

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

_____)	
CARDIONET, LLC,)	
)	
and)	Civil Action No. 1:17-cv-10445
)	
BRAEMAR MANUFACTURING, LLC,)	Hon. Indira Talwani
)	
Plaintiffs,)	JURY TRIAL DEMANDED
)	
v.)	
)	
INFOBIONIC, INC.,)	
)	
Defendant.)	
_____)	

FIRST AMENDED COMPLAINT AND JURY DEMAND

Plaintiffs CardioNet, LLC and Braemar Manufacturing, LLC (collectively, “CardioNet”), for their Complaint against InfoBionic, Inc. (“InfoBionic”), allege as follows:

THE PARTIES

1. Plaintiff CardioNet, LLC is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1000 Cedar Hollow Road, Malvern, PA 19355. CardioNet is a leading provider of ambulatory outpatient management solutions for monitoring clinical information regarding an individual’s health.

2. Plaintiff Braemar Manufacturing, LLC (“Braemar”) is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1285 Corporate Center Drive, Suite 150, Eagan, MN 55121. Braemar develops and manufactures ambulatory cardiac monitors for leading healthcare companies.

3. Upon information and belief, defendant InfoBionic, Inc. is a corporation organized under the laws of the State of Delaware, having its principal place of business at 600 Suffolk Street, Lowell, MA 01854.

JURISDICTION AND VENUE

4. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code.

5. This Court has jurisdiction over CardioNet's patent infringement claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

FACTS

7. U.S. Patent No. 7,941,207 (the "'207 patent"), entitled "Cardiac Monitoring," was duly and legally issued on May 10, 2011. CardioNet, Inc. was the original owner by assignment of all right, title, and interest in and to the '207 patent, including without limitation the right to sue and recover for past infringement thereof. A copy of the '207 patent is attached as Exhibit A to this Complaint.

8. On December 31, 2012, CardioNet, Inc. assigned all right, title, and interest in and to the '207 patent to Braemar. Effective the same day, Braemar granted CardioNet, Inc. an exclusive license to make, use, offer to sell, sell, import, license, and exploit the '207 patents. The license grants CardioNet, Inc. an exclusive license to the '207 patent in the field of applications and services for the monitoring and monitoring-related services of medical monitoring and diagnostic devices, while all other rights, title, and interest in the '207 patent are retained by Braemar. CardioNet, Inc. is now CardioNet, LLC as confirmed by an August 1, 2013 Certificate of Conversion to Limited Liability Company of CardioNet, Inc. (a Delaware corporation) to CardioNet, LLC (a Delaware limited liability company) filed with the Secretary of State for the State of Delaware.

9. CardioNet's Mobile Cardiac Outpatient Telemetry™ (MCOT™) is a market leader in the field of Mobile Cardiac Telemetry ("MCT"). The CardioNet MCOT™ was the first commercialized MCT device on the market and was the result of substantial investment by CardioNet. The CardioNet MCOT™ includes beat-to-beat, real-time analysis, automatic arrhythmia detection, and wireless ECG transmission.

10. CardioNet spends millions of dollars per year developing new technologies and protecting its inventions, including by filing for and obtaining United States patents. CardioNet has also taken steps to protect its trade secret information, including by limiting access to this information and requiring employees to sign nondisclosure and confidentiality agreements.

11. On information and belief, InfoBionic was founded in 2011. InfoBionic states that it "empowers physicians with the control they need to transform the efficiency with which they diagnose and monitor patients with cardiac arrhythmias." (Ex. B (7/28/2016 capture of <http://infobionic.com/our-story/>) at 1.)

12. InfoBionic claims that its "MoMe® Kardia system is the first and only wireless remote patient monitoring platform to bring all aspects of cardiac arrhythmia detection and monitoring management under physicians' direct control" (Ex. C (7/28/2016 capture of <http://infobionic.com/the-system/>) at 1.) The MoMe® Kardia System uses a "single universal device" that "enables physicians to remotely transition between Holter, Event, and MCT technologies based on patient need at any given time during their monitoring period." (*Id.* at 2.) The MoMe® Kardia System also uses a "Cloud-based model" with "the horsepower to continuously stream and process full disclosure data via a proprietary algorithm for analysis." (*Id.* at 4.) The MoMe® Kardia System allows Physicians "access to the monitoring data ... through the convenient web-based MoMe® Kardia physician portal." (*Id.* at 6.)

13. Upon information and belief, defendant InfoBionic has developed at least two generations of the MoMe® Kardia System. The First Generation MoMe® Kardia System refers

to any system that can be marketed pursuant to 510(k) No. K133753 (Ex. D).¹ The Second Generation MoMe[®] Kardia System refers to any system that can be marketed pursuant to 510(k) Nos. K152491 (Ex. E) and K160064 (Ex. F).

