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11 *Attorneys for Boston Heart Diagnostics
Corporation*

12 **UNITED STATES DISTRICT COURT**
13 **DISTRICT OF NEVADA**

14 BOSTON HEART DIAGNOSTICS
15 CORPORATION,

16 Plaintiff,

17 vs.

18 MD LABS, INC.

19 Defendant.
20
21

Case No.: 3:18-cv-00006-RCJ-WGC

**FIRST AMENDED COMPLAINT FOR
PATENT INFRINGEMENT**

(JURY DEMANDED)

22 Plaintiff Boston Heart Diagnostics Corporation (“BHDX” or “Plaintiff”) for its First
23 Amended Complaint against defendant MD Labs, Inc. (“MD Labs” or “Defendant”), alleges as
24 follows:

25 **PARTIES**

26
27 1. BHDX is a corporation organized under the laws of the Commonwealth of
28 Massachusetts with its principal place of business in Framingham, Massachusetts. BHDX is a

1 healthcare company that provides cardiovascular disease management through a combination
2 of proprietary lipid testing capabilities, sophisticated diagnostic tools, advanced therapy
3 guidelines, and patient support services.

4 2. Upon information and belief, MD Labs is a Nevada corporation with its principal
5 place of business in Reno, Nevada. Upon information and belief, MD Labs is a laboratory
6 testing company that provides clinical laboratory tests and services intended to predict
7 cardiovascular disease risk. MD Labs' business extends throughout the United States and this
8 District through its internet website at <http://mdlabs.com>.

9
10 **NATURE OF THE ACTION**

11
12 3. This is an action for patent infringement arising under the Patent Laws of the
13 United States, including 35 U.S.C. §§ 271, *et seq.*

14 **JURISDICTION**

15 4. This Court has original and exclusive subject matter jurisdiction over patent
16 infringement claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

17
18 5. This Court has personal jurisdiction over MD Labs because MD Labs is a
19 Nevada corporation with its principal place of business in this District. Moreover, upon
20 information and belief, MD Labs actively solicits health care providers, physicians and patients
21 in this District. MD Labs, through its employees and agents, serves health care providers,
22 physicians, and patients in this District through a highly-interactive website. Upon information
23 and belief, MD Labs specifically targets this District through the user-portal on its website that
24 permits healthcare providers and physicians in this District to access personal account
25 information and patient test results and patients to locate Nevada pharmacies that are certified
26 by MD Labs and provide MD Labs products and services. In addition, MD Labs is believed to
27
28

1 derive revenues from the services and products rendered and/or offered in this District such that
2 it should have reasonably expected to be subject to suit in this District.

3 **VENUE**

4 6. Venue is proper in this District under 28 U.S.C. § 1400(b) because MD Labs has
5 a regular and established place of business in this District because it maintains its principal
6 place of business and headquarters in this District. Moreover, MD Labs conducted and
7 continues to conduct its business in this District in a manner that infringes on the methods
8 protected by the patent in suit. Specifically, upon information and belief, MD Labs certifies
9 and implements its pharmacogenetics testing program at participating pharmacies in this
10 District, whose certified pharmacists advertise and sell MD Labs' products and services to
11 customers and patients in this District.
12

13 **UNITED STATES PATENT NO. 8,455,194**

14 7. BHDx is a heart health management company providing integrated diagnostic
15 and patient management solutions which advance cardiovascular disease risk assessment,
16 monitoring, and treatment. BHDx's goal is to predict, prevent, manage, and reverse
17 cardiovascular disease by improving patient assessment and management.
18

19 8. On or about June 4, 2013, United States Patent No. 8,455,194, which embodies
20 diagnostic methods for detecting the susceptibility of an individual to statin-induced myopathy
21 (the "'194 Patent"), was duly and legally issued by the United States Patent and Trademark
22 Office, and is valid and subsisting. A true and accurate copy of the '194 Patent is attached
23 hereto as **Exhibit A**.
24

25 9. The '194 Patent is owned by Isis Innovation Limited ("Oxford"), a technology
26 commercialization company and wholly-owned subsidiary of the University of Oxford.
27
28

1 10. In November 2011, Oxford granted an exclusive license under the '194 Patent
2 to BHDx thereby granting BHDx the right to use Oxford's Statin Induced Myopathy Genotype
3 (SLCO1B1) test (the "Oxford License Agreement").

