Study Protocol is attached hereto and incorporated herein as <u>Exhibit</u>	
16	$\underline{\mathbf{D}}$.	
17	73. As of March 29, 2021, the McManus Study Protocol remains publicly accessible on	
18	the ClinicalTrials.gov website at:	
19	https://clinicaltrials.gov/ProvidedDocs/94/NCT03761394/Prot_000.pdf.	
20	74. Page 13 of the McManus Study Protocol states as follows: "Medication Adherence:	
21	Medication adherence will be measured using the 8-item Morisky Adherence Questionnaire, a well-	
22	validated measure of patient-reported adherence. Morisky scores range from 0-8 (higher	
23	scores=poorer adherence)."	
24	75. In fact, for the MMAS-8, higher scores equate to <i>lower</i> adherence.	
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DEFENDANTS UMASS AND FARRELL'S INFRINGING CONDUCT

83. Upon information and belief, from in or around September 2018 to April 2019, Defendants UMASS and FARRELL conducted a clinical study (the "UMass/Farrell Study"), the results of which were published in a manuscript entitled, "Self-Management of Dyspnea in Chronic Obstructive Pulmonary Disease Patients" (the "UMass/Farrell Article"). Attached as <u>Exhibit F</u> is a true and correct copy of UMass/Farrell Article, hereby incorporated by reference in its entirety.

- 84. Page 23 of the UMass/Farrell Article sets forth a table labeled, "Morisky Medication Adherence Scale." Underneath a column header labeled "MMAS-4," the table lists four questions:
 - Do you ever forget to take your prescription drugs?
 - Are you careless at times about taking your drugs?
 - Do you sometimes stop taking your drugs when you feel better?
 - Do you sometimes stop taking your drugs if they make you feel worse?
- 85. These questions are not part of the MMAS-4. In fact, these questions belong to a different medication adherence scale developed by Plaintiff MORISKY.
- 86. In addition, on page 49 of the UMass/Farrell Manuscript, Appendix E sets forth the "Interpretation/Scoring" of the Morisky Scale as follows: "Score 1 point for every YES answer. 0 points = high adherence. 1-2 points = intermediate. 3-4 points = low adherence."
- 87. In fact, contrary to the explanation given in the UMass/Farrell Manuscript, 0 points equates to *low* adherence for the MMAS-4, and 3-4 points equates to *high* adherence for the MMAS-4.
- 88. Upon information and belief, from in or around September 2018 to April 2019, Defendants UMASS and FARRELL administered MMAS-4 tests in the UMass/Farrell Study, utilizing the MORISKY COPYRIGHTS and/or displaying the MORISKY MARKS.

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- 89. Plaintiff MORISKY never licensed and never authorized the use of the MORISKY COPYRIGHTS and/or the MORISKY MARKS by Defendants UMASS and FARRELL
- 90. Further, Plaintiffs never authorized Defendants UMASS and FARRELL's disclosure of the trade secret coding criteria for the MMAS-4 in the UMass/Farrell Manuscript.

DEFENDANTS UMASS AND CARRERA'S INFRINGING CONDUCT

- 91. Upon information and belief, from in or around Fall 2017 to Spring 2018,
 Defendants UMASS and CARRERA conducted a clinical study (the "UMass/Carrera Study"), the results of which were published in a manuscript entitled, "Implementation of the State Avoidable Rehospitalizations (STAAR) Initiative in a NP-led Transitional-Care Program to Reduce Readmission Rates and to Provide Safe Transitional Care in Post-Cardiac Surgery Patients: A Quality Improvement Project" (the "UMass/Carrera Article"). Attached as Exhibit G is a true and correct copy of UMass/Carrera Article, hereby incorporated by reference in its entirety.
- 92. Page 25 of the UMass/Carrera Article states as follows: "In order to measure the outcomes of this QI project, the following instruments were used: . . . Morisky Medication Adherence Scale (MMAS-4) questionnaires, . . . "
- 93. Page 27 of the UMass/Carrera Article states: "The MMAS-4 was used to evaluate the medication adherence because it was easy and quick to administer (scoring the Morisky scale Yes = 0 and No = 1). . In addition, the DNP student provided education using the teach/teach-back method (Appendix L) especially for those patients who scored low in medication adherence (0 = high, 1-2 = moderate, 3-4 = low)."
- 94. In fact, contrary to the explanation given by Defendants UMASS and CARRERA in the UMass/Carrera Article, 0 points equates to *low* adherence for the MMAS-4, and 3-4 points equates to *high* adherence for the MMAS-4.

