

No. 19-1149

**IN THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT**

CARDIONET, LLC and BRAEMAR MANUFACTURING, LLC,

Plaintiffs-Appellants

v.

INFOBIONIC, INC.

Defendant-Appellee

Appeal from the U.S. District Court for the District of Massachusetts,
No. 1:17-cv-10445-IT, Judge Indira Talwani

CORRECTED OPENING BRIEF OF APPELLANTS

Ching-Lee Fukuda
Bradford J. Badke
Todd M. Simpson
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, NY 10019
(212) 839-5300

Nathan A. Greenblatt
SIDLEY AUSTIN LLP
1001 Page Mill Rd., Bldg. 1
Palo Alto, CA 94304
(650) 565-7000
*Counsel for Plaintiffs-Appellants
CardioNet, LLC and Braemar
Manufacturing, LLC*

January 10, 2019

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Cardionet, LLC, et al. v. InfoBionic, Inc.

Case No. **19-1149**

CERTIFICATE OF INTEREST

Counsel for the:

(petitioner) (appellant) (respondent) (appellee) (amicus) (name of party)

Ching-Lee Fukuda, Esq.

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Cardionet, LLC	None	BioTelemetry, Inc.
Braemar Manufacturing, LLC	None	BioTelemetry, Inc.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (**and who have not or will not enter an appearance in this case**) are:

Jack W. Pirozzolo

FORM 9. Certificate of Interest

Form 9
Rev. 10/17

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

The patent at issue in this appeal is asserted in CardioNet, Inc. v. The ScottCare Corporation, 2:12-cv-02516 (E.D. Pa.).

1/10/2019

Date

/s/ Ching-Lee Fukuda

Signature of counsel

Ching-Lee Fukuda

Printed name of counsel

Please Note: All questions must be answered

cc: _____

Reset Fields

TABLE OF CONTENTS

STATEMENT OF RELATED CASES	1
STATEMENT OF JURISDICTION.....	1
STATEMENT OF THE ISSUES.....	2
INTRODUCTION.....	2
STATEMENT OF THE CASE	4
A. The Parties	4
1. CardioNet.....	4
2. InfoBionic	6
B. Background on Cardiac Monitoring Technology.....	8
1. The Cardiac Cycle	8
2. Cardiac Arrhythmias	10
3. ECG Technology.....	11
4. Challenges in Developing ECG Analysis Devices	15
C. Overview of the '207 Patent.....	16
D. An Example Embodiment of the '207 Patent	18
E. The Claims at Issue	21
F. The Proceedings Below	26
SUMMARY OF THE ARGUMENT	28
ARGUMENT	30
I. Standard of Review	30
II. Patent Eligibility Under Section 101.....	32
A. <i>Alice</i> Step 1: Abstract Idea.....	33
B. <i>Alice</i> Step 2: Inventive Concept	36
C. Claim Construction at the Pleading Stage.....	38
III. The District Court Erred in Finding the Asserted Claims of the '207 Patent to Be Ineligible Under Section 101	39
A. The Asserted Claims Recite Statutory Subject Matter.....	39
B. The Asserted Claims Do Not Recite an Abstract Idea, Under <i>Alice</i> Step 1	39
1. The Plain Focus of the Claims Is a Specific Device Rather than an Abstract Idea.....	40

2.	The District Court Erred by Finding, Without <i>Any</i> Supporting Evidence, that the Asserted Claims Fail to Improve Cardiac Monitoring Technology.....	43
3.	Precedent from the Same Field as the '207 Patent Supports Finding that the Asserted Claims Are Patent-Eligible	49
4.	Precedent from Fields Outside of Cardiac Monitoring Also Supports a Finding of Eligibility	52
C.	The Asserted Claims Contain an Inventive Concept Under <i>Alice</i> Step 2	54
1.	The District Court Erred by Finding, Without <i>Any</i> Supporting Evidence, that the Claims Are Generic and Conventional	55
2.	The District Court Erred in Finding that the Claims Lack Meaningful Limits	58
3.	The Machine-or-Transformation Test Supports a Finding of Patentability.....	61
4.	The District Court Erred by Neglecting to Solicit InfoBionic's Claim Construction Positions	62
	CONCLUSION	63

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Aatrix Software, Inc. v. Green Shades Software, Inc.</i> , 882 F.3d 1121 (Fed. Cir. 2018)	<i>passim</i>
<i>Alice Corp. Pty. v. CLS Bank Int’l</i> , 134 S. Ct. 2347 (2014).....	<i>passim</i>
<i>Amdocs (Isr.) Ltd. v. Openet Telecom, Inc.</i> , 841 F.3d 1288 (Fed. Cir. 2016)	37, 56
<i>Aponte-Torres v. Univ. of P.R.</i> , 445 F.3d 50 (1st Cir. 2006)	32
<i>Arrhythmia Research Tech., Inc. v. Corazonix Corp.</i> , 958 F.2d 1053 (Fed. Cir. 1992)	50, 51, 61
<i>Ass’n for Molecular Pathology v. Myriad Genetics, Inc.</i> , 133 S. Ct. 2107 (2013).....	33
<i>Bancorp Servs., L.L.C. v. Sun Life Assurance Co. of Canada (U.S.)</i> , 687 F.3d 1266 (Fed. Cir. 2012)	63
<i>Bascom Glob. Internet Servs. v. AT&T Mobility LLC</i> , 827 F.3d 1341 (Fed. Cir. 2016)	36, 37, 56, 59
<i>Berkheimer v. HP Inc.</i> , 881 F.3d 1360 (Fed. Cir. 2018)	<i>passim</i>
<i>Bilski v. Kappos</i> , 561 U.S. 593 (2010).....	<i>passim</i>
<i>Content Extraction and Transmission, LLC v. Wells Fargo Bank, NA</i> , 776 F.3d 1343 (Fed. Cir. 2014)	38, 62

DDR Holdings, LLC v. Hotels.com, L.P.,
773 F.3d 1245 (Fed. Cir. 2014) 36, 52

Enfish, LLC v. Microsoft Corp.,
822 F.3d 1327 (Fed. Cir. 2016) *passim*

Electric Power Grp. v. Alstrom S.A.,
830 F.3d 1350, 1353 (Fed. Cir. 2016) 42

FairWarning IP, LLC v. Iatric Sys., Inc.,
839 F.3d 1089 (Fed. Cir. 2016) 42, 53, 54

Flores v. OneWest Bank, F.S.B.,
886 F.3d 160 (1st Cir. 2018) 31, 45, 56

Intellectual Ventures I LLC v. Erie Indemnity Co.,
850 F.3d 1315 (Fed. Cir. 2017) 48

Marrero-Gutierrez v. Molina,
491 F.3d 1 (1st Cir. 2007) 30

Mayo Collaborative Servs. v. Prometheus Labs., Inc.,
132 S.Ct. 1289 (2012)..... 33

McRO, Inc. v. Bandai Namco Games Am. Inc.,
837 F.3d 1299 (Fed. Cir. 2016) *passim*

Nisselson v. Lernout,
469 F.3d 143 (1st Cir. 2006) 31, 45

Research Corp. Techs. v. Microsoft Corp.,
627 F.3d 859 (Fed. Cir. 2010) 35

Visual Memory LLC v. NVIDIA Corp.,
867 F.3d 1253 (Fed. Cir. 2017) 60

Statutes

28 U.S.C. § 1295(a)(1)..... 1

28 U.S.C. §§ 1331 and 1338(a) 1

35 U.S.C. § 101 *passim*
35 U.S.C. § 112 60

Other Authorities

Goldberger et al., “PhysioBank, PhysioToolkit, and
PhysioNet: Components of a New Research Resource for
Complex Physiologic Signals,” *Circulation* June 13, 2000 13

Lyon A, et al., 2018 “Computational techniques for ECG
analysis and interpretation in light of their contribution
to medical advances,” *J. R. Soc. Interface* 15:20170821 12

MIT-BIH Foreword to 1980 Arrhythmia Database..... 13

Rule 12(b)(6) 31

Sornmo L, et al., 2005 *Bioelectrical signal processing in
cardiac and neurological applications*, Burlington:
Academic Press 13

Stiell, et al., “Canadian Cardiovascular Society Atrial
Fibrillation Guidelines 2010: Management of Recent-
Onset Atrial Fibrillation and Flutter in the Emergency
Department,” *Canadian J. of Cardiology* 27 (2011)..... 11

U.S. Food and Drug Administration, “Premarket Notification
510(k)” 7

U.S. Patent and Trademark Office, “Cooperative Patent
Classification” 14

STATEMENT OF RELATED CASES

Pursuant to Fed. Cir. R. 47.5, Appellants state that no appeal from this same civil action was previously before this or any other appellate court. Appellants further state that the patent at issue in this appeal is asserted in *CardioNet, Inc. v. The ScottCare Corporation*, 2:12-cv-02516 (E.D. Pa.), and therefore the outcome of this appeal may affect that case.

STATEMENT OF JURISDICTION

Plaintiffs CardioNet, LLC and Braemar Manufacturing, LLC (collectively, “CardioNet”) filed this action against InfoBionic, Inc. (“InfoBionic”), asserting a single count of patent infringement of U.S. Patent No. 7,941,207 (“the ’207 patent”). Appx240-243. The district court had jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

On October 16, 2018, the district court granted InfoBionic’s motion to dismiss, finding the ’207 patent to be ineligible for patent protection under 35 U.S.C. § 101. On October 17, 2018, the district court issued a final judgment dismissing the case. On October 30, 2018, CardioNet filed a notice of appeal from the foregoing orders. The notice of appeal was docketed on November 2, 2018. Dkt. 0 (Notice of Docketing). This Court has jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

STATEMENT OF THE ISSUES

1. Whether the district court erred by finding claims 1, 2, 3, 7, 10, 11, 12, and 22 of the '207 patent, which claim an improved cardiac monitoring device, to be ineligible for patenting under 35 U.S.C. § 101.

INTRODUCTION

CardioNet is a leading provider of ambulatory outpatient management solutions for monitoring clinical information regarding an individual's health. CardioNet's Mobile Cardiac Outpatient Telemetry™ (MCOT™) system is a market leader in the field of mobile cardiac telemetry ("MCT"). The CardioNet MCOT™ system was the first commercialized MCT system on the market and was the result of substantial investment by CardioNet. CardioNet spends millions of dollars per year developing new technologies and protecting its inventions.

As claimed in the '207 patent, CardioNet invented a cardiac monitoring device to help clinicians diagnose and treat patients with two heart conditions associated with stroke, congestive heart failure, and cardiomyopathy—atrial fibrillation and atrial flutter. CardioNet's invention improved the field of cardiac monitoring by providing numerous advantages over existing technology, including more accurate

arrhythmia detection in a system suitable for use by ambulatory patients. The '207 invention improved cardiac monitoring by analyzing information about premature ventricular beats, along with analyzing information about the variability in a heart beat, to more accurately detect atrial fibrillation and atrial flutter and report the presence of those cardiac arrhythmias to doctors. Despite that improvement, the district court deemed the patent ineligible on the pleadings based on unsupported factual findings that (i) the '207 patent does not improve cardiac monitoring technology, and (ii) the '207 patent claims only conventional, generic technology.

In essence, the district court accepted InfoBionic's conclusory argument that the '207 patent merely recites conventional techniques for analyzing electrocardiograms, and says "do it on a computer." Neither the district court nor InfoBionic, however, cited any evidence that supports that false assertion. While the district court cited the '207 patent's descriptions of existing technology, it ignored the portions of the patent directed to inventive improvements. InfoBionic, in turn, submitted no expert declaration, prior art, treatise, article, admission, or other evidence proving that the techniques claimed by the '207

patent fail to improve cardiac monitoring technology or are merely conventional. The district court's holding should not stand in light of this complete lack of supporting evidence.

The district court's unsupported factual findings led it to err in both *Alice* steps, by finding that the asserted claims are directed to an abstract idea (step 1) and claim routine and conventional components (step 2).

Legal standards for dismissing cases on the pleadings are well-settled and apply equally to Section 101 challenges. Here, reversal is necessary because the district court failed to comply with these standards by resolving factual questions adversely to the non-movant CardioNet, based on InfoBionic's unsubstantiated attorney assertions about what is conventional in the art, and improperly found the claims ineligible for patenting. Accordingly, this Court should reverse the district court's Section 101 ruling.