4 11. Under the Oxford License Agreement, BHDx was granted an exclusive license
5 to "develop, make, have made, use, import and Market the Licensed Product, and to develop,
6 use, and Market the Licensed Service, in the Field and the Territory." Oxford License
7 Agreement, § 2.1.

8 12. BHDx offers the SLCO1B1 test, protected by the '194 Patent, exclusively
9 through its Framingham-based Clinical Laboratory Improvement Act ("CLIA") certified
10 laboratory. The SLCO1B1 test identifies patients who are at higher risk for developing severe
11 myopathy (muscle aches and pain) as a side effect of statin drugs prescribed to reduce low-
12 density lipoprotein cholesterol levels.

13 13. The Oxford License Agreement expressly grants to BHDx the right to bring this
14 action for injunctive relief and damages. Specifically, Article 6 of the Oxford License
15 Agreement grants BHDx the first right to take legal action against any misappropriation or
16 infringement of the '194 Patent.

17 14. On November 22, 2013, the U.S. Patent and Trademark Office ("PTO") received
18 a request for reexamination of claims 1 through 7 of the '194 Patent. On January 14, 2014, the
19 PTO initiated reexamination.

20 15. On January 6, 2015, the PTO issued an Ex Parte Reexamination Certificate for
21 the '194 Patent, re-issuing claims 1 through 7 as amended. Claims 8 through 14 were not
22 subject to reexamination. Claims 15 through 25 were added during the reexamination. A copy
23

of the Ex Parte Reexamination Certificate dated January 6, 2015, is attached hereto as **Exhibit**

B.

16. The patented method of the '194 Patent, as amended during the reexamination, involves three principal steps: (a) an "assaying" step, (b) a "determining" step, and (c) an "administering" step.

COUNT ONE: DIRECT INFRINGEMENT
OF THE '194 PATENT

17. The allegations set forth in paragraphs 1 through 16 are hereby realleged and incorporated as if set forth fully herein.

18. MD Labs offers genetic testing that seeks to identify those patients who are at higher risk of developing statin-induced myopathy due to a variation on their SLCO1B1 gene (the "MD Labs SLCO1B1 Test").

19. MD Labs actively offers, markets, and sells the MD Labs SLCO1B1 Test to patients and healthcare providers, such as physicians and pharmacists, throughout the United States, including in this District.

20. In offering, marketing, selling, and performing the MD Labs SLCO1B1 Test, MD Labs infringes the '194 Patent directly and/or through inducement.

21. Upon information and belief, MD Labs itself directly performs the "assaying" and "determining" steps of the method covered by the '194 Patent, when those claim terms are properly construed in accordance with the '194 Patent specification, prosecution history, and other evidence.

22. MD Labs enters into contractual relationships or agreements with participating physicians and pharmacists, whom MD Labs trains, instructs, guides, and directs, and expressly "certifies" as "participating" MD Labs-certified healthcare providers on MD Labs' website,

1 who act as agents on behalf of, or joint venturers with, MD Labs, and are compensated by MD
2 Labs in connection with the performance of each MD Labs SLCO1B1 Test.