- 95. In addition, the scoring criteria for the MMAS-4 that Defendants UMASS and CARRERA disclosed in the UMass/Carrera Article is considered a trade secret by Plaintiffs, and it is incorrect.
- 96. Defendants UMASS and CARRERA repeatedly disclosed incorrect and trade secret MMAS-4 scoring criteria throughout the UMass/Carrera Article.
- 97. On page 30 of the UMass/Carrera Article, in a note below Table 3, Defendants UMASS and CARRERA again disclosed incorrect trade secret coding of the MMAS-4, stating as follows: "The scoring of the Morisky Scale (Yes = 0 and No = 1)."
- 98. In Appendix K, on page 56 of the UMass/Carrera Article, Defendants UMASS and CARRERA list the MMAS-4 questions and, for the third time, provide incorrect and trade secret coding criteria for the MMAS-4, stating as follows: "Scoring the Morisky Scale: Yes = 0 and No = 1."
- 99. In a table at the bottom of page 56, Defendants UMASS and CARRERA also provide incorrect scoring criteria for the MMAS-4, stating the "High Adherence" equates to a MMAS-4 Score of 0, while "Low Adherence" equates to a MMAS-4 Score of 3-4.
- 100. Upon information and belief, from in or around Fall 2017 to Spring 2018,

 Defendants UMASS and CARRERA administered MMAS-4 tests in the UMass/Carrera Study,

 utilizing the MORISKY COPYRIGHTS and/or displaying the MORISKY MARKS.
- 101. Plaintiff MORISKY never licensed and never authorized the use of the MORISKY COPYRIGHTS and/or the MORISKY MARKS by Defendants UMASS and CARRERA
- 102. Further, Plaintiffs never authorized Defendants UMASS and CARRERA'S disclosure of the trade secret coding criteria for the MMAS-4 in the UMass/Carrera Article.

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DEFENDANT UMASS, TORRES, AND SHAW'S INFRINGING CONDUCT

- 103. On or around April 14, 2014, Plaintiff MORISKY and Defendant SHAW entered into a license agreement (hereinafter the "Shaw License Agreement") whereby said Defendant was permitted to administer MMAS-8 tests, and in so doing, utilize the MORISKY COPYRIGHTS and MORISKY MARKS for a period of one year. A copy of the Shaw License Agreement is attached hereto and incorporated herein as Exhibit H.
- 104. Section (C)(2) of the Shaw License Agreement provides: "Coding and scoring criteria of the MMAS-8 are trade secrets of [Plaintiff MORISKY] and confidential; as such they cannot be used or divulged, whether orally or in any publication, presentation, or report without [Plaintiff MORISKY's] prior written permission."
- 105. Section (C)(5) of the Shaw License Agreement provides: "In case of scientific, administrative or intellectual property misconduct in using the MMAS system of questionnaires or the trademarked MMAS or Morisky or similar names, [Plaintiff MORISKY] reserves the right to terminate this Agreement and to pursue all legal remedies. Licensee agrees to the jurisdiction of and venue in the State and Federal Courts in Los Angeles County, subject to the laws of California, irrespective of its conflict of laws provisions."
- 106. Section (C)(6) of the Shaw 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 occurs sooner."
- 107. The Shaw License describes the Title of Research as the following: "Medication Adherence, Health Literacy, and Cultural Health Beliefs in a Massachusetts Community Health Center" (the "Massachusetts Study").