STATEMENT OF THE CASE

A. The Parties

1. CardioNet

CardioNet is the world's leading supplier of mobile cardiac telemetry devices. CardioNet's Mobile Cardiac Outpatient Telemetry™

(MCOT™) devices help clinicians prevent morbidity, mortality, and disability with rapid diagnosis and treatment of patients with cardiovascular disease. CardioNet tracks patients' hearts 24 hours a day via a small sensor and monitor the patients wear as they continue with their normal daily routine.¹ When the monitor detects an abnormal heart event called an arrhythmia, it automatically transmits electrocardiographic information to the CardioNet monitoring center for analysis and response. The CardioNet monitoring center provides physicians with succinct, integrated information they need for diagnosis and therapy management.

CardioNet pioneered the MCT field. The CardioNet MCOT™ was the first device on the market to provide real-time ECG monitoring and 24/7/365 analysis and response for patients at home, at work, or traveling. Appx238. CardioNet became an operating company in 1999, after years of research and development into the integration of cardiac monitoring, wireless communications, GPS, and proprietary algorithms for detection of heart abnormalities. In February 2002, CardioNet

¹ See https://www.CardioNet.com/medical_02.htm (depicting the MCOT™); see also Appx040 at Fig. 1.

received FDA approval for its core monitoring technology and opened the first CardioNet monitoring center in Philadelphia. CardioNet spends millions of dollars each year developing new technologies and protecting its inventions, including by obtaining United States patents. Appx238. CardioNet and its affiliates have been granted 34 utility patents and 4 design patents for their cardiac monitoring technology.²

2. InfoBionic

InfoBionic directly competes with CardioNet in the MCT field. A former CardioNet employee co-founded InfoBionic in 2011. Former CardioNet employees make up a substantial portion of InfoBionic's management. Appx240(¶17). InfoBionic has stated publicly that CardioNet "is one of the companies we are trying to disrupt" with a competing product. Appx240(¶15). InfoBionic's competing product is the MoMe[®] Kardia System. InfoBionic has developed two generations of the product. Its 510(k)³ submission for the first generation MoMe[®]

² Co-plaintiff Braemar develops and manufactures ambulatory cardiac monitors for leading healthcare companies. CardioNet assigned the '207 patent to Braemar, which then granted CardioNet an exclusive license. Appx237(¶8).

³ "A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is,

Kardia System relied upon CardioNet's MCOT™ device as one of two predicate devices. Appx239(¶16).

On May 8, 2015, CardioNet filed case No. 1:15-cv-11803-IT (D.Mass.) against InfoBionic, asserting claims of patent infringement and trade secret misappropriation. Discovery in that case revealed that InfoBionic's Director of Electrocardiography Analysis, a former CardioNet employee, wrongfully retained and copied CardioNet's proprietary source code and later used it to develop InfoBionic's MoMe® Kardia System. Case No. 1:15-cv-11803-IT, Dkt. 135 at 7-8, 34-38. Soon thereafter, the InfoBionic stipulated to a consent judgment permanently enjoining InfoBionic from selling its first generation product, while allowing CardioNet's claims against InfoBionic's second generation product to proceed. Appx239(n.1).

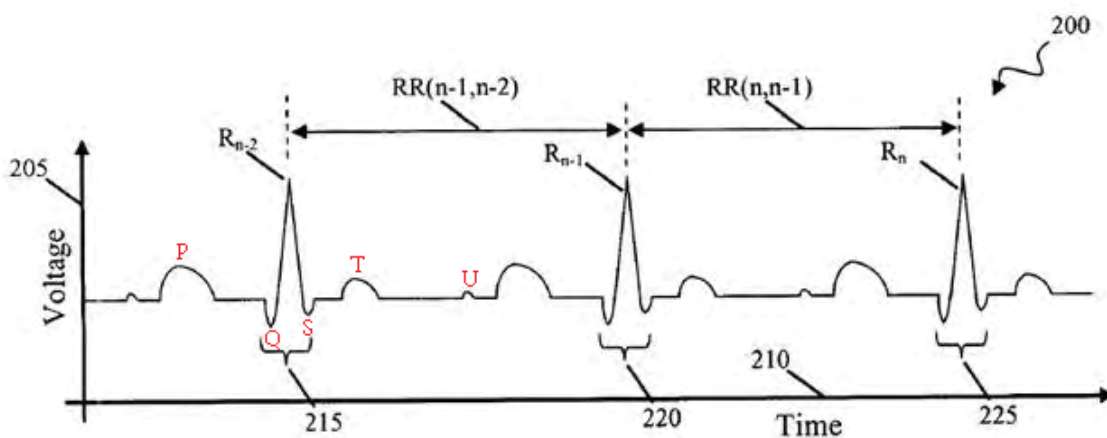
substantially equivalent, to a legally marketed device.” *See* <https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarket submissions/premarketnotification510k/default.htm>

B. Background on Cardiac Monitoring Technology

1. The Cardiac Cycle

The heart has four chambers: two upper atria, and two lower ventricles. The right atria receives oxygen-depleted blood from the body. The left atria receives oxygenated blood from the lungs. The atria contract to force the blood to the corresponding ventricle. Then, the right ventricle contracts to pump the oxygen-depleted blood to the lungs, while the left ventricle contracts to pump the oxygenated blood to the rest of the body via the aorta.

A normal heart beat results from an electrical impulse originating in specialized cells called the “sinus node” and ultimately progressing down specialized cells called Purkinje fibers from the atria to the ventricles causing the ventricles to contract. The electrical signals of the heart can be measured by placing electrodes on a person’s skin. The signals can then be plotted on a graph. In a healthy heart, the electrical signals have a regular pattern as shown below. Appx040.



**Fig. 1: A Cardiac Signal
(Annotated Version of '207 Patent, Fig. 2)**

Such a figure is called an electrocardiogram (“ECG”).

Appx048(4:45-46).⁴ The “P-wave,” marked with the letter P in the figure, corresponds to contraction of the atria. The “QRS complex” corresponds to the contraction of the ventricles. *Id.*(4:53-55). The “R-wave” is the peak of the QRS complex. *Id.*(4:55-58). The “T-wave” corresponds to recovery of the heart as it returns to its quiescent state, ready to beat again. An “R to R” or “RR” interval is the timing between R-waves. *Id.*(4:58-59). A person’s heart rate is typically measured by

⁴ More precisely, Figure 2 is a scalar trace of an electrocardiogram. Multiple electrodes are typically placed on a patient’s chest to measure the electrical activity of the heart from different angles. Each angle, or “lead,” produces a different “trace.” Only one trace is shown in Figure 2.

averaging several R to R intervals. At a typical resting heart rate of around 75 beats per minute, each heart beat takes about 0.8 seconds.

2. Cardiac Arrhythmias

Abnormal heart beats can result from disease or aberrant electrical impulses in the heart. Appx047(1:20-22). Such abnormalities often can be felt as thumping or pounding sensations in the chest.

Abnormal heart beats can also be asymptomatic (unfelt). Abnormal individual heart beats can be classified into a number of different categories such as premature ventricular contractions (“PVCs”), supra-ventricular beats, dropped, missed, or paused beats, etc. A PVC is a ventricular contraction that occurs earlier than normal, which may be felt as a skipped beat or palpitation.

When aberrant beats occur in patterns, various kinds of cardiac “arrhythmias” can be identified. Such arrhythmias include couplets (two) of PVCs, runs of PVCs (more than 3-4 is often referred to as ventricular tachycardia), supra-ventricular tachycardia, bradycardia, atrial tachycardia, atrial flutter, and atrial fibrillation. Atrial fibrillation and atrial flutter (collectively, “AF”) involve the loss of synchrony between the atria and the ventricles. Appx047(1:24-35).

Arrhythmias may be paroxysmal (occasional and unpredictable) or more consistent and frequent. ECGs of cardiac arrhythmias can be considerably more complex than ECGs of normal heart beats.⁵

Monitoring the heart's electrical activity for arrhythmia-related anomalies can reveal diseases that range from benign to deadly, including myocardial infarction (heart attack), stroke, congestive heart failure, cardiomyopathy, atrial scars, atrial infarction, atrial enlargement, Wolf-Parkinson-White syndrome, atrioventricular block, pericarditis, hyperkalemia, hypercalcemia, ventricular hypertrophy, infiltrative myocardial disease, and others. *E.g.*, Appx047(1:20-22). For that reason, physicians, academics, and industry have worked for over a century to improve cardiac monitoring technology.

3. ECG Technology

ECG technology has evolved significantly since its early days in the late 19th century. Early “commercial” ECG equipment was large, bulky, and cumbersome and often used ink to trace the ECG signals

⁵ See, e.g., Stiell, et al., “Canadian Cardiovascular Society Atrial Fibrillation Guidelines 2010: Management of Recent-Onset Atrial Fibrillation and Flutter in the Emergency Department,” *Canadian J. of Cardiology* 27 (2011) at 42 (showing an ECG during atrial fibrillation).

onto rolls of paper. Early ECG machine manufacturers produced ECG “rulers” to help calculate heart rates and widths of the various ECG components (p, QRS, and T waves). Advances incorporated by ECG recording equipment manufacturers included digitizing the ECG signals into a form that could be printed.

In addition to the ECG equipment advances, manufacturers began to introduce a variety of software beat analysis algorithms to analyze the ECG itself. The intention was to ease and reduce the physician’s review burden by producing reports which could show, for example, heart rate widths of the p, QRS, and T waves. As software technology further evolved, manufacturers included more diagnostic criteria within these reports, including automatic assessments of potential arrhythmias, myocardial infarctions or ischemia, bundle-branch blockages, and other ECG abnormalities. Computer-based ECG analysis opened up new possibilities unavailable to physicians examining ECG print-outs with the naked eye.⁶

⁶ See Lyon A, et al., 2018 “Computational techniques for ECG analysis and interpretation in light of their contribution to medical advances,” J. R. Soc. Interface 15:20170821 (“However, visual inspection of the ECG provides discrete clinically interpreted features which cannot

Creation of new, computer-based ECG-analysis algorithms has required extensive investment in research and development by both the academic community and industry.⁷ The numerous patents and articles cited by the '207 patent testify to that investment, including the following:

- U.S. Patent No. 4,958,641, “Heart data monitoring method and apparatus”;
- U.S. Patent No. 5,423,863, “Method of recognizing a ventricular cardiac pathological condition for automatic

objectively capture the diversity of ECG abnormalities and morphologies. This is why computational methods are required...”); *see also* Sornmo L, et al., 2005 Bioelectrical signal processing in cardiac and neurological applications, Burlington: Academic Press at 1 (stating that “the complexity of a signal is often quite considerable, and, therefore, biomedical signal processing has become an indispensable tool for extracting clinically significant information hidden in the signal.”).⁷ *See, e.g.*, Appx038-039(“References Cited”); Appx048(3:21-26)(citing MIT-BIH arrhythmia database); *see also* <http://www.physionet.org/physiobank/database/html/mitdbdir/foreword.htm> (MIT-BIH arrhythmia database 1980 foreword stating that “[f]or a number of years our group [at MIT] has been investigating methods for real-time ECG rhythm analysis. In the course of this work, we have developed an extensive annotated digital ECG database. The database has been enormously helpful to us in algorithm development and evaluation. The creation of this resource required a major effort, and was funded, in part, by both government and industry....Although the MIT-BIH Arrhythmia Database has been available for almost 17 years at this writing [in 1997], it remains in demand among researchers and instrument developers.”); Goldberger et al., “PhysioBank, PhysioToolkit, and PhysioNet: Components of a New Research Resource for Complex Physiologic Signals,” *Circulation* June 13, 2000.

defibrillation purposes, and monitor-defibrillator for implementing said method”;

- U.S. Patent No. 5,456,261, “Cardiac monitoring and diagnostic system”;
- U.S. Patent No. 5,840,038, “Method and apparatus for signal averaging and analyzing high resolution P wave signals from an electrocardiogram”;
- U.S. Patent No. 6,308,094, “System for prediction of cardiac arrhythmias”;
- U.S. Patent No. 6,178,347, “Apparatus for frequency analysis of atrial fibrillation”;
- Cerutti, S. et al., “Analysis of the Dynamics of RR Interval Series for the Detection of Atrial Fibrillation Episodes,” Department of Biomedical Engineering, Polytechnic University, Milano Italy, *Computers in Cardiology* 1997, vol. 24, pp. 77-80

The U.S.P.T.O. uses several classifications specific to the field of ECG analysis, such as A61B 5/04012, -014, -015, -017, and -018, that collectively contain thousands of patents.⁸ CardioNet itself invests millions of dollars each year into research and development to improve its ECG equipment and algorithms. Appx238(¶10).⁹

⁸ See <https://www.uspto.gov/web/patents/classification/cpc/html/cpc-A61B.html#A61B5/04>; Appx038(“Int. Cl. A61B 5/04”).