3 23. Upon information and belief, pursuant to these contractual relationships or
4 agreements, MD Labs provides these participating “certified” physicians and pharmacists with,
5 among other things, the MD Labs’ SLCO1B1 Rxight® PGx Test (the “MD Labs Test Kit”),
6 which physicians and pharmacists use to collect patient DNA samples, which they provide to
7 MD Labs.
8

9 24. Upon information and belief, MD Labs “assays” a patient’s DNA sample, within
10 the meaning of the ’194 Patent, at its genetic testing laboratory to identify clinical genetic
11 variants in a patient’s SLCO1B1 gene.
12

13 25. As detailed in the Personalized Medication Review® Clinical Report (the “PMR
14 Clinical Report”) MD Labs prepares for each patient, which MD Labs provides to its certified
15 physicians and pharmacists and refers to as a “lifetime blueprint for [a patient]’s current and
16 future medication therapy needs,” MD Labs “determines” the appropriate dosage of a statin,
17 within the meaning of the ’194 Patent.
18

19 26. Upon information and belief, through the PMR Clinical Report provided by MD
20 Labs to its certified physicians and pharmacists, among other training and educational materials,
21 MD Labs directs, trains, guides, and instructs its certified physicians and pharmacists to
22 interpret the PMR Clinical Report to provide individual statin dosage and treatment programs
23 for patients.
24

25 27. Upon information and belief, through the detailed information,
26 recommendations, training, guidelines, and instructions provided by MD Labs to physicians
27 and pharmacists in the PMR Clinical Report and other materials, trainings, and communications
28

1 from MD Labs, MD Labs directs and controls physicians and pharmacists to perform the
2 “administering” step of the patented method as its agents, or acts in concert with physicians and
3 pharmacists as a partner or joint venturer, and thus jointly performs the “administering” step of
4 the patented method.

5
6 28. As a result of MD Labs’ infringing activities, BHDX has suffered damage in an
7 amount to be proved at trial.

8 29. In addition, MD Labs’ infringement of the ’194 Patent is ongoing. Unless
9 restrained and enjoined by the Court, MD Labs will continue to infringe the ’194 Patent, causing
10 BHDX irreparable harm.

11
12 **COUNT TWO: INDUCING INFRINGEMENT**
13 **OF THE ’194 PATENT**

14 30. The allegations set forth in paragraphs 1 through 29 are hereby realleged and
15 incorporated as if set forth fully herein.

16 31. MD Labs offers, markets, sells, and performs the MD Labs SLCO1B1 Test
17 throughout the United States.

18 32. By using the MD Labs SLCO1B1 Test, pharmacists and physicians directly
19 infringe the ’194 Patent, and MD Labs knowingly encourages and induces that infringement.
20

21 33. Without limitation, MD Labs specifically markets and advertises the MD Labs
22 SLCO1B1 Test for use in identifying patients who are at risk of developing statin-induced
23 myopathy. MD Labs also employs sales representatives who actively instruct and encourage
24 physicians and pharmacists to order and use the MD Labs SLCO1B1 Test.
25

26 34. Upon information and belief, MD Labs further knowingly encourages and
27 induces physicians’ and pharmacists’ infringement of the ’194 Patent by performing the
28

1 “assaying” step of the patented method under the control and direction of the physicians and
2 pharmacists, pursuant to written agreements.

3 35. Upon information and belief, MD Labs further knowingly encourages and
4 induces physicians’ and pharmacists’ infringement by providing the MD Labs Test Kit, PMR
5 Clinical Reports, training, guidance, and other educational information that instructs
6 pharmacists and physicians to “determine” the appropriate dosage of a statin, within the
7 meaning of the ’194 Patent.
8

9 36. By this and other conduct, MD Labs knowingly and actively induces physicians
10 and pharmacists to “administer” appropriate statin dosages, within the meaning of the ’194
11 Patent.
12

13 37. Upon information and belief, MD Labs engages in the above-described activity
14 with actual knowledge of the ’194 Patent.
15

16 38. Upon information and belief, MD Labs engages in the above-described activity
17 with the specific intent to induce physicians and pharmacists to infringe the ’194 Patent.
18

19 39. As a result of MD Labs’ infringing activities, BHDX has suffered damage in an
20 amount to be proved at trial.
21

22 40. In addition, MD Labs’ infringement of the ’194 Patent is ongoing. Unless
23 restrained and enjoined by the Court, MD Labs will continue to infringe the ’194 Patent, causing
24 BHDX irreparable harm.