- 108. Upon information and belief, Defendant SHAW administered MMAS-8 tests pursuant to the Shaw License Agreement.
- 109. Upon information and belief, at the time Defendant SHAW entered into the Shaw License Agreement, Defendant SHAW was a researcher at the University of Arizona and did not transfer any rights under the Shaw License Agreement to Defendant UMASS, including but not limited to the rights to use the MORISKY COPYRIGHTS and/or display the MORISKY MARKS.
- 110. Upon information and belief, Defendants UMASS, TORRES, and SHAW conducted a second clinical study from January 2014 to December 2018 (the "RxHL Study").
- 111. In or around 2017, Defendants UMASS, SHAW, and TORRES reported the results of the RxHL Study in at least one poster presentation (the "Shaw/Torres Poster Presentation") entitled, "RxHL: Medication Beliefs, Adherence, and Health Literacy in a Massachusetts Community Health Center." A true and correct copy of the Shaw/Torres Poster Presentation is attached hereto and incorporated by reference in its entirety as Exhibit I.
- 112. In a table entitled "Multimethod Research Design," the Shaw/Torres Poster Presentation lists "Morisky medication adherence scale."
- 113. In a table entitled "Preliminary Findings: Adherence and Beliefs about Medicines," the Shaw/Torres Poster Presentation provides a pie chart labeled "Morisky Adherence Scores," and displays "High," "Med," and "Low" percentages.
- 114. Upon information and belief, from in or around January 2014 to December 2018, Defendants UMASS, TORRES, and SHAW administered MMAS-8 tests in the RxHL Study, utilizing the MORISKY COPYRIGHTS and/or displaying the MORISKY MARKS.

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115. At the time of the RxHL Study, Defendants UMASS, TORRES, and SHAW did not have a valid license to administer MMAS-8 tests, use the MORISKY COPYRIGHTS, or display the MORISKY MARKS, because the Shaw License Agreement had expired.

116. In or around October 2018, Defendants UMASS and TORRES published the results of the RxHL Study in a second article entitled, "Social Determinants of Cardiometabolic Disease Control: An Ecosocial Approach" (the "UMass/Torres Article"). Attached as <u>Exhibit J</u> is a true and correct copy of UMass/Torres Article, hereby incorporated by reference in its entirety.

117. Pages 45 and 46 of the UMass/Torres Articles provides as follows:

"Of the four approaches typically used to measure medication adherence (self-report, electronic monitoring, pill count, and pharmacy fill rates (Morisky, et al. 2008, 11)), the RxHL study used self-report and manual pill count. Self-reported medication adherence is assessed using the Morisky 8-Item Medication Adherence Scale at baseline and at 3-months follow-up. Responses from the 8-items create a score ranging from 0-8. Response categories are yes/no for each item and a 5-point Likert response for the last item. The original scale score is categorized into three groups: high adherence (0), medium adherence (1-2), and low adherence (3-8). The RxHL study reversed the order such that a higher score (7.01-8.00) reflects high adherence, a medium score (5.01-7.00) reflects adequate adherence and lower score (0-5) reflects low adherence. We then dichotomized the groups into adequate/high adherence (1) (scores ranging 5.01-8.0) and low adherence (0) (scores ranging 0-5) (Morisky et al, 2008; Kelly et al., 2016).

- 118. Notably, contrary to the explanation given by Defendants UMASS and TORRES in the UMass/Torres Article, high adherence equates to *higher* scores for the MMAS-8, and lower adherence equates to *lower* scores for the MMAS-8.
- 119. Page 57 of the UMass/Torres Article states as follows: "Participant characteristics of medication adherence are shown in Table 1b. Among the entire study sample (N=361), self-reported

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adequate medication adherence using the 8-item Morisky Medication Adherence Scale was 70.4% compared to 55.4% adequate adherence (>80%) . . ."

