

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK**

BOSTON HEART DIAGNOSTICS CORPORATION,)	
)	
Plaintiff)	
)	JURY DEMANDED
v.)	
)	
MEDICAL DIAGNOSTIC LABORATORIES, L.L.C.,)	
)	
Defendant.)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Boston Heart Diagnostics Corporation (“BHDX” or “Plaintiff”) for its Complaint against defendant Medical Diagnostic Laboratories, L.L.C. (“MDL” or “Defendant”), alleges as follows:

PARTIES

1. BHDX is a corporation organized under the laws of the Commonwealth of Massachusetts with its principal place of business in Framingham, Massachusetts. BHDX is a healthcare company that provides cardiovascular disease management through a combination of proprietary lipid testing capabilities, sophisticated diagnostic tools, advanced therapy guidelines, and patient support services.

2. Upon information and belief, MDL is a New Jersey corporation with its principal place of business in Hamilton Township, New Jersey. Upon information and belief, MDL is a laboratory testing company that provides clinical laboratory tests and services intended to predict cardiovascular disease risk. MDL’s business extends throughout the United States and New York State through its internet website at <http://www.mdlab.com>.

NATURE OF THE ACTION

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

JURISDICTION

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

5. This Court has personal jurisdiction over MDL. Upon information and belief, MDL actively solicits health care providers, physicians and patients in New York. MDL, through its employees and agents, serves health care providers, physicians, and patients in New York through a highly-interactive website. Upon information and belief, MDL specifically targets New York through the user-portal on its website that permits healthcare providers and patients in New York to access personal account information and test results, order testing supplies, and render payments. In addition, MDL is believed to derive revenues from the services and products rendered and/or offered in New York such that it should have reasonably expected to be subject to suit in New York.

VENUE

6. Venue is proper in this District under 28 U.S.C. § 1400(b), because MDL conducted and continues to conduct its business in this District in a manner that infringes on the methods protected by the patent in suit and has a regular and established place of business in this District. Specifically, upon information and belief, MDL sponsors and conducts an ongoing clinical study in this District.

UNITED STATES PATENT NO 8,455,194

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

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

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

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

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

12. BHDx offers the SLCO1B1 test, protected by the '194 Patent, exclusively through its Framingham-based Clinical Laboratory Improvement Act ("CLIA") certified laboratory. The SLCO1B1 test identifies patients who are at higher risk for developing severe

myopathy (muscle aches and pain) as a side effect of statin drugs prescribed to reduce low-density lipoprotein cholesterol levels.

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

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

15. On January 6, 2015, the PTO issued an Ex Parte Reexamination Certificate for the '194 Patent, re-issuing claims 1 through 7 as amended. Claims 8 through 14 were not subject to reexamination. Claims 15 through 25 were added during the reexamination. A copy 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. MDL 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 "MDL SLCO1B1 Test").

19. MDL actively offers, markets, and sells the MDL SLCO1B1 Test to patients and health care providers including physicians throughout the United States, including in this District.

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

21. Upon information and belief, MDL 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. Among other things, MDL provides physicians with MDL's specimen collection kits and its Pharmacogenetics (“PGx”) Test Requisition Form (“MDL's PGx Form”), a copy of which is attached as **Exhibit C**, for collecting a DNA sample and requesting a complete genetic variation panel of SLCO1B1 for that sample.

23. In response to receiving its MDL PGx Form and other information provided by MDL's sales representatives and other agents, MDL “determines” the appropriate dosage of a statin, within the meaning of the '194 Patent, for physicians.

24. For instance, through MDL's Electronic Results Options (“MDL's Electronic Results”) such as Allscripts® and eClinicalWorks™, MDL provides clinical guidance to physicians for medication dosing based the result of the assay that MDL performs.

25. Through the detailed information, recommendations, and instructions provided to physicians, MDL directs and controls physicians and pharmacists to perform the “administering” step of the patented method or acts in concert with physicians, as a partner or joint venturer, and thus jointly performs the “administering” step of the patented method.