25 **COUNT THREE: EXCEPTIONAL CASE**
26

27 41. The allegations set forth in paragraphs 1 through 40 are hereby realleged and
28 incorporated as if set forth fully herein.

1 42. Pursuant to 35 U.S.C. § 287(a), BHDx has provided MD Labs with notice of its
2 exclusive rights under the '194 Patent.

3 43. Notwithstanding the notice provided by BHDx, MD Labs continues to offer,
4 market, sell, and perform the MD Labs SLCO1B1 Test, thereby acting in reckless
5 disregard of the likelihood that MD Labs is directly infringing, jointly infringing, and/or
6 inducing infringement of the '194 Patent.

7
8 44. Accordingly, MD Labs' continuing infringement of the '194 Patent is willful
9 and deliberate.

10
11 **JURY DEMAND**

12 45. Plaintiff demands a jury trial on all issues so triable.

13 **PRAYERS FOR RELIEF**

14 WHEREFORE, Plaintiff prays for relief as follows:

- 15 (i) For entry of judgment by this Court that MD Labs, its officers, agents, servants,
16 employees, representatives, attorneys and all persons acting in active concert or
17 participation with MD Labs, have infringed the '194 Patent, either directly and/or
18 by inducing others' infringement;
- 19
20 (ii) For entry of an order by this Court enjoining and restraining MD Labs, its officers,
21 agents, servants, employees, representatives, attorneys, and all persons acting in
22 active concert or participation with MD Labs, from making, using, selling, or
23 offering for sale the MD Labs SLCO1B1 Test or otherwise infringing the '194
24 Patent;
- 25 (iii) For entry of judgment by this Court awarding damages under 35 U.S.C. § 284 to
26 compensate BHDx for MD Labs' past, continuing or future infringement of the
27 '194 Patent through the date such judgment is entered, including: (a) an accounting
28 of all infringing acts; (b) treble damages for the exceptional case of MD Labs'

willful infringement under 35 U.S.C. § 284; and (c) BHDx's costs and attorneys' fees, plus interest, incurred in prosecuting this action under 35 U.S.C. § 285;

(iv) For entry of an order requiring MD Labs to surrender or destroy, within ten days from the entry of any final judgment or preliminary decree: (a) any and all property which unlawfully violates the '194 Patent; (b) any and all product literature MD Labs owns or possesses which unlawfully violates the '194 Patent; and (c) all other works owned by MD Labs that infringe the '194 Patent;

(v) Such other and further relief as the Court deems just and proper.

Dated: March 13, 2018.

**BOSTON HEART DIAGNOSTICS
CORPORATION,**

BY ITS ATTORNEYS,

HUMPHREY LAW PLLC

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CERTIFICATE OF SERVICE

Pursuant to FRCP 5(b) and 5(d), I certify under penalty of perjury that I am an attorney at Humphrey Law PLLC, 140 Washington Street, Suite 210, Reno, Nevada 89503, and that on March 13, 2018, I served the foregoing documents described below:

- **FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT**, filed March 13, 2018.

I served the above-named document(s) by the following means to the persons as listed below:

☒ **ECF System**, to all those persons registered with the Court's CM/ECF system in this case.

☐ **United States mail, First-Class, postage fully prepaid**, deposited for mailing at Reno, Nevada, upon all those persons listed below:

Daniel T Shvodian
Perkins Coie LLP
3150 Porter Drive
Palo Alto, CA 94340-1212

Robert W. Delong
Parsons Behle & Latimer
50 W. Liberty Street, Suite 750
Reno, NV 89501

I declare under penalty of perjury that the foregoing is true and correct.

DATED: March 13, 2018.

HUMPHREY LAW PLLC

By: /s/ L. Edward Humphrey
L. Edward Humphrey, Esq.