- 120. Page 71 of the UMass/Torres Articles sets forth a table ("Table 1b"), labeled "Table 1b. Participant characteristics for medication adherence (Morisky self-report and pill count) and medication use."
- 121. Table 1b lists the following "Characteristics": "Morisky Medication Adherence Score (self-report)"; "Morisky, overall (n=361)"; "Morisky, if Diabetes (n=171)"; "Morisky, if Hypertension (n=309)"; "Morisky, if Dyslipidemia (n=239)"; and "Morisky, if Depression (n=96)."
- 122. Page 80 of the UMass/Torres Article contains a table ("Table 6"), entitled "Table 6. Mean pill count adherence by self-reported Morisky medication adherence." Below the table, there is a note that states, "T-test of continuous pill count % mean adherence by low-adequate self-reported Morisky adherence."
- 123. Page 85 of the UMass/Torres Study Article provides a figure ("Figure 3"), entitled Medication Adherence, Health Literacy and Culture Health Beliefs (RxHL) Study Activities and Timeline." Figure 3 contains a text box which contains the label "3-month follow-up (N~383)," followed by two bullet-point items" "Pill Count" and "8-item Morisky Medication Adherence Scale."
- 124. Page 149 of the UMass/Torres Study Article provides as follows: "to examine the relationship between race/ethnicity and medication adherence as measured by self-report (8-item Morisky Medication Adherence Scale (MMAS)) and by pill count. We hypothesized that there are differences between groups in both medication adherence measurement approaches."

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125. Defendants UMASS and TORRES did not have a valid license to use the MORISKY COPYRIGHTS or display the MORISKY MARKS in the UMass/Torres Study Article, because the Shaw License Agreement had expired.

- 126. Plaintiffs never authorized Defendants UMASS and TORRES' disclosure of the trade secret coding criteria for the MMAS-8 in the UMass/Torres Article. Further, in disclosing the trade secret coding criteria for the MMAS-8, Defendants UMASS and TORRES breached Section (C)(2) of the Shaw License Agreement.
- 127. In or around October 1, 2019, Defendants UMASS and SHAW published a third publication entitled, "The RxHL study: community-responsive research to explore barriers to medication adherence" (the "RxHL Study Article"). Attached as Exhibit K is a true and correct copy RxHL Study Article, hereby incorporated by reference in its entirety.
- 128. Page 2 of the RxHL Study Article states: "To assess medication adherence, we combined self-report as a subjective measure with manual pill counts over 3 months as an objective measure of adherence."
- 129. Footnote 29 of the RxHL Study Article contains a reference to Plaintiff MORISKY as follows: "Morisky DE, Ang A, Krousel-Wood M et al. Predictive validity of a medication adherence measure in an outpatient setting. J Clin Hypertens 2008; 10: 348–54."
- 130. Footnote 30 of the RxHL Study Article contains a second reference to Plaintiff MORISKY as follows: "Morisky DE, DiMatteo MR. Improving the measurement of self-reported medication nonadherence: final response. J Clin Epidemiol 2011; 64: 262–3."
- 131. The Acknowledgements section on page 10 of the RxHL Study Article contains a reference to the MMAS COPYRIGHTS and Plaintiff MORISKY as follows: "Use of the ©MMAS 23 -

is protected by US copyright laws. Permission for use is required. A license agreement is available from: Donald E. Morisky, ScD, ScM, MSPH, Professor, Department of Community Health Services, UCLA School of Public Health, 650 Charles E. Young Drive South, Los Angeles, CA 90095-1772, USA."

- 132. Defendants UMASS and SHAW did not have a valid license to use the MORISKY COPYRIGHTS or display the MORISKY MARKS in the RxHL Study Article, because the Shaw License Agreement had expired.
- 133. Plaintiff MORISKY never licensed and never authorized the use of the MORISKY COPYRIGHTS and/or the MORISKY MARKS by Defendants UMASS, TORRES, and SHAW in any of the RxHL Study, the Shaw/Torres Poster Presentation, the UMass/Torres Study Article, or the RxHL Study Article.