⁹ See, e.g., U.S. Patent No. 8,515,529 (“Detecting sleep disorders using heart activity”).

4. Challenges in Developing ECG Analysis Devices

Automatic detection of arrhythmias remains an extremely challenging problem. ECG recordings are highly diverse, and many different techniques exist for analyzing them.¹⁰ Published algorithms or methods when put into practice may not be accurate or precise enough for real-time, everyday clinical use. *See* Appx048(3:30-34). For instance, a major challenge has been the handling of noise in the signal, the accompanying ECG baseline wander, external interferences, and electrode movement, among others, all of which confounded any real-time analysis algorithm, especially using power-limited, memory-limited devices designed for ambulatory patients. *Id.* Having high sensitivity in detecting arrhythmias (i.e., avoiding false negatives), having high positive predictivity (i.e., avoiding false positives), and utilizing algorithms to increase efficiency and speed delivery of medical care, are all critical in a clinical setting where a physician may base a medical decision on the device-generated reports. *See id.*(3:21-28). Ultimately any automatic analysis technique must be thoroughly

¹⁰ Many such techniques are described in the references cited by the '207 patent. *See* Appx038-039("References Cited").

verified and validated to be incorporated into any medical device marketed anywhere in the world where formal regulatory agency approvals are required.

C. Overview of the '207 Patent

The '207 patent arose out of CardioNet's development of its MCOT™ device based on CardioNet's desire to include superior automatic arrhythmia detection capabilities in the MCOT™.

CardioNet's Lev Korzinov, a Ph.D engineer experienced in developing algorithms for automatic arrhythmia detection suitable for ambulatory medical devices, developed a new device for detecting atrial fibrillation and atrial flutter that exceeded expectations with its high performance. *See* Appx048(3:16-26). CardioNet promptly applied for a patent, and later filed a continuation application that was granted as the '207 patent. Appx038.

The '207 patent is titled "Cardiac Monitoring." It issued on May 10, 2011. Appx038. The '207 patent claims devices and methods for detecting and reporting atrial fibrillation and atrial flutter arrhythmias in cardiac patients. Atrial fibrillation refers to the atria fibrillating in an irregular chaotic fashion, causing loss of synchrony between the

atria and ventricle. Atrial flutter refers to atria quickly fluttering in a periodic fashion, which also causes loss of synchrony between the atria and ventricle. *See* Appx047(1:23-32). Atrial fibrillation can lead to irregular ventricular beating, blood stagnation, clotting, and has been associated with stroke, congestive heart failure, and cardiomyopathy (progressive heart disease). *Id.* Atrial flutter is also associated with stroke, congestive heart failure, and cardiomyopathy. *Id.* Real-time monitoring of these conditions “can speed the delivery of any urgent medical care.” Appx048(3:35-39).

The '207 patent introduced several new techniques for automatically diagnosing AF. The new techniques include accounting for the presence of premature ventricular beats which can interfere with AF detection. *See* Appx047(1:57-65). The new techniques also include using a non-linear transformation of an R to R interval in order to more accurately detect AF. *See* Appx047(1:49-56). These new techniques contrasted with techniques employed by existing cardiac monitors, which simply calculated the variability of R to R intervals, and then used a linear threshold to identify AF events. In other words, the '207 patent recognized that, even though premature ventricular

beats are “generally unrelated to AF,” Appx051(9:15-16), accounting for the presence of those particular irregular beats improves AF detection accuracy, as can using a more sophisticated (non-linear) measure of heart beat variability.

The '207 patented device offers a number of important advantages over pre-existing technology: it can distinguish AF from other cardiac arrhythmias, has improved positive predictability of AF, and can identify sustained AF episodes that have increased clinical significance. Appx048(3:6-16). It is well adapted to monitoring cardiac signals of ambulatory patients in real time, as it has minimal delay and requires minimal computational resources. The ability of the device to function without training, *i.e.*, without analysis of pre-existing data with known properties, also sets it apart from other methods. *Id.*(3:35-44).

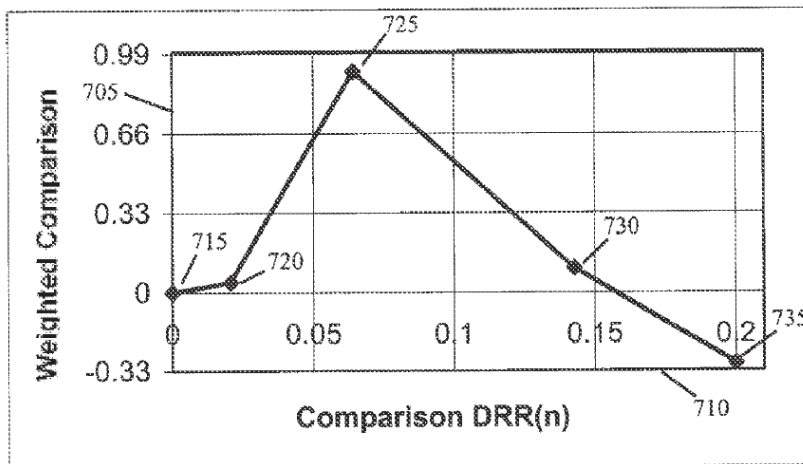
D. An Example Embodiment of the '207 Patent

Figure 10 of the patent depicts an embodiment of the '207 patent's system, that utilizes two of the new techniques CardioNet invented that are disclosed nowhere in the prior art. Namely, Figure 10 depicts a process for identifying the onset of AF in a patient's heart beat, that utilizes a non-linear transformation of an R to R interval, and uses

premature ventricular beats to improve AF detection. The process first compares two adjacent R to R intervals using Equation 1:

$$DRR(n) = \text{ABS} \left(\frac{RR(n, n-1)}{RR(n, n-1) + RR(n-1, n-2)} - \frac{1}{2} \right)$$

Appx051(9:64-10:1); Appx047(2:30-34). The system then weights these R to R interval comparisons using the novel non-linear transformation function in Figure 7 of the patent:



This non-linear transformation function is designed to weight the R to R interval comparison as being (i) largely irrelevant to AF when the factor is in the lower range of potential physiological values, (ii) overweight when the comparison is in a midrange of potential physiological values, and (iii) negatively indicative of AF when the comparison is at the upper range of potential physiological values. Appx050(8:1-18).

The process depicted in Figure 10 further includes the inventive technique of improving AF detection accuracy using information about premature ventricular beats associated with the calculated R to R interval comparisons. Appx051(10:1-3). If a premature ventricular beat is present, the system assigns a “penalty” value to the R to R interval comparison that “reflects a decreased likelihood that the variability is indicative of an AF event.” *Id.*(10:12-16). For instance, the patent describes assigning a value of negative 0.06 to R to R interval comparisons associated with ventricular beats, and assigning a value of 0 to the immediately succeeding R to R interval comparisons. *Id.*(10:17-25).

Next, the system creates an array of several (*e.g.*, 100) such R to R interval comparisons, that have been weighted using the non-linear transformation and “penalized” based on premature ventricular beat information. *Id.*(10:4-8). The system calculates the average of a certain number of recent beats (*e.g.*, 5), and compares the average to a threshold such as 0.22 to determine whether AF has occurred in the patient’s heart. *Id.*(10:26-35).

The district court made no factual finding that any of these process steps alone, or in the sequence described were contained in the prior art, or practiced by physicians.

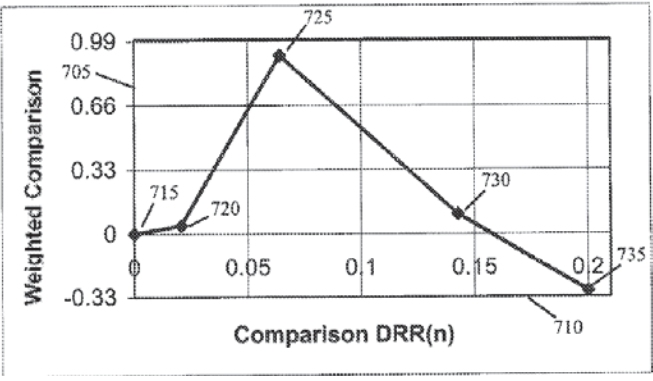
E. The Claims at Issue

CardioNet asserted claims 1, 2, 3, 7, 10, 11, 12, and 22 of the '207 patent. Appx240(¶20). The district court addressed only these claims in its dismissal order. Appx013-016. Claim 1 is an independent claim. Claims 2, 3, 7, 10, 11, and 12 depend from claim 1. Appx052-053. Claim 22 depends from independent claim 20. Appx053.

Each of the asserted claims is directed to a physical device or article for detecting and reporting the presence of AF in a cardiac patient. All of the asserted claims include the novel technique of accounting for premature ventricular beats to improve AF detection, and asserted claims 10 and 22 also include the novel technique of using a non-linear transformation function of a beat-to-beat interval.

The following table illustrates how the embodiment depicted in the '207 patent in Figure 10 corresponds to claims 1 and 10 (which depends from claim 1).

Claims 1 and 10	Figure 10
1. A device, comprising:	“Fig. 8 shows an example of instrumentation for cardiac monitoring...[including] sensor 305, signal amplifier/process 310, AF (AF) detector 320...” Appx050(8:63-66).
a beat detector to identify a beat-to-beat timing of cardiac activity;	“QRS detector 805 is a device such as a circuit” Appx051(9:4-6).
a ventricular beat detector to identify ventricular beats in the cardiac activity;	“Ventricular beat detector 810 is a device such as a circuit” Appx051(9:9-10).
variability determination logic to determine a variability in the beat-to-beat timing of a collection of beats;	<p>“the expression in Equation 1 [] reflect[s] the beat-to-beat variability in heart rate.” Appx051(9:64-10:1).</p> $DRR(n) = \text{ABS}\left(\frac{RR(n, n-1)}{RR(n, n-1) + RR(n-1, n-2)} - \frac{1}{2}\right).$ <p>“The system can create an array...that includes both the ventricular beat indicators and the R to R interval comparisons...for between 10 and 200 (e.g., 100) of the most recent beats.” Appx051(10:4-8).</p>
relevance determination logic to identify a relevance of the variability in the beat-to-beat timing to at least one of atrial fibrillation and atrial flutter; and	<p>“The system can also weight the comparisons...using, e.g., transformation function 700 (Fig. 7).” Appx051(10:9-11).</p> <p>“The system can also assign a preset value to the R to R interval comparisons associated with ventricular beats...The preset value</p>

	<p>can be a penalty value...” Appx051(10:12-16).</p> <p>“Using both the weighted and preset timing comparisons, the system can calculate the average...If the system determines that the average is greater than 0.22 for the last five beats...the system triggers the start of an AF event” Appx051(10:26-31).</p>
<p>[claim 10] The device of claim 1, wherein the relevance determination logic comprises logic to identify the relevance of the variability using a non-linear function of a beat-to-beat interval;</p>	<p>“The system can also weight the comparisons...using, e.g., [non-linear] transformation function 700 (Fig. 7).” Appx051(10:9-11).</p> 
<p>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 detector.</p>	<p>“Using...the preset timing comparisons [associated with ventricular beats]...the system triggers the start of an AF event” Appx051(10:26-31); <i>id.</i>(10:12-16).</p>

As can be seen in the above table, the language of claims 1 and 10 capture inventive concepts of the '207 patent. The “ventricular beat detector” and “event generator” elements capture the inventive technique of accounting for premature ventricular beats to improve AF detection accuracy. The “ventricular beat detector” limitation requires that the device detect premature “ventricular beats in the cardiac activity,”¹¹ while the “event generator” limitation requires “generat[ing] 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[.]” The element “[t]he device of claim 1, wherein the relevance determination logic comprises logic to identify the relevance of the variability using a non-linear function of a beat-to-beat interval” captures the inventive technique of using a non-linear transformation function of a beat-to-beat interval.

