

**UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF FLORIDA**

Case No.

JURY TRIAL REQUESTED

COMMONWEALTH LABORATORIES, INC.,
a Massachusetts Corporation,

Plaintiff,

v.

GENOVA DIAGNOSTICS, INC.,
a Delaware Corporation,

Defendant.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Commonwealth Laboratories, Inc. (“Commonwealth” or “Plaintiff”) hereby
sues Defendant, Genova Diagnostics, Inc. (“Genova” or “Defendant”) for patent infringement.

In support, Plaintiff alleges as follows:

THE PARTIES

1. Commonwealth is a corporation organized and existing under the laws of the
State of Massachusetts, having a business address at 39 Norman Street, Salem, Massachusetts
01970, and is a state and federally licensed clinical laboratory that specializes in testing for levels
of methane and hydrogen in the breath to help aid in the diagnosis of multiple digestive
disorders.

2. Genova is a corporation organized and existing under the laws of the State of
Delaware, with its principal place of business located at 63 Zillicoa Street, Asheville, North

Higer Lichter & Givner

Carolina 28801, which offers test kits used for testing for levels of hydrogen and methane in the breath in order to diagnose and/or help aid in the diagnosis of multiple digestive disorders.

JURISDICTION AND VENUE

3. This Court has Federal subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§1331 and 1338(a) because it arises under the patent laws of the United States, Title 35 of the United States Code, as it alleges acts of patent infringement.

4. Jurisdiction in Florida is proper over Defendant in this action because Defendant has committed the tort of patent infringement in the State of Florida, including in this judicial district.

5. Venue is proper under 28 U.S.C. §1391(b) because, on information and belief, Defendant has offered for sale and sold infringing products and services throughout this District, as shown in the attached screenshots of Defendant's website located at www.gdx.net (the "Genova Website"). True and correct copies of screenshots from Defendant's website are attached as **Composite Exhibit A**. Venue is also proper in this District pursuant to 28 U.S.C. §1400(b).

GENERAL ALLEGATIONS

The Technology

6. On or about September 24, 2013, Cedars-Sinai Medical Center ("CSMC"), a California nonprofit public benefit corporation and owner by assignment of all rights in and to the United States Patent No. 6,805,852 (the "852 Patent"), entered into an exclusive license agreement with Commonwealth, granting to Commonwealth all substantial rights in and to the '852 Patent (the "Exclusive License Agreement").

7. As a result of the Exclusive License Agreement, Commonwealth is the exclusive

licensee of all substantial rights in and to the following United States Patent:

United States Patent No. 6,805,852 issued on October 19, 2004, entitled “Methods of Irritable Bowel Syndrome and Other Disorders Caused by Small Intestinal Bacterial Overgrowth” (hereinafter “the ‘852 Patent.”). A true and correct copy of the ‘852 Patent is attached as **Exhibit B** hereto.

8. The ‘852 Patent describes a method for diagnosing Irritable Bowel Syndrome (“IBS”) and other disorders caused by Small Intestinal Bacterial Overgrowth (“SIBO”). The patented method includes analyzing the content of carbon dioxide, methane, or hydrogen gas contained in a breath specimen, which is taken after a human has ingested a substrate such as lactulose, xylose, lactose, or glucose.

9. Genova makes, has made, offers for sale, and/or sells breath testing kits and performs breath testing analysis. The primary use of Genova’s breath test kits and the primary purpose of its breath specimen analysis is to diagnose and/or help physicians identify and diagnose the cause of a patient’s gastrointestinal disorders, including diagnosing IBS caused by SIBO.

10. Genova also offers breath testing services for the evaluation of digestive disorders, including SIBO and lactose intolerance. These tests analyze breath specimens by identifying and quantifying levels of methane and hydrogen in the breath after a patient ingests a specific substrate as a bacteria for the marker. According to Genova’s website, Genova offers SIBO test kits using lactulose as the operative substrate. See, Genova Diagnostics, Inc., *Bacterial Overgrowth of the Small Intestine: Kit Instructions* (accessed on January 13, 2014), available at <http://www.gdx.net/core/domestic-kit-instructions/Bacterial-Overgrowth-Instructions.pdf>.

COUNT I
DIRECT INFRINGEMENT OF U.S. PATENT NO. 6,805,852

Plaintiff re-alleges and incorporates by reference paragraphs one (1) through ten (10) as if fully set forth herein.

11. This is a claim of patent infringement against Genova.

12. Commonwealth is the exclusive licensee of all substantial rights in and to the '852 Patent, which is attached as **Exhibit B**. The '852 Patent is both valid and enforceable.