FIRST CAUSE OF ACTION

COPYRIGHT INFRINGEMENT (17 U.S.C. §§ 101, et seq.) (BY PLAINTIFF MORISKY AGAINST ALL DEFENDANTS)

- 134. Plaintiff MORISKY realleges each allegation contained in the preceding paragraphs and incorporates them by this reference as though fully set forth herein.
- 135. At all times relevant hereto, Plaintiff MORISKY was the owner of all copyright rights or rights to assert copyright claims for the MORISKY COPYRIGHTS and all derivative works. Plaintiff MORISKY has complied in all respects with the Copyright Act of 1976, 17 U.S.C. §§ 101, et seq., and all other laws governing copyright.
- 136. Plaintiff MORISKY is informed and believes and thereon alleges that Defendants UMASS and D. MCMANUS without authorization, have infringed the MORISKY COPYRIGHTS

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- 142. Plaintiff MORISKY is informed and believes and thereon alleges that Defendants UMASS and SHAW without authorization, have infringed the MORISKY COPYRIGHTS by using, copying, counterfeiting, distributing, or otherwise exploiting the same in the RxHL Study Article.
- 143. Plaintiff MORISKY is informed and believes and thereon alleges that the aforementioned Defendants, by means of the actions complained of herein, without authorization, have infringed and will continue to infringe the MORISKY COPYRIGHTS by using, copying, counterfeiting, distributing, or otherwise exploiting the same without a license to do so.
- 144. Plaintiff MORISKY is entitled to an injunction (a) restraining Defendants and all persons acting in concert with them, from engaging in further such acts in violation of the copyright laws, (b) requiring Defendants to remove incorrect coding and scoring of the MMAS tests in published articles.
- 145. As a direct result of Defendants' infringement, Plaintiff MORISKY has sustained damages in an amount to be determined at trial.
- 146. Pursuant to 17 U.S.C. §§ 502, 503, 504, and 505, Plaintiff MORISKY is entitled to an award of actual damages, injunctive relief, the impoundment and destruction of the infringing materials, and his attorneys' fees and costs against all Defendants.
- 147. In addition, Plaintiff MORISKY is further entitled to statutory damages for infringement and willful infringement of the Morisky MMAS-8 Copyright by Defendants UMASS and D. MCMANUS in the SAGE-AF Study; Defendants UMASS, D. MCMANUS, and FITZGIBBONS in the McManus Study Protocol; Defendants UMASS and TORRES in the UMass/Torres Article; and Defendants UMASS and SHAW in the RxHL Study Article.
- 148. In addition, Plaintiff MORISKY is further entitled to statutory damages for infringement and willful infringement of the Morisky MMAS-4 Copyright by Defendants UMASS

and FARRELL in the UMass/Farrell Study, and by Defendants UMASS and CARRERA in the 2 UMass/Carrera Study. 3 SECOND CAUSE OF ACTION 4 FALSE DESIGNATION OF ORIGIN/FEDERAL UNFAIR COMPETITION 5 (15 U.S.C. § 1125(a) 6 (BY PLAINTIFF MORISKY AGAINST ALL DEFENDANTS) 7 149. MORISKY realleges each allegation contained in the preceding paragraphs and 8 incorporates them by this reference as though fully set forth herein. 9 150. Plaintiff MORISKY is informed and believes and thereon alleges that Defendants 10 UMASS and D. MCMANUS have infringed the MORISKY MARKS by using the same without 11 authorization in the SAGE-AF Study after expiration of the UMass/McManus License Agreement. 12 151. Plaintiff MORISKY is informed and believes and thereon alleges that Defendants 13 UMASS, D. MCMANUS, and FITZGIBBONS have infringed the MORISKY MARKS by using the 14 same without authorization in the McManus Study Protocol after expiration of the UMass/McManus 15 License Agreement. 16 Plaintiff MORISKY is informed and believes and thereon alleges that Defendants 152. 17 UMASS and FARRELL have infringed the MORISKY MARKS by using the same without 18 authorization in the UMass/Farrell Article. 19 153. Plaintiff MORISKY is informed and believes and thereon alleges that Defendants 20 UMASS and CARRERA have infringed the MORISKY MARKS by using the same without 21 authorization in the UMass/Carrera Article. 22 154. Plaintiff MORISKY is informed and believes and thereon alleges that Defendants 23 UMASS, TORRES, and SHAW have infringed the MORISKY MARKS by using the same without 24 authorization in the RxHL Study and the Shaw/Torres Poster Presentation. 25 - 27 -26 **COMPLAINT**