Like claims 1 and 10, each asserted claim includes language that captures one or more of the inventive concepts of the '207 patent.

¹¹ The patent defines “ventricular beats” as “premature ventricular beats.” '207 patent at 9:10-12; Appx013(n.4) (adopting construction).

Claims 2, 3, 7, 10, 11, and 12 depend from claim 1, and thereby incorporate the above elements related to premature ventricular beat analysis. Claim 2 provides more specificity about how the system must perform the ventricular beat analysis, requiring that the relevance determination logic “accommodate variability in the beat-to-beat timing caused by ventricular beats by weighting ventricular beats as being negatively indicative of the one of atrial fibrillation and atrial flutter.” Claim 22 provides similar specificity, reciting “identifying a beat of the collection as a ventricular beat,” and “weighting the beat as being negatively indicative of the one of atrial fibrillation and atrial flutter.”

Asserted claim 22, like claim 10, includes the novel technique of using a non-linear transformation function of a beat-to-beat interval.¹² Claim 22 recites (via dependence on claim 20) an article that determines “a relevance of the variability over a collection of beats to one of atrial fibrillation and atrial flutter using a non-linear function of a beat-to-beat interval.”

In addition to claiming novel techniques invented by CardioNet, the asserted claims have specific requirements tying them to a cardiac-

¹² Claim 22 includes that element via claim 20.

monitoring device for detecting AF. Asserted dependent claims 2, 3, and 11 recite additional requirements related to the AF-detection algorithm. Asserted dependent claims 7 and 12 recite additional requirements related to the physical device or its use (*i.e.*, transmitting data to a remote receiver, ECG electrodes). These additional limitations reinforce the fact that the asserted claims are directed to specialized cardiac monitoring devices that detect AF.

F. The Proceedings Below

CardioNet filed the instant case on March 16, 2017, asserting that InfoBionic infringes the '207 patent by making, using, selling, offering for sale, and/or importing in the United States a cardiac monitoring system called the Second Generation MoMe® Kardia System.

Appx032(¶19). CardioNet filed an amended complaint on May 18, 2017. Appx236. InfoBionic filed a motion to dismiss based on 35 U.S.C. § 101.

On October 16, 2018, the district court entered an order granting InfoBionic's motion to dismiss, finding the asserted claims of the '207 patent to be ineligible for patenting under 35 U.S.C. § 101. Appx001. The district court first found, in step 1 of the *Alice* inquiry, that the asserted claims are directed to an abstract idea. The district court

stated that “[r]eview of the ’207 patent shows that the claims add conventional computer components to the abstract idea that AF can be distinguished by focusing on the variability of the irregular heartbeat.” Appx008. The district court accepted that “[t]he idea of using a machine to monitor and analyze heart beat variability and interfering beats so as to alert the user of potential AF events *may well improve the field of cardiac telemetry*,” but inconsistently concluded that the patent failed step 1 of the *Alice* inquiry because “*Plaintiffs do not identify improvements to any particular computerized technology.*” Appx009 (emphasis added).

The district court then found, in step 2 of the *Alice* inquiry, that the claims did not recite an inventive concept. The district court stated that “[n]othing in these claims imposes a meaningful limit on the abstract idea of identifying AF by looking at the variability in time between heartbeats and taking into account ventricular beats.” Appx014-017. The district court accepted InfoBionic’s conclusory argument that the asserted claims recite “generic and conventional” elements that “provide no meaningful details on how to implement [the AF detection algorithm], and thus add nothing inventive.” Appx016.

The district court ignored factual disputes—including the parties’ dispute about whether negatively weighting premature ventricular beats to identify AF was conventional—that should have precluded judgment on a motion to dismiss under this Court’s precedent. The district court instead stated that “there are no disputes of fact as the court accepts the Plaintiffs’ non-conclusory factual assertions in the complaint and the patent as true.” Appx017.

Having deemed ineligible the only asserted patent, the district court dismissed the case. Appx018.

CardioNet now appeals the district court’s Section 101 order and dismissal.

SUMMARY OF THE ARGUMENT

The district court committed reversible error by finding, on the pleadings, that the asserted claims fail to improve cardiac monitoring technology and merely recite conventional techniques for diagnosing atrial fibrillation and atrial flutter. In so finding, the district court ignored contrary evidence in the patent, which describes new techniques, including accounting for premature ventricular beat information and use of a non-linear R to R transform to improve AF

detection. Appx047(1:49-65). The patent describes numerous advantages of using its novel techniques, including the ability to distinguish different types of arrhythmias, improved AF detection accuracy, and suitability for monitoring ambulatory patients.

Appx048(3:6-43). The district court's conclusory opinion did not address these facts in erroneously declaring that the '207 patent merely recites generic and conventional diagnostic techniques. Instead, the district court accepted InfoBionic's unsubstantiated attorney assertion that doctors had always used the patented technique. The district court failed, as required for a motion to dismiss, to accept as true the well-pleaded facts in the complaint and draw all reasonable inferences in favor of the non-moving party.

The district court compounded its primary error with several others. The court erred by defining the alleged abstract idea in an overly narrow manner limited to solving a specific problem (automatically detecting AF) in a specific field (cardiac monitoring technology) in a specific way (analyzing heart beat variability and premature ventricular beats). The district court also erred by relying on cases in which the evidence conclusively showed at the pleading

stage that the patent lacked novelty. Unlike those cases, in this case no concession or similar undisputed facts undergird the district court's decision. The cardiac monitoring technology at issue here does not permit a court to conclusively state, based on its own experience, what techniques were conventional in the art when the patent was filed in 2007. The district court further erred by deeming the claims overbroad despite the presence of claim elements that specify how the claimed device identifies the presence of AF.

All told, these errors resulted in the district court erroneously holding that the asserted claims of the '207 patent are ineligible. That decision should be reversed.

ARGUMENT

I. Standard of Review

In patent appeals, this Court applies the law of the regional circuit, here the First Circuit, to issues not unique to patent law.

Berkheimer v. HP Inc., 881 F.3d 1360, 1364 (Fed. Cir. 2018). The First Circuit reviews an order granting a motion to dismiss de novo, “taking as true the well-pleaded facts in the complaint and drawing all reasonable inferences in favor of the non-moving party.” *Marrero-*

Gutierrez v. Molina, 491 F.3d 1, 5 (1st Cir. 2007); *Flores v. OneWest Bank, F.S.B.*, 886 F.3d 160, 162 (1st Cir. 2018).

“Dismissing a case under Rule 12(b)(6) on the basis of an affirmative defense,” such as patent ineligibility, “requires that ‘(i) the facts establishing the defense are definitively ascertainable from the complaint and the other allowable sources of information, and (ii) those facts suffice to establish the affirmative defense with certitude.”

Nisselson v. Lernout, 469 F.3d 143, 150 (1st Cir. 2006) (internal quotes omitted); *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1125 (Fed. Cir. 2018) (“patent eligibility can be determined at the Rule 12(b)(6) stage . . . only when there are no factual allegations that, taken as true, prevent resolving the eligibility question as a matter of law.”).

A district court errs if it bases a dismissal, at the pleading stage, on a factual determination that conflicts with well-pled allegations in the complaint. *See Aatrix*, 882 F.3d at 1125; *Nisselson*, 469 F.3d at 150 (noting that “documents annexed” to the complaint are considered on a motion to dismiss). In particular, “[w]hether something is well-understood, routine, and conventional *to a skilled artisan* at the time

of the patent is a factual determination.” *Berkheimer*, 881 F.3d at 1369 (emphasis added); *Aatrix*, 882 F.3d at 1128 (“[w]hether the claim elements or the claimed combination are well-understood, routine, conventional is a question of fact.”). Therefore, a district court errs when it concludes, on the pleadings, that patented claims are routine and conventional, contrary to plausible contrary allegations in the complaint or patent. *See Aponte-Torres v. Univ. of P.R.*, 445 F.3d 50, 54 (1st Cir. 2006) (“a court may enter judgment on the pleadings only if the uncontested and properly considered facts conclusively establish the movant’s entitlement to a favorable judgment.”). In addition, a district court errs in drawing conclusions that depend on the perspective of a skilled artisan, without any evidentiary support regarding such a perspective. *Berkheimer*, 881 F.3d at 1369.

II. Patent Eligibility Under Section 101

Section 101 states, “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35 U.S.C. § 101. This provision contains an “implicit exception for [l]aws of nature,

natural phenomena, and abstract ideas are not patentable.” *Alice Corp. Pty. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2354 (2014) (quoting *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013)). Courts must “tread carefully” in applying the exception, however, because “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.” *Id.*; *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289, 1293 (2012). The Supreme Court has fashioned a two-step analysis for patent eligibility.

A. *Alice* Step 1: Abstract Idea

First, a court must determine whether the claims at issue are directed to laws of nature, natural phenomena, or abstract ideas. *Alice*, 133 S.Ct. at 2355. This appeal involves the abstract idea category. The courts have not provided a single, comprehensive definition of an “abstract idea,” but have offered guidance. The Supreme Court has defined an abstract idea as “[a]n idea of itself...a fundamental truth; an original cause; a motive[.]” *Alice*, 134 S.Ct. at 2355 (citations omitted). This Court has stated that claims are directed to an abstract idea if, “considered in light of the specification...‘their character as a whole is

directed to” an abstract idea. *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335 (Fed. Cir. 2016) (quoting *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed. Cir. 2015)).

Both the Supreme Court and this Court have repeatedly emphasized that an improvement to an existing technological process is unlikely to be deemed an abstract idea. The Supreme Court explained in *Alice* that claims that “improved an existing technological process” are unlikely to succumb to the abstract idea exception. *Id.* at 2358. The improvement may be for any technological process, including cardiac telemetry, and not solely limited to computerized technology. Similarly, this Court stated that courts must evaluate whether the claims “improve[] the relevant technology or are instead directed to a result or effect that itself is the abstract idea and merely invoke generic processes and machinery.” *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1314 (Fed. Cir. 2016); *see also Enfish*, 822 F.3d at 1335 (holding that “it is relevant to ask whether the claims are directed to an improvement to computer functionality versus being directed to an abstract idea, even at the first step of the Alice analysis.”). Courts must focus on that evaluation because “fundamental economic and

conventional business practices are often found to be abstract ideas,” while technological improvements are not. *Enfish*, 822 F.3d at 1335-36.

It is also important in step 1 of *Alice* to rely on precedent, by “compar[ing] claims at issue to those claims already found to be directed to an abstract idea in previous cases.” *Enfish*, 822 F.3d at 1334; *Alice*, 134 S.Ct. at 2356.

Both the Supreme Court and this Court have cautioned against reading the “abstract idea” exception too broadly, lest the exception swallow the rule, and stymie technological advancement. *See, e.g., Research Corp. Techs. v. Microsoft Corp.*, 627 F.3d 859, 868 (Fed. Cir. 2010) (“this court also will not presume to define ‘abstract’ beyond the recognition that this disqualifying characteristic should exhibit itself so manifestly as to override the broad statutory categories of eligible subject matter and the statutory context that directs primary attention on the patentability criteria of the rest of the Patent Act.”); *McRO*, 837 F.3d at 1313 (“courts must be careful to avoid oversimplifying the claims”) (citation omitted); *Alice*, 134 S. Ct. at 2354 (“we tread carefully in construing this exclusionary principle lest it swallow all of patent law.”).