13. Commonwealth has the right to sue, and recover damages, for infringement of the '852 Patent.

14. On information and belief, Genova is directly selling, offering for sale, importing, or using breath tests, which are used to diagnose and/or help physicians identify and diagnose IBS and other disorders caused by SIBO through analyzing the content of methane, carbon dioxide, or hydrogen gas contained in a breath specimen after a human has ingested a substrate such as lactulose, glucose, lactose, or xylose.

15. Further, Genova performs the testing and analysis necessary to diagnose IBS and other disorders caused by SIBO.

16. As such, Genova directly infringes or through the doctrine of equivalents infringes the '852 Patent in this judicial district and elsewhere throughout the United States.

17. By making, using, importing, offering for sale, and/or selling the breath test kits described above within the United States, and by conducting the testing and analysis described above, Defendant is liable for direct infringement of the '852 Patent pursuant to 35 U.S.C. § 271(a).

18. Defendant's infringement includes at least Claim 1 and Claim 4 of the '852 Patent, which state:

1. A method of diagnosis irritable bowel syndrome comprising:

detecting the presence of small intestinal bacterial overgrowth in a human subject having at least one symptom associated with a suspected diagnosis of irritable bowel syndrome, whereby the suspected diagnosis of irritable bowel syndrome is corroborated by the presence of small intestinal bacterial overgrowth.

4. A method of diagnosing irritable bowel syndrome, comprising:

detecting by analyzing the content of a gas mixture, the presence of small intestinal bacterial overgrowth in a human subject having at least one symptom associated with a suspected diagnosis of irritable bowel syndrome, said gas mixture being at least partially produced by the intestinal microflora of said human subject and being exhaled by said human subject after ingesting a controlled quantity of a substrate, whereby the suspected diagnosis of irritable bowel syndrome is corroborated by the presence of small intestinal bacterial overgrowth.

See Ex. B.

19. Commonwealth has been irreparably harmed and damaged as a result of Genova's direct infringement of the '852 Patent.

20. Genova should be ordered to pay Plaintiff not only its damages, costs, and expenses, but also pre-judgment and post-judgment interest as provided by 35 U.S.C. §284. In addition, Plaintiff requests the Court enter judgment its favor and enter an order finding that this is an exceptional case within the meaning of U.S.C. §285 and awarding Plaintiff its reasonable attorneys' fees, as well as all other relief to which Plaintiff may show itself to be entitled.

COUNT II
INFRINGEMENT BY INDUCEMENT OF U.S. PATENT NO. 6,805,852

Plaintiff re-alleges and incorporates by reference paragraphs one (1) through ten (10) as if fully set forth herein.

21. Commonwealth is the exclusive licensee of all substantial rights in and to the '852

Patent, which is attached as **Exhibit B**. The '852 Patent is both valid and enforceable.

22. Commonwealth has the right to sue, and recover damages, for infringement of the '852 Patent.

23. On information and belief, Genova is directly selling, offering for sale, importing or using breath tests, which are used to diagnose and/or help physicians identify and diagnose IBS and other disorders caused by SIBO through analyzing the content of methane, carbon dioxide, or hydrogen gas contained in a breath specimen after a human has ingested a substrate such as lactulose, glucose, lactose, or xylose.

24. Further, Genova performs the testing analysis necessary to diagnose IBS and other disorders caused by SIBO.

25. As such, Genova infringes the '852 Patent by inducement in this judicial district and elsewhere throughout the United States.

26. By making, using, importing, offering for sale, and/or selling the breath test kits described above within the United States, and by conducting the testing and analysis described above, Defendant is liable for infringement by inducement of the '852 Patent pursuant to 35 U.S.C. § 271(b).

27. Defendant's infringement includes at least Claim 1 and Claim 4 of the '852 Patent, which state:

1. A method of diagnosis irritable bowel syndrome comprising: detecting the presence of small intestinal bacterial overgrowth in a human subject having at least one symptom associated with a suspected diagnosis of irritable bowel syndrome, whereby the suspected diagnosis of irritable bowel syndrome is corroborated by the presence of small intestinal bacterial overgrowth.

4. A method of diagnosing irritable bowel syndrome, comprising:

detecting by analyzing the content of a gas mixture, the presence of small intestinal bacterial overgrowth in a human subject having at least one symptom associated with a suspected diagnosis of irritable bowel syndrome, said gas mixture being at least partially produced by the intestinal microflora of said human subject and being exhaled by said human subject after ingesting a controlled quality of a substrate, whereby the suspected diagnosis of irritable bowel syndrome is corroborated by the presence of small intestinal bacterial overgrowth.