26. As a result of MDL's infringing activities, BHDx has suffered damage in an amount to be proved at trial.

27. In addition, MDL's infringement of the '194 Patent is ongoing. Unless restrained and enjoined by the Court, MDL will continue to infringe the '194 Patent, causing BHDx irreparable harm.

COUNT TWO: INDUCING INFRINGEMENT
OF THE '194 PATENT

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

29. MDL offers, markets, sells, and performs the MDL SLCO1B1 Test throughout the United States.

30. By using the MDL SLCO1B1 Test, physicians directly infringe the '194 Patent, and MDL knowingly encourages and induces that infringement.

31. Without limitation, MDL specifically markets and advertises the MDL SLCO1B1 Test for use in identifying patients who are at risk of developing statin-induced myopathy. MDL also employs sales representatives who actively instruct and encourage physicians to order and use the MDL SLCO1B1 Test.

32. MDL further knowingly encourages and induces physicians' infringement of the '194 Patent by performing the "assaying" step of the patented method under their control and direction, pursuant to written agreements.

33. MDL further knowingly encourages and induces physicians' infringement by providing the MDL SLCO1B1 Test, specimen collection kits, MDL's reporting tool, clinical

reports, and other information that instructs physicians and recommends appropriate statin dosages.

34. By this and other conduct, MDL knowingly and actively induces physicians to administer statin dosages within the meaning of the '194 Patent.

35. MDL engages in the above-described activity with actual knowledge of the '194 Patent.

36. MDL engages in the above-described activity with the specific intent to induce physicians to infringe the '194 Patent.

37. As a result of MDL's infringing activities, BHDX has suffered damage in an amount to be proved at trial.

38. In addition, MDL's infringement of the '194 Patent is ongoing. Unless restrained and enjoined by the Court, MDL will continue to infringe the '194 Patent, causing BHDX irreparable harm.

COUNT THREE: EXCEPTIONAL CASE

39. The allegations set forth in paragraphs 1 through 38 are hereby realleged and incorporated as if set forth fully herein.

40. Pursuant to 35 U.S.C. § 287(a), BHDX has provided MDL with notice of its exclusive rights under the '194 Patent.

41. Notwithstanding the notice provided by BHDX, MDL continues to offer, sell, and perform the MDL SLCO1B1 Test, thereby acting in reckless disregard of the likelihood that MDL is directly infringing, jointly infringing, and/or inducing infringement of the '194 Patent.

42. Accordingly, MDL's continuing infringement of the '194 Patent is willful and deliberate.

JURY DEMAND

43. Plaintiff demands a jury trial on all issues so triable.

PRAYERS FOR RELIEF

WHEREFORE, Plaintiff prays for relief as follows:

- (i) For entry of judgment by this Court that MDL, its officers, agents, servants, employees, representatives, attorneys and all persons acting in active concert or participation with MDL, have infringed the '194 Patent, either directly and/or by inducing others' infringement;
- (ii) For entry of an order by this Court enjoining and restraining MDL, its officers, agents, servants, employees, representatives, attorneys, and all persons acting in active concert or participation with MDL, from making, using, selling, or offering for sale the MDL SLCO1B1 Test or otherwise infringing the '194 Patent;
- (iii) For entry of judgment by this Court awarding damages under 35 U.S.C. § 284 to compensate BHDx for MDL's past, continuing or future infringement of the '194 Patent through the date such judgment is entered, including: (a) an accounting of all infringing acts; (b) treble damages for the exceptional case of MDL's 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 MDL 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 MDL owns or possesses which unlawfully violates the '194 Patent; and (c) all other works owned by MDL that infringe the '194 Patent;
- (v) Such other and further relief as the Court deems just and proper.

**BOSTON HEART DIAGNOSTICS
CORPORATION,**

BY ITS ATTORNEYS,

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