B. *Alice* Step 2: Inventive Concept

If a claim as a whole is directed to an abstract idea, then the second step of the *Alice* analysis requires considering the claim elements separately and in an ordered combination to identify an inventive concept. *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1255 (Fed. Cir. 2014); *Alice*, 134 S.Ct. at 2350. Step 2 of *Alice* focuses on whether the claims simply recite conventional steps, or not. As the Supreme Court explained, “[s]imply appending conventional steps, specified at a high level of generality, [i]s not enough to supply an inventive concept.” *Alice*, 134 S.Ct. at 2357 (internal quotes omitted). On the other hand, a “new and useful” application of an idea makes a claim patent eligible. *Id.*, at 2354

Likewise, this Court has long held—and recently reiterated—that “the second step of the *Alice*/*Mayo* test is satisfied when the claim limitations involve more than performance of well-understood, routine, and conventional activities previously known to the industry.” *Aatrix*, 882 F.3d at 1128; *Bascom Glob. Internet Servs. v. AT&T Mobility LLC*, 827 F.3d 1341, 1350 (Fed. Cir. 2016) (“it is of course now standard for a § 101 inquiry to consider whether various claim element simply recite

“well-understood, routine, conventional activit[ies].”). A claim passes step 2 of *Alice* if it contains either a non-conventional element, or arranges known pieces in a non-conventional manner. *See Bascom*, 827 F.3d at 1350 (“As is the case here, an inventive concept can be found in the non-conventional and non-generic arrangement of known, conventional pieces.”); *Amdocs (Isr.) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1297 (Fed. Cir. 2016) (claims that “involve[] some arguably conventional components” are patentable when they “also involve[] limitations that when considered individually and as an ordered combination recite an inventive concept.”).

Whether the claims recite an inventive concept is a factual question. *Aatrix*, 882 F.3d at 1126; *Berkheimer*, 881 F.3d at 1370. On a motion to dismiss, the factual question is answered by accepting plausible allegations in the complaint and patent as true. For instance, in finding that the claims recited an inventive concept in *Bascom*, the Federal Circuit found that “the patent describes how its particular arrangement of elements is a technical improvement over prior art ways of filtering such content.” 827 F.3d 1341, 1349-50. In *Berkheimer*, the Federal Circuit likewise relied on the patent’s specification in

concluding that fact questions precluded dismissal on the pleadings. 881 F.3d at 1370. In *Aatrix*, the Federal Circuit relied on allegations in the complaint regarding benefits of the invention in reversing a dismissal. 882 F.3d at 1127.

The machine-or-transformation test can be instructive in determining whether an abstract idea has been transformed into an inventive concept. *Bilski v. Kappos*, 561 U.S. 593, 600 (2010). The machine-or-transformation test requires for patentability that the claims are “tied to a particular machine or apparatus” or “transform[] a particular article into a different state or thing.” *Id.*

C. Claim Construction at the Pleading Stage

In applying Section 101 at the pleading stage, the court construes the patent claims in a manner most favorable to the non-moving party. *See Content Extraction and Transmission, LLC v. Wells Fargo Bank, NA*, 776 F.3d 1343, 1349 (Fed. Cir. 2014). For the Section 101 analysis, the narrowest proposed construction is the most favorable to the non-moving party. *See id.* (“manner most favorable . . . necessarily assum[es] that all of [challenged] claims required a machine, even

though several claims do not expressly recite any hardware structures”).

III. The District Court Erred in Finding the Asserted Claims of the '207 Patent to Be Ineligible Under Section 101

A. The Asserted Claims Recite Statutory Subject Matter

There is no dispute that asserted claims 1, 2, 3, 7, 10, 11, 12, and 22 each recite a “device” or “article” for cardiac monitoring that qualifies as a “machine” or “manufacture” under the statute. 35 U.S.C. § 101 (“any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” is eligible for a patent); *see generally* Appx006 (starting analysis with *Alice* Step 1). Thus, to negate eligibility, there must be evidence showing, as a matter of law, that each asserted claim is directed to an abstract idea and contains no inventive concept.

B. The Asserted Claims Do Not Recite an Abstract Idea, Under *Alice* Step 1

The district court identified the alleged abstract idea of each asserted claim as the “idea that AF can be distinguished by focusing on the variability of the irregular heartbeat.” Appx008. The district court accepted that “[t]he idea of using a machine to monitor and analyze heart beat variability and interfering beats so as to alert the user of

potential AF events *may well improve the field of cardiac telemetry*,” but nevertheless concluded that the patent failed step 1 of the *Alice* inquiry because “Plaintiffs do not identify improvements to any particular computerized technology.” Appx009 (emphasis added). The district court erred for a number of reasons set out below. Most importantly, the district court erred by making the unsupported factual finding, contrary to evidence in the patent, that the asserted claims fail to improve cardiac monitoring technology.

1. The Plain Focus of the Claims Is a Specific Device Rather than an Abstract Idea

The asserted claims, on their face, do not merely recite “an idea of itself,” a “fundamental truth,” an “original cause,” or “a motive.” *Alice*, 134 S.Ct. at 2355. A device comprising a beat detector, ventricular beat detector, heart beat variability determination logic, and an event generator for reporting atrial fibrillation and atrial flutter—even ignoring the additional elements present in the dependent claims—does not qualify under any of those definitions of an “abstract idea.” Instead, as CardioNet argued below, the claims cover a specific device, having specific components, for reporting specific medical conditions in the human heart (atrial fibrillation and atrial flutter). Appx445.

Accordingly, there is a fundamental mismatch between the notion of an abstract idea and the claims at issue here.

In fact, the alleged abstract idea here is so narrow that it is limited not only to a specific field (cardiac monitoring technology), but also to solving a specific problem in the field (automatically detecting AF) in a specific way (analyzing heart beat variability and premature ventricular beats).¹³ It is paradoxical to deem so narrow an invention an abstract idea. If solving a specific problem in a specific field in a specific way qualifies as an abstract idea, the abstract idea exception will swallow the rule. *Alice*, 134 S. Ct. at 2354.

For that reason, the abstract ideas identified by courts generally stretch beyond a specific problem in a single field. For example, the abstract idea in *Alice* was “the concept of intermediated settlement,” a fundamental economic practice. *Alice*, 134 S.Ct. at 2356. The abstract idea in *Bilski* was “the concept of risk hedging.” *Id.* The abstract idea in *Flook* was a mathematical “formula itself.” *Id.* at 2358. The abstract idea in *Berkheimer* was “parsing, comparing, storing, and editing data.”

¹³ By “interfering beats,” the district court presumably meant premature ventricular beats.

881 F.3d at 1366. The abstract idea in *FairWarning IP, LLC v. Iatric Sys., Inc.*, 839 F.3d 1089, 1093 (Fed. Cir. 2016) was the “concept of analyzing records of human activity to detect suspicious behavior.” The abstract idea in *Electric Power Grp. v. Alstrom S.A.* was “collecting information, analyzing it, and displaying certain results of the collection and analysis.” 830 F.3d 1350, 1353 (Fed. Cir. 2016). In each case, the abstract idea was broad. In each case, the abstract idea could apply beyond a specific problem in a specific field.¹⁴ Those characteristics made the idea “abstract.”

The claims here do not share these characteristics. Instead, as in *Enfish*, the “the plain focus of the claims is on an improvement to [medical device] functionality itself, not on economic or other tasks for which a [medical device] is used in its ordinary capacity.” 822 F.3d at 1336. The district court erred by classifying a cardiac monitoring device that detects atrial fibrillation and atrial flutter by analyzing heart beat variability and premature ventricular beats as an abstract idea.

¹⁴ The principle that limiting an abstract idea to a specific field does not necessarily confer eligibility reinforces this point, because by definition the abstract idea itself is not limited to that specific field.

2. The District Court Erred by Finding, Without Any Supporting Evidence, that the Asserted Claims Fail to Improve Cardiac Monitoring Technology

The key error the district court committed in step 1 of its *Alice* analysis was finding that each asserted claim recites an abstract idea, despite the fact that the claims improve existing cardiac monitoring technology, as the court conceded may be the case.

The heart of the district court’s *Alice* step 1 analysis is a factual finding that the asserted claims are not improvements to cardiac monitoring technology. The district court expressed its factual finding in a few different ways. First, the district court found that “the claims add conventional computer components to the abstract idea that AF can be distinguished by focusing on the variability of the irregular heartbeat.” Appx008. Second, the district court concluded that “the claims that Plaintiffs assert do not recite any specific implementation or improvement in computerized medical technology.” Appx009. Third, the district court held that “[t]he idea of using a machine to monitor and analyze heart beat variability and interfering beats so as to alert the user of potential AF events may well improve the field of cardiac telemetry, but Plaintiffs do not identify improvements to any particular

computerized technology.” *Id.* In other words, the district court found that the asserted claims of the ’207 patent amount to nothing more than performing pre-existing methods for cardiac monitoring on a computer.

The district court’s finding is contrary to fact and fails to draw all reasonable inferences in CardioNet’s favor. As explained above in Statement of the Case Section C, and as the district court appears to acknowledge, the ’207 patent introduced several new techniques that improved the field of cardiac monitoring technology. The new techniques include using premature ventricular beats to compensate for ventricular arrhythmias, and using a non-linear transformation of an R to R interval, enabling more accurate detection of atrial fibrillation and atrial flutter. *See* Appx048(3:6-16); *see also* Appx439-442 (CardioNet’s briefing below describing new techniques introduced by the ’207 patent). The district court ignored these facts in finding that the asserted claims of the ’207 patent fail to improve cardiac monitoring technology.

The patented device also offers a number of important advantages which were not present in the field of cardiac monitoring: it can distinguish AF from other types of cardiac arrhythmia, has improved

positive predictability of AF, and can identify sustained AF episodes that have increased clinical significance. Appx048(3:6-16). It is also well-adapted to monitor the cardiac signals of ambulatory patients in real-time. *Id.* at 3:35-44. The improvements of the '207 patent can be a matter of life and death—they help “speed the delivery of urgent medical care.” *Id.* at 3:38-39. All of the asserted claims embody one or more of the novel techniques of the '207 patent. *See supra*, Statement of the Case Section E. The district court ignored these facts as well in finding that the asserted claims of the '207 patent fail to improve cardiac monitoring technology.

The foregoing facts before the district court must be accepted as true on a motion to dismiss and all reasonable inferences must be drawn in CardioNet's favor. *See Flores*, 886 F.3d at 162; *Nisselson*, 469 F.3d at 150. These facts dictate that the asserted claims are **not** directed to an abstract idea and **are** directed to an improvement in existing technology, namely devices for monitoring and reporting atrial fibrillation and atrial flutter. *See Alice*, 134 S.Ct. at 2358 (claims that “improve[] an existing technological process” are unlikely to be deemed an abstract idea); *Enfish*, 822 F.3d at 1335 (relying on patent

specification to conclude patent provided an improvement over existing technology, and stating that “it [is] relevant to ask whether the claims are directed to an improvement to computer functionality versus being directed to an abstract idea, even at the first step of the *Alice* analysis.”); *McRO*, 837 F.3d at 1314 (claims that “improve[] the relevant technology” are patent-eligible); *see also supra* Statement of the Case Section B (describing the field of cardiac monitoring).

The district court erred by failing to accept the foregoing facts as true. But even if the district court could weigh other facts against the specification’s teachings on a motion to dismiss (which it cannot), the district court still erred because no other facts exist in the record (much less evidence from the perspective of a skilled artisan). Importantly, the district court cited *no evidence* other than the patent itself to support its factual finding that the patent fails to improve cardiac monitoring technology. Appx008-009. Even the portions of the patent cited by the district court, however, prove the opposite of the district court’s conclusion. The portions of the patent relied on by the district court highlight the novel techniques of the ’207 patent including use of “non-linear statistics” and “identifying a ventricular beat and assigning

a preset value indicating that the variability is negatively indicative of atrial fibrillation.” *See* Appx047(1:46-2:12).¹⁵ The only evidence cited by the district court thus supports patentability.

Not only did the district court cite no non-patent evidence in its opinion, but *no evidence* exists in the record that proves that the asserted claims fail to improve cardiac monitoring technology. For instance, InfoBionic did not rely on any prior art that discloses negatively weighting premature ventricular beats or the use of non-linear statistics to identify AF.¹⁶ Nor did InfoBionic rely on an expert declaration demonstrating that either technique, individually or in combination with the other elements of the asserted claims, was known. InfoBionic submitted no evidence of any prior cardiac monitoring technology achieving a sensitivity to AF in excess of 90% and a positive predictivity in excess of 96%, much less a technology suitable for

¹⁵ The district court also cited InfoBionic’s briefing, but InfoBionic’s briefing merely cited case law that has nothing to do with the ’207 patent’s invention. *See* Appx399.