See Ex. B.

28. Commonwealth has been irreparably harmed and damaged as a result of Genova's patent infringement of the '852 Patent.

29. Genova should be ordered to pay Plaintiff not only its damages, costs, and expenses, but also pre-judgment and post-judgment interest as provided by 35 U.S.C. §284. In addition, Plaintiff requests the Court enter judgment in its favor and enter an order finding that this is an exceptional case within the meaning of U.S.C. §285 and awarding Plaintiff its reasonable attorneys' fees, as well as all other relief to which Plaintiff may show itself to be entitled.

COUNT III
CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 6,805,852

Plaintiff re-alleges and incorporates by reference paragraphs one (1) through ten (10) as if fully set forth herein.

30. Commonwealth is the exclusive licensee of all substantial rights in and to the '852 Patent, which is attached as **Exhibit B**. The '852 Patent is both valid and enforceable.

31. Commonwealth has the right to sue, and recover damages, for infringement of the '852 Patent.

32. On information and belief, Genova is directly selling, offering for sale, importing or using breath tests, which are used to diagnose and/or help physicians identify and diagnose

IBS and other disorders caused by SIBO through analyzing the content of methane, carbon dioxide, or hydrogen gas contained in a breath specimen after a human has ingested a substrate such as lactulose, glucose, lactose, or xylose.

33. Further, Genova performs the testing analysis necessary to diagnose IBS and other disorders caused by SIBO.

34. As such, Genova is a contributory infringer of the '852 Patent in this judicial district and elsewhere throughout the United States.

35. By making, using, importing, offering for sale, and/or selling the breath test kits described above within the United States, and by conducting the testing and analysis described above, Defendant is liable for contributory infringement of the '852 Patent pursuant to 35 U.S.C. § 271(c).

36. Defendant's infringement includes at least Claim 1 and Claim 4 of the '852 Patent, which reads as follows:

1. A method of diagnosis irritable bowel syndrome comprising:

detecting the presence of small intestinal bacterial overgrowth in a human subject having at least one symptom associated with a suspected diagnosis of irritable bowel syndrome, whereby the suspected diagnosis of irritable bowel syndrome is corroborated by the presence of small intestinal bacterial overgrowth.

4. A method of diagnosing irritable bowel syndrome, comprising:

detecting by analyzing the content of a gas mixture, the presence of small intestinal bacterial overgrowth in a human subject having at least one symptom associated with a suspected diagnosis of irritable bowel syndrome, said gas mixture being at least partially produced by the intestinal microflora of said human subject and being exhaled by said human subject after ingesting a controlled quantity of a substrate, whereby the suspected diagnosis of irritable bowel syndrome is corroborated by the presence of small intestinal bacterial overgrowth.

See Ex. B.

37. Commonwealth has been irreparably harmed and damaged as a result of Genova's patent infringement of the '852 Patent.

38. Genova should be ordered to pay Plaintiff not only its damages, costs, and expenses, but also pre-judgment and post-judgment interest as provided by 35 U.S.C. §284. In addition, Plaintiff requests the Court enter judgment in its favor and enter an order finding that this is an exceptional case within the meaning of U.S.C. §285 and awarding Plaintiff its reasonable attorneys' fees, as well as all other relief to which Plaintiff may show itself to be entitled.

PRAYER OR RELIEF

WHEREFORE, for all of the foregoing reasons, Plaintiff requests this Court grant relief in the following manner:

a. Preliminarily and permanently enjoining Defendant and their agents, servants, employees, and those people in active concert or participation with them from infringing U.S. Patent No. 6,805,852.

b. Awarding damages to Plaintiff, including no less than a reasonable royalty, for Defendant's actions of infringing U.S. Patent No. 6,805,852 based upon Defendant's sales, offer of sales, use, and importation of breath tests, as well as Defendant's performance of breath testing and analysis, which are used to diagnose and/or help physicians to identify and diagnose IBS and other disorders caused by SIBO.

c. Awarding Plaintiff all other monetary remedies available under the common law, including but not limited to, penalties and fines, compensatory damages, treble damages,

disgorgement of profits, interest, costs, and attorney's fees as legally permitted by each court respectively.

d. Awarding any and all other relief that this Court deems just.

DEMAND FOR JURY TRIAL

Commonwealth hereby demands a trial by jury of all issues so triable.

Dated: January 13, 2014

Respectfully submitted,

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