14. Upon information and belief, defendant InfoBionic actively solicits and does business throughout this Judicial District, including making, using, offering for use, selling, offering for sale, and/or importing the Second Generation MoMe[®] Kardia System, including the MoMe[®] Kardia Device that records and transmits a patient's electrocardiographic signal (Ex. E) and the MoMe[®] Software System that detects arrhythmias and enables human review of arrhythmia data (Ex. F).

15. InfoBionic's MoMe[®] Kardia System directly competes with CardioNet's MCOT[™] System. InfoBionic has stated publicly that CardioNet "is one of the companies we are trying to disrupt with the MoMe[™] system." (Ex. G (11/25/2016 capture of <http://www.wpiventureforum.org/monthly10912.html>) at 2.)²

16. The 510(k) submission for the First Generation MoMe[®] Kardia System relied upon CardioNet's MCOT[™] device as one of two predicate devices. (Ex. D at 5, 7.) The 510(k) submission states that "[t]he MoMe System Indications for use are aligned with both the CardioNet and Preventice Indications" and that "[a]ll three devices are monitoring devices and are classified under the same FDA classification code of 21 CFR 870.1025, DSI." (*Id.* at 8.) The Software System 510(k) submission for the Second Generation MoMe[®] Kardia System relied upon the First Generation MoMe[®] Kardia System as the sole predicate device (Ex. E at 4), and the MoMe[®] Kardia 510(k) submission for the Second Generation MoMe[®] Kardia System

¹ Pursuant to this Court's Consent Judgment as to InfoBionic's "First-Generation" Product (D.I. 170) in C.A. No. 1:15-cv-11803-IT involving the same parties and accused product, InfoBionic is permanently enjoined and restrained from making, using, offering to sell, or selling within the United States or importing into the United States any First Generation MoMe[®] Kardia System and from engaging in any other act of infringement described in 35 U.S.C. § 271 with regard to any First Generation MoMe[®] Kardia System and the patents at issue in that case. Nothing in this Complaint should be construed so as to conflict with this Consent Judgment.

² On information and belief, InfoBionic added "Kardia" to the original MoMe[®] name. Accordingly, certain exhibits cited herein refer to the MoMe[®] Kardia System as simply the "MoMe[™] system."

indicates that the MoMe[®] Kardia Device is to be used with the MoMe[®] Software System (Ex. F at 4).

17. At least four of the six members of the InfoBionic management team as it existed on the date of this filing were previously employed by CardioNet: Ms. Anna McNamara; Mr. Chris Strasinski; Mr. Philip Leone; and Mr. Bill Swavely. (Ex. H (11/25/2016 capture of <http://infobionic.com/management-team/>.) Additionally, Dr. Ravi Kuppuraj was a member of the InfoBionic management team at least as recently as January 2015 and also was previously employed by CardioNet. (Ex. I (1/8/2015 capture of <http://infobionic.com/persons/ravi-kuppuraj-phd/>.)

COUNT I - INFRINGEMENT OF '207 PATENT

18. CardioNet repeats and realleges the allegations contained in paragraphs 1 through 17 as if fully set forth here.

19. InfoBionic has infringed and is continuing to infringe the '207 patent by making, using, selling, offering for sale, and/or importing in the United States and in this Judicial District, products, and/or software that incorporate or make use of one or more of the inventions covered by the '207 patent, including but not limited to the MoMe[®] Kardia System, thereby infringing one or more claims of the '207 patent.

20. InfoBionic's Second Generation MoMe[®] Kardia System satisfies each and every element of one or more claims of the '207 patent, including, and without limitation, claims 1, 2, 3, 7, 10, 11, 12, and 22 of the '207 patent. (Ex. J.)

21. For example, claim 1 of the '207 patent recites:

A device, comprising:

a beat detector to identify a beat-to-beat timing of cardiac activity;

a ventricular beat detector to identify ventricular beats in the cardiac activity;

variability determination logic to determine a variability in the beat-to-beat timing of a collection of beats;

relevance determination logic to identify a relevance of the variability in the beat-to-beat timing to at least one of the atrial fibrillation and atrial flutter; and

an event generator to generate an event when the variability in the beat-to-beat timing is identified as relevant to the at least one of atrial fibrillation and atrial flutter in light of the variability in the beat-to-beat timing caused by ventricular beats identified by the ventricular beat detection.

22. To the extent the preamble is considered a limitation, the Second Generation MoMe[®] Kardia System satisfies the preamble of claim 1 of the '207 patent: "A device." (Ex. J at 1-2.) The Second Generation MoMe[®] Kardia System includes a "wearable MoMe[®] Kardia Device that acquires and stores ECG and motion (accelerometer) data and transmits that data via cellular technology to the MoMe[®] Software System ..., a web-based remote server software with proprietary algorithms for analysis" (Ex. F at 4.)

23. The Second Generation MoMe[®] Kardia System satisfies the following limitation of claim 1 of the '207 patent: "a beat detector to identify a beat-to-beat timing of cardiac activity." (Ex. J at 3-7). The MoMe[®] Kardia System "receives ECG and optional activity data" and "provides information on arrhythmias detected, arrhythmia durations, activity levels, heart rate variability and patient reported symptoms." (Ex. E at 4.) The MoMe[®] Kardia Device "[c]ontinuously streams full disclosure data to the Cloud for analysis." (Ex. C at 3.)