¹⁶ Infobionic cited only a single alleged prior art reference in its briefing—U.S. Patent Pub. 2002/0065473. *See* Appx392. But the ’207 patent issued over that reference, which among other things does not disclose a ventricular beat detector or an event generator that indicates AF in light of the identified ventricular beats. The district court did not rely on this reference in its decision.

ambulatory patients. *See* Appx048(3:21-26). InfoBionic cited no treatise or article to prove its argument that the alleged abstract idea of the '207 patent was well known or long prevalent in the medical field. *Compare Alice*, 134 S.Ct. at 2356 (citing articles and treatise to prove abstract idea was “long prevalent in our system of commerce”); *Bilski*, 130 S.Ct. at 3231 (same). InfoBionic submitted no evidence of how doctors traditionally viewed ECGs, to support its allegation that the asserted “claims automatically identify[] [AF] in the same way doctors have always done.” *See* Appx390-392. In short, the only evidence relied upon by Infobionic, and relied upon by the district court—the '207 patent—strongly supports the conclusion that the patent claims an improvement in cardiac monitoring technology.

This is not a case where it is readily apparent to lay judges, and indisputable, that the abstract idea is commonplace. *See Intellectual Ventures I LLC v. Erie Indemnity Co.*, 850 F.3d 1315, 1327-29 (Fed. Cir. 2017) (affirming finding that “the invention is drawn to the abstract idea of creating an index and using that index to search for and retrieve data,” finding that “a hardcopy-based classification system (such as library-indexing system) employs a similar concept”). Nor is this a case

where the district court properly relied on a concession that the inventive concept was routine. *See Berkheimer*, 881 F.3d at 1368 (citing cases that relied on concessions to support dismissal on the pleadings). Far from it—CardioNet vigorously argued that the patent improved the field of cardiac monitoring technology, and specifically pointed out to the district court the nature of the patent’s improvement and evidence in the patent showing the same. *See, e.g.*, Appx440, Appx443-446; Appx492-493. Simply put, the record lacks *any* evidence that supports the district court’s key factual finding, much less conclusive evidence when viewed in the light most favorable to CardioNet.

Accordingly, the district court’s factual finding, at the pleading stage, that the ’207 patent fails to improve the field of cardiac monitoring technology was error. That, even by itself, warrants reversal.

3. Precedent from the Same Field as the ’207 Patent Supports Finding that the Asserted Claims Are Patent-Eligible

It is also important at *Alice* step 1 to compare the claims at issue to claims evaluated in prior Section 101 cases. *See Enfish*, 822 F.3d at 1334 (“both this court and the Supreme Court have found it sufficient to

compare claims at issue to those claims already found to be directed to an abstract idea in previous cases”); *Alice*, 134 S.Ct. at 2356 . Here, that comparison supports a finding that the asserted claims are not directed to an abstract idea.

In *Arrhythmia Research Tech., Inc. v. Corazonix Corp.*, 958 F.2d 1053 (Fed. Cir. 1992), this Court considered a Section 101 challenge to a patent directed to analyzing ECG signals.¹⁷ The patented method and apparatus was designed to show whether the patient is at high risk of a cardiac arrhythmia called ventricular tachycardia. *Id.* at 1059. This Court found the claims patent-eligible, despite the fact that “[i]t was undisputed that the individual mathematical procedures that describe these steps are all known in the abstract,” and despite the fact that the output of the method was simply a determination about the

¹⁷ The fact that this Court decided *Arrhythmia* before *Alice* does not diminish its precedential value. In *Alice* itself, the Supreme Court relied on pre-*Alice* precedent to assess whether the claims recited an abstract idea, and the Court has done likewise in each of its Section 101 cases. See 134 S.Ct. at 2356. Moreover, the Supreme Court has deemed the pre-*Alice* machine-or-transformation test (which is related to the *Freeman-Walter-Abele* test used in *Arrhythmia*) to still be valuable. See *Bilski*, 130 S.Ct. at 3227 (“the machine-or-transformation test is a useful and important clue”). In addition, the findings in *Arrhythmia* that the invention improved ECG analysis technology and did pose a risk of preemption would lead to the same outcome under existing law.

characteristics of the ECG signal’s energy level. *Id.* at 1055, 1059. The Court reasoned that the claims “are directed to a specific apparatus of practical utility and specified application and meet the requirements of 35 U.S.C. § 101.” *Id.* at 1061.

The *Arrhythmia* decision provides an important guidepost for the Court because it finds claims in the same field as the ’207 patent to be patent-eligible. Like the claims in *Arrhythmia*, the claims here involve a device that analyzes an ECG signal to detect the presence of a specific cardiac arrhythmia. Like the claims in *Arrhythmia*, the claims here “are directed to a specific apparatus of practical utility and specified application.” In fact, the claims here pass the Section 101 test even more readily than the claims in *Arrhythmia*, because as discussed in the preceding section the claims here introduce new techniques to the field of cardiac monitoring, rather than simply combine conventional elements. The claims here should thus be found patent-eligible.

The district court did not cite any case finding claims in the same field as the ’207 patent to be ineligible under Section 101. The district court’s decision is thus anomalous. It stands out as the only decision

identified by either party or the court that finds a patent on cardiac monitoring technology ineligible.¹⁸

4. **Precedent from Fields Outside of Cardiac Monitoring Also Supports a Finding of Eligibility**

As explained above in Statement of the Case Section C, the '207 patent introduced several new techniques that improved the field of cardiac monitoring. For that reason, the asserted claims here are akin to claims found eligible in *McRO*, *Enfish*, and *DDR*, where the claims introduced new techniques to solve a technological problem. *See McRO, Inc.*, 837 F.3d at 1316 (finding eligible claims “directed to a patentable, technological improvement over the existing, manual 3-D animation techniques”); *Enfish*, 822 F.3d at 1336 (finding eligible claims directed to “a specific improvement to the way computers operate”); *DDR*, 773 F.3d at 1255 (finding claims eligible, stating that “these claims stand apart because they do not merely recite the performance of some business practice known from the pre-Internet world along with the requirement to perform it on the Internet.”).

¹⁸ The same district court found two CardioNet patents to be ineligible in a separate, ongoing case between the parties, Case No. 1:15-cv-11803-IT. No appealable judgment has been entered yet in that case.

For similar reasons, the asserted claims here cannot fairly be analogized to claims that merely recite computerized data manipulation. The district court cited *FairWarning*, 839 F.3d at 1093 and *Berkheimer*, 881 F.3d at 1366, for the proposition that “computer-implemented claims for collecting and analyzing data to find specific events may be patent ineligible abstract ideas.” Appx007. The district court did not expressly compare the asserted claims here to the claims at issue in *FairWarning* or *Berkheimer*, but the district court’s citation of those two decisions suggests that the district court considered the claims to be comparable. The asserted claims here, however, are easily distinguishable from the claims in *FairWarning* and *Berkheimer* that this Court found to recite abstract ideas.

In *FairWarning*, the “claims merely implement an old practice in a new environment.” 839 F.3d at 1094. The claims merely ask “the same questions (though perhaps phrased with different words) that humans in analogous situations detecting fraud have asked for decades, if not centuries.” *Id.* at 1095. Similarly, in *Berkheimer*, the patent owner identified no evidence that the claims “improve[] computer functionality in some way.” 881 F.3d at 1367. This Court stated that

“[n]o such evidence exists on this record. Indeed, Mr. Berkheimer admitted that parsers had existed for years prior to his patent.” *Id.* No corresponding facts or concessions are present here. Indeed, the district court itself acknowledged that the patented techniques “may well improve the field of cardiac telemetry.” Appx009. The district court’s citations to *FairWarning* and *Berkheimer* therefore cannot sustain its decision.

C. The Asserted Claims Contain an Inventive Concept Under *Alice* Step 2

The district court erroneously found, in step 2 of the *Alice* inquiry, that the claims did not recite an inventive concept. The district court stated that “[n]othing in these claims imposes a meaningful limit on the abstract idea of identifying AF by looking at the variability in time between heartbeats and taking into account ventricular beats.” Appx014-017. The district court accepted InfoBionic’s unsupported, conclusory argument that the asserted claims recite “generic and conventional” elements that “provide no meaningful details on how to implement [the AF detection algorithm], and thus add nothing inventive.” Appx016.

The district court erred by finding, contrary to evidence in the patent, that the asserted claims merely recite generic and conventional elements. The district court also erred by overlooking claim elements that impose meaningful limits on the allegedly abstract idea of the patent. Finally, the district court erred by failing to develop a complete record on claim construction issues.

1. The District Court Erred by Finding, Without Any Supporting Evidence, that the Claims Are Generic and Conventional

The district court found that claims 1, 2, 3, 7, 10, 11, 12, and 22 of the '207 patent “merely recite the conventional components that perform their usual functions put together in a standard way to perform a commonplace diagnostic method.” *Id.* at 12.

The district court, however, cited no evidence to support its conclusion, other than the patent itself. But nothing in the patent says that the claims merely computerize a routine diagnostic method. To the contrary, as explained in detail above, the patent discloses and claims a novel device for diagnosing AF. *See supra* Statement of the Case Sections C, E. The device provides a technological solution to a technological problem—accurate identification and reporting of AF.

Particularly when all reasonable inferences are drawn in CardioNet's favor, the '207 patent, which was granted by the Patent Office on the basis of its disclosures, cannot possibly prove itself ineligible based on the alleged absence of an inventive concept. *Flores*, 886 F.3d at 162.

The fact that several components in the claims, such as the premature ventricular beat detector, were previously known does not change that conclusion. *See* Appx051(9:22-25) (identifying a pre-existing ventricular beat detector from Mortara Instrument Inc.). The '207 patent explains how to put the claimed components to a new use to improve cardiac monitoring technology. *See supra*, Statement of the Case Section C; *Amdocs*, 841 F.3d at 1302 (claims that “involve[] some arguably conventional components” are patentable when they “also involve[] limitations that when considered individually and as an ordered combination recite an inventive concept.”). Even if each and every element in the claims were generic—which is not the case here—the claims would still pass muster. *See Bascom*, 827 F.3d at 1350 (“As is the case here, an inventive concept can be found in the non-conventional and non-generic arrangement of known, conventional pieces.”). Contrary to the district court's finding, nothing in the patent

suggests that the claims merely computerize pre-existing techniques for diagnosing AF. *See McRO*, 837 F.3d at 1314 (“Defendants point to the background section of the patents, but that information makes no suggestion that animators were previously employing the type of rules required by claim 1.”); Appx439-442, Appx452 (CardioNet’s briefing below that explained how the claims improve on previous cardiac monitors).

Aside from the patent, the district court cites no prior art, no physician, no expert, no treatise, no article, no concession—*nothing*—that supports the district court’s holding that the ’207 patent lacks an inventive concept. The district court appears to have been persuaded by InfoBionic’s unsupported attorney argument that claim 1 identifies AF in “the same way a human would[.]” *See* Appx398 (citing no evidence); *see also McRO*, 837 F.3d at 1314 (noting that “Defendants provided no evidence that the process previously used by animators is the same as the process required by the claims.”). The district court committed a fundamental error by accepting, without *any* supporting evidence, much less evidence from the perspective of a skilled artisan, the false

notion that the '207 patent merely computerizes a routine diagnostic method.

This case is a textbook example of why this Court reiterated in *Berkheimer* and *Aatrix* that district courts should not resolve factual questions on the pleadings. In particular, “[w]hether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a factual determination.” *Berkheimer*, 881 F.3d at 1369; *Aatrix*, 882 F.3d at 1128 (“[w]hether the claim elements or the claimed combination are well-understood, routine, conventional is a question of fact.”). The district court erroneously determined, on the pleadings, that the '207 patent claims conventional and generic ECG analysis techniques, without having received any evidence from InfoBionic on that front—much less the conclusive, undisputed evidence required to dismiss a case and find a patent ineligible on the pleadings.

2. The District Court Erred in Finding that the Claims Lack Meaningful Limits

The district court also erred in concluding that “[n]othing in these claims [1, 2, 3, 7, 10, 11, 12, and 22] imposes a meaningful limit on the abstract idea of identifying AF by looking at the variability in time between heartbeats and taking into account ventricular beats.”