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- 155. Plaintiff MORISKY is informed and believes and thereon alleges that Defendants UMASS and TORRES have infringed the MORISKY MARKS by using the same without authorization in the UMass/Torres Article.
- 156. Plaintiff MORISKY is informed and believes and thereon alleges that Defendants UMASS and SHAW have infringed the MORISKY MARKS by using the same without authorization in the RxHL Study Article.
- 157. As herein alleged, the aforementioned Defendants' unauthorized use of the MORISKY MARKS in connection with their studies and related publications constitutes unfair competition and false designation of origin in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), because Defendants' use of the marks suggests a false designation of the origin of the unauthorized MMAS diagnostic tests used, identified, and published. Further, such acts of infringement by Defendants further suggests a false association with MORISKY and/or that MORISKY approved of or authorized the use of the unauthorized MMAS diagnostic tests used, identified, and published by Defendants.
- 158. As a direct and legal result Defendants' unauthorized use of the MORISKY MARKS, Defendants have damaged and will continue to damage MORISKY and MORISKY'S goodwill and reputation; and have caused and are likely to continue to cause a loss of profits for MORISKY. Defendants' actions have caused and will continue to cause irreparable harm to MORISKY and to the public, who is confused by Defendants' unauthorized use of the MORISKY MARKS, unless restrained and enjoined by this Court. MORISKY has no adequate remedy at law to prevent Defendants from continuing their infringing actions and from injuring MORISKY.
- 159. As a further direct and legal result of Defendants' actions, MORISKY has been damaged and will continue to sustain damage and is entitled to receive compensation arising from Plaintiff MORISKY'S lost profits and efforts necessary to minimize and/or prevent customer and

consumer confusion, in an amount to be proven at the time of trial. In addition, MORISKY is entitled to disgorge Defendants' profits, and is entitled to interest and to his attorney's fees and costs in bringing this action, all in an amount to be proven at the time of Trial. MORISKY is further entitled to injunctive relief as set forth above, and to all other and further forms of relief this Court deems appropriate.

THIRD CAUSE OF ACTION

TRADE SECRET MISAPPROPRIATION (18 U.S.C. § 1836, et seq.) (BY PLAINTIFFS AGAINST DEFENDANTS UMASS, FARRELL, AND CARRERA)

- 160. Plaintiffs reallege each allegation contained in the preceding paragraphs and incorporate them by this reference as though fully set forth herein.
- 161. Plaintiffs own confidential information, proprietary and trade secret information, as alleged above, including but not limited to the MMAS coding and scoring criteria.
- 162. Plaintiffs' confidential, proprietary, and trade secret information relates to products and services used, sold, shipped and/or ordered in, or intended to be used, sold, shipped, and/or ordered in, interstate or foreign commerce.
- 163. Plaintiffs have taken reasonable measures to keep such information secret and confidential. For example, Plaintiffs require any licensee of the MORISKY COPYRIGHTS to contractually agree to maintain the confidentiality of the coding and scoring criteria.
- 164. In fact, Plaintiffs required Defendants to contractually agree to maintain the confidentiality of the coding and scoring criteria of the MMAS in the UMass/McManus License Agreement.
- 165. Plaintiffs' confidential, proprietary, and trade secret information derives independent economic value from not being generally known to, and not being readily ascertainable through

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proper means by, another person who can obtain economic value from the disclosure or use of the information.