24. On information and belief, the Second Generation MoMe[®] Kardia System satisfies the following limitation of claim 1 of the '207 patent: "a ventricular beat detector to identify ventricular beats in the cardiac activity." (Ex. J at 8-9.)

25. The Second Generation MoMe[®] Kardia System satisfies the following limitation of claim 1 of the '207 patent: "variability determination logic to determine a variability in the beat-to-beat timing of a collection of beats." (Ex. J at 9-11.) The MoMe[®] Kardia System "receives ECG and optional activity data" and "provides information on ... heart rate variability" (Ex. E at 4.)

26. On information and belief, the Second Generation MoMe[®] Kardia System satisfies the following limitation of claim 1 of the '207 patent: "relevance determination logic to

identify a relevance of the variability in the beat-to-beat timing to at least one of the atrial fibrillation and atrial flutter.” (Ex. J at 11-13.)

27. On information and belief, the Second Generation MoMe[®] Kardia System satisfies the following limitation of claim 1 of the '207 patent: “an event generator to generate an event when the variability in the beat-to-beat timing is identified as relevant to the at least one of atrial fibrillation and atrial flutter in light of the variability in the beat-to-beat timing caused by ventricular beats identified by the ventricular beat detection.” (Ex. J at 13-16.)

28. InfoBionic became aware of the '207 patent at least as early as June 26, 2014, which is the date of the first citation of the '207 patent as prior art of record during the prosecution of U.S. Patent No. 9,307,914, which has been assigned to InfoBionic. Additionally, Ms. McNamara is currently a member of InfoBionic's management team. While she was previously employed with CardioNet she became aware of the '207 patent at least due to her involvement in a lawsuit between Plaintiffs and, *inter alia*, Mednet HealthCare Technologies, Inc.

29. Upon information and belief, InfoBionic likely became aware of the '207 patent also through the knowledge of its multiple other executives who were former executives or employees of CardioNet who had extensive responsibilities involving CardioNet's patented technologies.

30. InfoBionic has committed and continues to commit acts of infringement under 35 U.S.C. § 271. Upon information and belief, InfoBionic's acts of infringement are willful, intentional, and without lawful justification, entitling Plaintiffs to damages and treble damages pursuant to 35 U.S.C. § 284 and reasonable attorneys fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285. In committing these acts of infringement, InfoBionic acted despite an objectively high likelihood that its actions constituted infringement of at least one valid and enforceable claim of the '207 patent, and InfoBionic actually knew or should have known that its actions constituted an unjustifiably high risk of infringement of at least one valid and enforceable claim of the '207 patent.

31. The acts of infringement by InfoBionic set forth above have caused and will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against InfoBionic as follows:

- A. Declaring that the '207 patent was duly and legally issued, and is valid and enforceable;
- B. Declaring that InfoBionic has infringed the '207 patent;
- C. Declaring that InfoBionic has willfully infringed the '207 patent;
- D. Awarding to Plaintiffs damages caused by InfoBionic's infringement, including all lost profits resulting from InfoBionic's acts of infringement, and reasonable royalties, together with pre-judgment and post-judgment interest;
- E. Awarding to Plaintiffs treble damages for infringement of the '207 patent as a consequence of InfoBionic's willful infringement;
- F. Preliminarily and permanently enjoining InfoBionic, its officers, agents, servants, employees, attorneys, all parent and subsidiary corporations and affiliates, its assigns and successors in interest, and those persons in active concert or participation with InfoBionic who receive notice of the injunction, from continuing acts of infringement of the '207 patent;
- G. Adjudging this an exceptional case and awarding to Plaintiffs their reasonable attorneys fees pursuant to 35 U.S.C. § 285;
- H. Awarding to Plaintiffs their costs and disbursements incurred in this action; and
- I. Awarding to Plaintiffs such other and further relief as this Court may deem just and proper.

JURY TRIAL DEMANDED

Pursuant to Fed. R. Civ. P. 38(b), Plaintiffs demand a trial by jury on all of the claims so triable.

Respectfully submitted,

SIDLEY AUSTIN LLP

Dated: May 18, 2017

By: /s/ Bradford J. Badke

Bradford J. Badke (*pro hac vice*)

Ching-Lee Fukuda (*pro hac vice*)

Todd M. Simpson (*pro hac vice*)

SIDLEY AUSTIN LLP

787 Seventh Avenue

New York, NY 10019

jbadke@sidley.com

clfukuda@sidley.com

tsimpson@sidley.com

+1 212 839 5300

Jack W. Pirozzolo (BBO # 564879)

SIDLEY AUSTIN LLP

60 State Street, 36th Floor

Boston, MA 02109

jpirozzolo@sidley.com

+1 617 223 0300

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on May 18, 2017, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the attorney of record for each party.

By: /s/ Bradford J. Badke