Appx014. As explained above in Statement of the Case, Section E, each claim requires one or more inventive concepts introduced by the '207 patent. For instance, claims 2 and 22 recite “weighting ventricular beats as being negatively indicative of the one of atrial fibrillation and atrial flutter.” No pre-existing cardiac monitor used this technique, which improves AF detection accuracy. The claims pass *Alice* step 2 for that reason alone. *See Aatrix*, 882 F.3d at 1128 (“the second step of the *Alice*/*Mayo* test is satisfied when the claim limitations involve more than performance of well-understood, routine, and conventional activities previously known to the industry.”)(internal quotations omitted); *Bascom*, 827 F.3d at 1349-50.

In addition, the claims are not overly broad. The claims recite specific components (*e.g.*, beat detector, ventricular beat detector) that use an improved ECG-analysis technique to identify a specific pair of heart arrhythmias (AF). *See supra*, Statement of the Case, Sections C, E. The patent defines “ventricular beats” as “premature ventricular beats,” further narrowing the claim scope. Appx051(9:10-12); Appx013(n.4). The dependent claims recite even more narrow requirements with great specificity, such as “weighting ventricular

beats as being negatively indicative” of AF, and comparing times between R-waves in three successive QRS complexes. The district court’s opinion fails to explain why these limitations fail to impose “meaningful limits” on the alleged abstract idea.

Furthermore, any concern about claim breadth in this case should be addressed through Section 112 on a full record, not in a shorthand fashion on a motion to dismiss under Section 101. *See Visual Memory LLC v. NVIDIA Corp.*, 867 F.3d 1253, 1261 (Fed. Cir. 2017) (“whether a patent specification teaches an ordinarily skilled artisan how to implement the claimed invention presents an enablement issue under 35 U.S.C. § 112, not an eligibility issue under § 101.”). The district court cited no evidence, and there is none, that an ordinary skilled artisan would be unable to understand and implement the claimed invention, based on the patent’s teachings. The district court’s concern about claim breadth, and its abbreviated discussion on an almost non-existent record, cannot justify its ineligibility finding for the ’207 patent.

3. The Machine-or-Transformation Test Supports a Finding of Patentability

The district court mentioned the machine-or-transformation test in its opinion, but did not apply the test to the asserted claims. Appx011. In doing so, the district court overlooked an important clue to patentability. *Bilski*, 561 U.S. at 600. The asserted claims recite specific components (beat detector, premature ventricular beat detector, etc.) and functions that tie the claims to a particular machine. The claims cover a specific medical device, with specific components, for reporting specific medical conditions in the human heart (atrial fibrillation and atrial flutter). Like the claims in *Arrhythmia Research*, which similarly covered a specific device for analyzing ECG data to diagnose a cardiac arrhythmia, the claims here “are directed to a specific apparatus of practical utility...and meet the requirements of 35 U.S.C. § 101.” 958 F.2d at 1061. Applying the machine-or-transformation test reinforces the conclusion that the claims are not directed to an abstract idea, and even if they were, they apply the abstract idea in a sufficiently concrete way to pass the Section 101 eligibility filter.

4. The District Court Erred by Neglecting to Solicit InfoBionic’s Claim Construction Positions

In applying Section 101 at the pleading stage, the court construes the patent claims in a manner most favorable to the non-moving party. *See Content Extraction*, 776 F.3d at 1349. For the Section 101 analysis, the narrowest proposed construction is the most favorable to the non-moving party. Here, the district court solicited only CardioNet’s claim construction positions in ruling on InfoBionic’s Section 101 motion. Appx530(23:4-15).¹⁹ The district court did not solicit InfoBionic’s claim construction positions, which may have been more narrow than CardioNet’s proposed constructions considered by the court. InfoBionic did not present its claim construction positions in briefing or at oral argument. The district court therefore did not have a complete picture of the parties’ claim construction positions in ruling on the Section 101 motion. Lacking InfoBionic’s claim construction positions, the district court was unable to ensure that it construed the patent claims in a manner most favorable to the non-moving party, *i.e.*, by adopting the

¹⁹ The district court correctly adopted Plaintiffs’ construction of the term “ventricular beats” to mean “premature ventricular beats that are irregular beats that interrupt the normal heart rhythm.” Appx013(n.4).

narrowest proposed construction. While claim construction is not an inviolable prerequisite to deciding a Section 101 motion on the pleadings, *see Bancorp Servs., L.L.C. v. Sun Life Assurance Co. of Canada (U.S.)*, 687 F.3d 1266, 1273 (Fed. Cir. 2012), here the district court lacked a complete record to assess whether claim construction would affect the patent-eligibility of the claims at issue. This error compounded the district court's primary error of making factual findings that contradict the teachings of the patent, without any supporting evidence.

CONCLUSION

For the above reasons, the district court's judgment should be reversed.

Dated: January 2, 2019

Respectfully submitted,

/s/ Ching-Lee Fukuda
Ching-Lee Fukuda
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, NY 10019
(212) 839-5300
Counsel for Appellants

ADDENDUM –

The District Court's Section 101 Order and Dismissal Order

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CARDIONET, LLC, and BRAEMAR
MANUFACTURING, LLC,

Plaintiffs,

v.

INFOBIONIC, INC.,

Defendant.

*
*
*
*
*
*
*
*
*
*

Civil Action No. 17-cv-10445-IT

MEMORANDUM AND ORDER

October 16, 2018

TALWANI, D.J.

Plaintiffs CardioNet, LLC (“CardioNet”) and Braemar Manufacturing, LLC (“Braemar”) allege that products manufactured and distributed by Defendant InfoBionic, Inc. (“InfoBionic”) infringe on Plaintiffs’ patent, U.S. Patent Number 7,941,207 (“the ’207 patent”). Am. Compl. (“Complaint”) [#25]. InfoBionic moves to dismiss Plaintiffs’ Complaint [#25], arguing that the ’270 patent is invalid under 35 U.S.C. § 101 as construed by Alice Corp. Pty. Ltd. v. CLS Bank Intern., 134 S. Ct. 2347, 2354 (2014), and its progeny, because the asserted claims are directed to an abstract idea and are patent-ineligible. Mot. to Dismiss 1 [#36]. Finding that the claims at issue are directed at patent-ineligible concepts, and that the elements of each claim do not transform the claim into a patent-eligible application, the court ALLOWS Defendant’s Motion to Dismiss [#36].

I. Background

The '207 patent was issued to CardioNet in 2011. CardioNet assigned the '207 patent to Braemar, and Braemar granted CardioNet an exclusive license to make, use, offer to sell, sell, import, license, and exploit the '207 patent. Compl. ¶¶ 7-8 [#25].

The '207 patent is entitled “Cardiac Monitoring.” Id. ¶ 7 [#25]. It relates to “[s]ystems and techniques for monitoring cardiac activity.” Compl. Ex. A ('207 Patent) 2 [#25-1]. The patented methods monitor the electrical activity of the heart to identify two types of heart arrhythmias, atrial fibrillation and atrial flutter (collectively, “AF”), both of which are associated with stroke, congestive heart failure, and cardiomyopathy. Id. at 11 col. 1:31-32. The '207 patent claims to distinguish AF from other types of cardiac arrhythmia by monitoring the variability between heartbeats, id. at col. 1:49-50, in a manner that can “provid[e] improved positive predictability of AF,” and “identify sustained AF episodes, where AF continues for more [than] approximately 20 beats and has an increased clinical significance.” Id. at 12 col. 3:14-15, 17-20. The patent claims that the systems and techniques “are well-adapted to monitoring cardiac signals of ambulatory patients who are away from controlled environments such as hospital beds or treatment facilities.” Id. at col. 3:27-30. The patent further claims that “the described systems and techniques are also well-adapted to real-time monitoring of arrhythmia patients, where minimal delays in distinguishing between different types of cardiac arrhythmia can speed the delivery of any urgent medical care,” and “require minimal computational resources.” Id. at col. 3:35-40.

The Complaint [#25] asserts that InfoBionic’s first and second generation MoMe Kardia Systems infringe one or more claims of the '207 patent, including claims 1, 2, 3, 7, 10, 11, 12, and 22. Compl. ¶¶ 19-31 [#25].

II. Discussion

A. *Standard*

To survive a motion to dismiss, a plaintiff “must state a claim that is plausible on its face.” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). In resolving the motion, the court must “begin by identifying and disregarding statements . . . that merely offer ‘legal conclusion[s] couched as . . . fact[.]’” Occasion-Hernández v. Fortuño-Burset, 640 F.3d 1, 12 (1st Cir. 2011) (alteration in original) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 668 (2009)). Nonconclusory factual statements contained in the pleadings must then be viewed as true, id., and the court must view these facts in the light most favorable to the nonmovant and draw all reasonable inferences therefrom to the nonmovant’s behalf. Id. at 17.

“While most Rule 12(b)(6) motions are premised on a plaintiff’s putative failure to state an actionable claim, such a motion may sometimes be premised on the inevitable success of an affirmative defense.” Nisselson v. Lernout, 469 F.3d 143, 150 (1st Cir. 2006). “Dismissing a case under Rule 12(b)(6) on the basis of an affirmative defense requires that ‘(i) the facts establishing the defense are definitively ascertainable from the complaint and the other allowable sources of information, and (ii) those facts suffice to establish the affirmative defense with certitude.’” Id. (quoting Rodi v. S. New Eng. Sch. of Law, 389 F.3d 5, 12 (1st Cir. 2004)); see also Aatrix Software, Inc. v. Green Shades Software, Inc., 882 F.3d 1121, 1125 (Fed. Cir. 2018) (“patent eligibility can be determined at the Rule 12(b)(6) stage . . . only when there are no [plausible] factual allegations that . . . preclude dismiss[al]”).

Because the court accepts the factual allegations in the complaint and other allowable sources of information as true for purposes of a motion to dismiss, “[i]f there are claim construction disputes, . . . the court [may] proceed by adopting the non-moving party’s construction,” and construing the patent claims in a manner most favorable to the non-moving

party. Aatrix Software, 882 F.3d at 1125; see also Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n, 776 F.3d 1343, 1349 (Fed. Cir. 2014) (court applies the non-moving party's construction of the terms of the patent for purposes of the motion).

Section 101 states, “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35 U.S.C. § 101. The subject matter of a patent must be patentable under § 101; otherwise, the patent is invalid. See Content Extraction, 776 F.3d at 1346. The Supreme Court has held that this section contains an “implicit exception: [l]aws of nature, natural phenomena, and abstract ideas are not patentable.” Alice, 134 S. Ct. at 2354 (quoting Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116 (2013)). Although “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,” these three patent-ineligible exceptions prevent “monopolization” of the “basic tools of scientific and technological work,” Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012), and the “inhibit[ion of] further discovery by improperly tying up the future use of these building blocks of human ingenuity,” Alice, 134 S. Ct. at 2354 (internal quotation marks omitted) (quoting Mayo, 132 S. Ct. at 1301).

“[I]n applying the § 101 exception, [the court] must distinguish between patents that claim the ‘building[g] block[s]’ of human ingenuity and those that integrate the building blocks into something more, thereby ‘transform[ing] them into a patent-eligible invention.’” Id. at 2354, (quoting Mayo, 132 S. Ct. at 1294, 1303). To do so, the court must perform a two-step analysis.

First, the court must determine whether the claims at issue are directed to laws of nature,

natural phenomena, or abstract ideas. Id. at 2355.¹ Claims are directed to an abstract idea if, “considered in light of the specification, . . . ‘their character as a whole is directed to’” an abstract idea. Enfish, LLC v. Microsoft Corp., 822 F.3d 1327, 1335 (Fed. Cir. 2016) (quoting Internet Patents Corp. v. Active Network, Inc., 790 F.3d 1343, 1346 (Fed. Cir. 2015)). “The ‘abstract ideas’ category embodies ‘the longstanding rule that [a]n idea of itself is not patentable.’” Alice, 134 S. Ct. at 2355 (internal quotation marks omitted) (alteration in original) (quoting Gottschalk v. Benson, 409 U.S. 63, 67 (1972)). In Benson, for example, the court rejected claims involving an algorithm for “converting [binary-coded decimal] numerals to pure binary form,” holding that the claimed patent was “in practical effect . . . a patent on the algorithm itself.” 409 U.S. at 71-72. Similarly, in Parker v. Flook, the court held a mathematical formula for computing ‘alarm limits’ in a catalytic conversion process was an abstract idea. 437 U.S. 584, 594-95 (1978).