- 166. Defendants UMASS and FARRELL misappropriated Plaintiffs' confidential, proprietary, and trade secret information by disclosing MMAS-4 coding criteria in the UMass/Farrell Article. Defendants UMASS and FARRELL'S misappropriation of Plaintiffs' confidential, proprietary, and trade secret information was intentional, knowing, willful, and malicious. Defendants UMASS and FARRELL have attempted and continue to attempt to conceal their misappropriation.
- 167. Defendants UMASS and CARRERA misappropriated Plaintiffs' confidential, proprietary, and trade secret information by disclosing MMAS-4 coding criteria in the UMass/Carrera Article. Defendants UMASS and CARRERA'S misappropriation of Plaintiffs' confidential, proprietary, and trade secret information was intentional, knowing, willful, and malicious. Defendants UMASS and CARRERA have attempted and continue to attempt to conceal their misappropriation.
- 168. As the direct and proximate result of the aforementioned Defendants' conduct, Plaintiffs have suffered and, if Defendants' conduct is not stopped, will continue to suffer, severe competitive harm, irreparable injury, and significant damages, in an amount to be proven at trial. Because Plaintiffs' remedy at law is inadequate, Plaintiffs seek, in addition to damages, temporary, preliminary, and permanent injunctive relief to recover and protect their confidential, proprietary, and trade secret information and to protect other legitimate business interests. Plaintiffs' business operates in a competitive market and will continue suffering irreparable harm absent injunctive relief.
- 169. Plaintiffs have been damaged by all of the foregoing and are entitled to an award of exemplary damages and attorney's fees.

FOURTH CAUSE OF ACTION

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

(BY PLAINTIFFS AGAINST DEFENDANTS UMASS, FARRELL, AND CARRERA)

- 170. Plaintiffs reallege each allegation contained in the preceding paragraphs and incorporate them by this reference as though fully set forth herein.
- 171. 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.
- 172. 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.
- 173. In fact, Plaintiffs required Defendants to contractually agree to maintain the confidentiality of the coding and scoring criteria of the MMAS in the UMass/McManus License Agreement.
- 174. Defendants UMASS and FARRELL knew or should have known under the circumstances that the MMAS-4 coding criteria misappropriated by them in the UMass/Farrell Article were trade secrets.
- 175. Defendants UMASS and CARRERA knew or should have known under the circumstances that the MMAS-4 coding criteria misappropriated by them in the UMass/Carrera Article were trade secrets.
- 176. The aforementioned Defendants misappropriated and threaten to further misappropriate trade secrets at least by acquiring trade secrets with knowledge of or reason to know

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that the trade secrets were acquired by improper means, and Defendants are using and threatening to use the trade secrets acquired by improper means without Plaintiffs' knowledge or consent.

- 177. As the direct and proximate result of Defendants' conduct, Plaintiffs are threatened with injury and have been injured in an amount in excess of the jurisdictional minimum of this Court and that will be proven at trial. Plaintiffs have also incurred, and will continue to incur, additional damages, costs, and expenses, including attorney's fees, as a result of the Defendants' misappropriation. As a further proximate result of the misappropriation and use of Plaintiffs' trade secrets, Defendants were unjustly enriched.
- 178. Defendants' acts were willful, malicious, and fraudulent, and Plaintiffs are entitled to exemplary damages under California Civil Code § 3426.3(c).
- 179. Defendants' conduct constitutes a transgression of a continuing nature for which Plaintiffs have no adequate remedy at law. Unless this Court enjoins Defendants, they will continue to use Plaintiffs' trade secret information to enrich themselves. Plaintiffs are entitled to an injunction against the misappropriation and continued threatened misappropriation of trade secrets under California Civil Code § 3426.2, and Plaintiffs ask this Court to restrain Defendants from using all trade secret information misappropriated from Plaintiffs.
- 180. Pursuant to California Civil Code § 3426.4 and related law, Plaintiffs are entitled to an award of attorneys' fees for Defendants' misappropriation of trade secrets.

FIFTH CAUSE OF ACTION

UNFAIR COMPETITION [BUSINESS AND PROFESSIONS CODE §17200, ET SEQ.] (BY PLAINTIFFS AGAINST ALL DEFENDANTS)

181. Plaintiffs reallege each allegation contained in the preceding paragraphs and incorporate them by this reference as though fully set forth herein.

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COMPLAINT

182. Defendants have committed all of the aforesaid acts willfully, maliciously, and oppressively, without regard to Plaintiffs' legal, contractual, and exclusive proprietary rights.

183. Defendants' acts and practices as detailed above constitute acts of unlawful, unfair, or fraudulent business acts and practices within the meaning of California Business and Professions Code § 17200.

184. Pursuant to California Business and Professions Code §17203, Plaintiffs seek an order from this Court prohibiting Defendants from engaging or continuing to engage in the unlawful, unfair, or fraudulent business acts or practices set forth herein.

185. Plaintiffs have incurred and will continue to incur attorney fees in enforcing the rights described herein and seek recovery of their attorney fees incurred pursuant to Code of Civil Procedure § 1021.5.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court enter judgment in their favor and against Defendants as follows:

- 1. For actual damages in an amount according to proof at trial, and for any additional profits attributable to infringements of Plaintiff MORISKY's copyright in the MMAS-4 and MMAS-8, in accordance with proof at trial;
- 2. For actual damages in an amount according to proof at trial, and for any additional profits attributable to infringements of Plaintiff MORISKY'S MARKS, in accordance with proof at trial;
- 3. For statutory damages for copyright infringement and/or willful copyright infringement of the MMAS-8 by Defendants UMASS, D. MCMANUS,

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FITZGIBBONS, TORRES, and SHAW, and of the MMAS-4 by Defendants UMASS, FARRELL, and CARRERA;

- 4. For statutory damages for trademark infringement and/or willful trademark infringement of the MORISKY MARKS by Defendants UMASS, D. MCMANUS, FITZGIBBONS, TORRES, and SHAW, and of the MMAS-4 by Defendants UMASS, FARRELL, and CARRERA;
- 5. For issuance of preliminary and permanent injunctive relief against Defendants, and each of them, and their respective officers, agents, representatives, servants, employees, attorneys, successors and assigns, and all others in active concert or participation with Defendants, enjoining them to:
 - a. Refrain from using the MMAS-4, MMAS-8, the Morisky Widget, or the MORISKY MARKS until a license is obtained, including the maintenance on websites, posted on the Internet, or in any publication, the articles, publications, and reports described herein, or any such articles, publication, and reports in the future which use or reference the MMAS-4, MMAS-8, the Morisky Widget, or the MORISKY MARKS;
 - b. Refrain from selling, offering to sell, advertising, promoting, or passing off, inducing, or enabling others to sell, offer to sell, advertise, promote, or pass off any diagnostic tools like the Morisky Widget provided by Plaintiffs under a name or mark the same as the MORISKY MARKS;
 - c. Refrain from otherwise unfairly competing with Plaintiffs in any manner, including but not limited to, infringing usage of the MORISKY MARKS, or any confusingly similar marks;

d. Remove incorrect MMAS coding and scoring criteria from Defendants' 1 2 publication, and/or issue corrigenda to correct such incorrect coding and scoring 3 criteria; and e. Deliver upon oath, to be impounded during the pendency of this action, and for 4 5 destruction pursuant to judgment herein, all originals, copies, facsimiles, reproductions, or duplicates of any work shown by the evidence to infringe any of 6 7 the MORISKY COPYRIGHTS. 6. 8 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 Defendants, 10 under oath, setting forth that Defendants have complied with the injunction, as well as 11 the steps they have taken to comply; 12 7. For compensatory damages in an amount according to proof at trial; 13 8. For costs of suit herein incurred: 14 9. For attorneys' fees; 10. For prejudgment interest in the amount of ten percent (10%) per annum or the 15 16 maximum amount allowed by law; and 17 11. For such other and further relief the Court deems just and proper. 18 19 Dated: April 12, 2021 KENNETH I. GROSS & ASSOCIATES 20 S/ Kenneth I. Gross 21 By: 22 Kenneth I. Gross, Esq. Kimberly L. Fong, Esq. 23 SF TECH ATTORNEY, PC Attorneys for Plaintiffs 24 MMAS Research LLC and Dr. Donald E. Morisky 25 - 35 -26 **COMPLAINT** 27