If the claims at issue are directed to laws of nature, natural phenomena, or abstract ideas, the court then considers the elements of each claim both “individually and ‘as an ordered combination’” to determine whether the additional elements “‘transform the nature of the claim’ into a patent-eligible application.” Alice, 134 S. Ct. at 2350 (quoting Mayo, 132 S. Ct. at 1298, 1297). The Supreme Court has “described step two of this analysis as a search for an ‘inventive concept’ – i.e., an element or combination of elements that is ‘sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.’” Id. (alteration in original) (quoting Mayo, 132 S. Ct. at 1294). “Purely ‘conventional or obvious’ ‘[pre]-solution activity’ is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.” Mayo, 566 U.S. at 79 (quoting Flook, 437 U.S. at

¹ Because Defendant argues that the ’207 patent is directed to an abstract idea, the court focuses its discussion on this exclusion.

590); see also Bilski v. Kappos 561 U.S. 593, 610-11 (2010) (“[T]he prohibition against patenting abstract ideas ‘cannot be circumvented by’ . . . adding ‘insignificant post-solution activity.’” (quoting Diamond v. Diehr, 450 U.S. 175, 191-92 (1981))). To survive step two, the additional activity must “transform the claim into ‘significantly more than a patent upon the’ ineligible concept itself.” Rapid Litig. Mgmt., Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1047 (Fed. Cir. 2016) (quoting Mayo, 132 S. Ct. at 1294).

B. Step One: Are Claims Directed to a Patent Ineligible Concept?

InfoBionic contends that “[t]he ’207 patent claims are directed to the abstract idea of identifying [AF] by looking at the variability in time between heartbeats and taking into account ventricular beats.” Def.’s Mem. 11 [#37]. InfoBionic argues that because AF “are characterized by the ‘loss of synchrony between the atria and the ventricles’ leading to ‘irregular’ heart beating, looking at the variability in time between heartbeats, taking into account any ventricular beats, has long been the way to diagnose these conditions.” Id. (quoting ’207 Patent 11 col. 1:23-29 [#25-1]). InfoBionic argues further that “[t]he ’207 patent . . . claims automatically identifying [AF] in the same way doctors have always done,” and “broadly claims the automated process itself without specifying a particular implementation.” Id. InfoBionic asserts that the ’207 patent “does not claim any new or improved approach to detecting [AF].” Id. Plaintiffs dispute that the ’207 patent is directed to an abstract idea, and argue instead that the ’207 patent “represents an improvement to the function of cardiac monitoring devices,” Pls.’ Opp’n 10 [#40], and that the asserted claims “are directed to a concrete improvement in the signal processing and analysis capabilities of cardiac monitoring devices.” Id. at 14.

To determine whether computerized technology is directed to an abstract idea, the court “asks whether the focus of the claims is on the specific asserted improvement in computer

capabilities . . . or, instead, on a process that qualifies as an ‘abstract idea’ for which computers are merely invoked as a tool.” Enfish, 822 F.3d at 1335-36. If “the plain focus of the claims is on an improvement to computer functionality itself,” it is not directed to an abstract idea. Id. at 1336. However, if the “claims ‘simply add[] conventional computer components to well-known business practices,’ . . . or ‘a purely conventional computer implementation of a mathematical formula,’ or ‘generalized steps to be performed on a computer using conventional computer activity,’” it is directed to an abstract idea. In re TLI Commc’ns LLC Patent Litig., 823 F.3d 607, 612 (Fed. Cir. 2016) (quoting Enfish, 822 F.3d at 1338).

The Federal Circuit has found that computer-implemented claims for collecting and analyzing data to find specific events may be patent-ineligible abstract ideas. In FairWarning IP, LLC v. Iatric Sys., Inc., for example, the Federal Circuit considered a patent that “relate[d] to a system and method of detecting fraud and/or misuse in a computer environment based on analyzing data.” 839 F.3d 1089, 1093 (Fed. Cir. 2016). The patented method “collect[ed] information regarding accesses of a patient’s personal health information, analyze[d] the information according to one of several rules . . . to determine if the activity indicates improper access, and provide[d] notification if it determine[d] that improper access ha[d] occurred.” Id. In holding that the patent was an ineligible abstract idea, the court emphasized that “the ‘realm of abstract ideas’ includes ‘collecting information, including when limited to particular content,’” and that “analyzing information by steps people go through in their minds, or by mathematical algorithms, without more, [are] essentially mental processes within the abstract-idea category.” Id. (quoting Elec. Power Grp., LLC v. Alstom S.A., 830 F.3d 1350, 1353 (Fed. Cir. 2016)). The court also explained that “merely presenting the results of abstract processes of collecting and analyzing information, without more (such as identifying a particular tool for presentation), is

abstract as an ancillary part of such collection and analysis.” Id. (quoting Elec. Power, 830 F.3d at 1353). The court concluded that because the claims at issue were “directed to collecting and analyzing information to detect misuse and notifying a user when misuse is detected,” the claims were patent ineligible. Id. at 1094.

Similarly, in Berkheimer v. HP Inc., the Federal Circuit found at step 1 that the claims of a patent for a digital asset management system were “directed to the abstract ideas of parsing, comparing, storing and editing data,” and were similar to other claims the court had found directed to an abstract idea in prior cases. 881 F.3d 1360, 1366 (Fed. Cir. 2018) (citing In re TLI Commc’ns LLC Patent Litig., 823 F.3d at 613 (claims recited method for recording images, transmitting the images and classification information, and storing the images based on the classification information directed to the abstract idea of “classifying and storing digital images in an organized manner”), and Content Extraction, 776 F.3d at 1347 (claims recited method of extracting data from hard copy documents, recognizing specific information from the data and storing the information directed to the abstract idea of collection data, recognizing certain data within the collected data set, and storing that recognized data in a memory)).

Review of the ’207 patent shows that the claims add conventional computer components to the abstract idea that AF can be distinguished by focusing on the variability of the irregular heartbeat. The specifications describe “systems and techniques” with various methods for monitoring that variability. ’207 Patent 11 col. 1:46–12, col. 3:5 [#25-1]. The patent claims at issue in this case thus appear to be similarly directed to collecting and analyzing information to detect particular anomalies, and notifying the user when the anomaly is detected.

Plaintiffs respond that the ’207 patent is not directed to an abstract idea because it “represents an improvement to the function of cardiac monitoring devices.” Pls.’ Opp’n 14 [#40].

They argue that “[t]hrough the use of specifically programmed rules, termed ‘determination logic,’ coupled with beat detecting technology and an event generator, the invention improves a function specific to cardiac monitoring devices, namely the processing and analysis of cardiac signals to achieve more accurate and clinically significant AF detection.” *Id.* (internal citation omitted).

Plaintiffs’ response is more appropriately given at step 2. In any event, as InfoBionic argues, and as discussed more at step 2 *infra*, the claims that Plaintiffs assert do not recite any specific implementation or improvement in computerized medical technology. *See* ’207 Patent [#25-1]; Def.’s Mem. 15 [#37]. The idea of using a machine to monitor and analyze heart beat variability and interfering beats so as to alert the user of potential AF events may well improve the field of cardiac telemetry, but Plaintiffs do not identify improvements to any particular computerized technology. Thus, the ’207 patent is directed to an abstract idea.

C. Step Two: Does the Inventiveness of the Claim make it Patent Eligible?

Plaintiffs contend that the claims of the ’207 patent recite an inventive concept because they “utilize determination logic together with beat detectors and event generators to solve the technical problem of cardiac monitors incorrectly identifying AF events.” Pls.’ Opp’n 20 [#40]. Plaintiffs compare the ’207 patent claims to the claims in Bascom Global Internets Servs., Inc. v. AT&T Mobility LLC, 827 F.3d 1341 (Fed. Cir. 2016), and Amdocs (Israel) Ltd. v. Openet Telecom, Inc., 841 F.3d 1288 (Fed. Cir. 2016), and to the T wave filter claimed by U.S. Patent No. 7,009,715 that this court found patent-eligible in the earlier litigation between these parties. Pls.’ Opp’n 20-23 [#40].

In Bascom, the Federal Circuit found that the patented claims recited an inventive concept because they used a software-based invention to improve performance of a prior art

internet filter. 827 F.3d at 1351. Bascom recognized that “[f]iltering content on the Internet was already a known concept,” but noted that “prior art filters were either susceptible to hacking and dependent on local hardware and software, or confined to an inflexible one-size-fits-all scheme,” and that the patent “describes how its particular arrangement of elements is a technical improvement over prior art ways of filtering such content.” Id. at 1350. It emphasized that the patented claims “do not preempt the use of the abstract idea of filtering content on the Internet or on generic computer components performing conventional activities.” Id. at 1352.

In Amdocs, the Federal Circuit found that the claim for a computer program for processing network accounting information recited an inventive concept because it utilized a “distributed, remote enhancement that produced . . . reduced data flows and the possibility of smaller databases.” 841 F.3d at 1302. The arrangement was “not so broadly described to cause preemption concerns,” but rather was “narrowly circumscribed to the particular systems outlined,” which “served to improve the performance of the system itself.” Id.

Plaintiffs argue that their patent claims are analogous to those in Bascom and Amdocs because “the claims here improve on previous cardiac monitors that inaccurately identified AF in the presence of a premature ventricular beat and offer further advantages over the prior art that allow accurate AF identification outside the clinic and in real time,” thus reciting “a technological solution to a technological problem.” Pls.’ Opp’n 21 [#40] (citing Amdocs, 841 F.3d at 1288).

Plaintiffs also assert that the patent is analogous to the T wave filter claimed by U.S. Patent No. 7,009,715. In the earlier CardioNet litigation, this court found that the T wave filter claim recited an inventive concept because the patented process of “*diminishing* the intensity of the T wave while *preserving or amplifying* the R wave in an electrocardiogram . . . cannot be

performed in the human mind,” and is therefore “tied to a machine” and meets the “machine-or-transformation test.” CardioNet, LLC v. InfoBionic, Inc., 2017 WL 1788650, at *9-10 (D. Mass. May 4, 2017) (order allowing in part and denying in part renewed motion for judgment on the pleadings).

Under the machine-or-transformation test, however, a claimed process is patent eligible under § 101 if “it is tied to a particular machine or apparatus” and “the use of a specific machine or transformation of an article . . . impose[s] meaningful limits on the claim's scope to impart patent-eligibility.” SiRF Tech., Inc. v. Int’l Trade Comm’n, 601 F.3d 1319, 1332 (Fed. Cir. 2010) (quoting In re Bilski, 545 F.3d 943, 954, 961 (Fed. Cir. 2008)).

“In order for the addition of a machine to impose a meaningful limit on the scope of a claim, it must play a significant part in permitting the claimed method to be performed, rather than function solely as an obvious mechanism for permitting a solution to be achieved more quickly, i.e., through the utilization of a computer for performing calculations.”

Id. at 1333. “[S]imply implementing a mathematical principle on a physical machine, namely a computer, [i]s not a patentable application” of an otherwise abstract idea. Alice, 134 S. Ct. at 2357 (quoting Mayo, 132 S. Ct. at 1301).

InfoBionic argues that the ’207 patent appears to recite “collecting cardiac data, determining its relevance, and then identifying a cardiac event,” without identifying any specific “technical solutions or detailed software for performing the claimed functions.”² Def.’s Mem. 17, 23 [#37]. InfoBionic contends further that the patent recites only technological functions which “can be performed using conventional, off-the-shelf, cardiac monitoring equipment and

² InfoBionic argues that “the recited ‘beat detector’ and ‘ventricular beat detector’ can be any equipment that detects heartbeats,” and that “the ‘variability determination logic’ by its literally terms can be *anything* that ‘determines [] variability,’ the ‘relevance determination logic’ literally can be *anything* that ‘identif[ies] a relevance of the variability,’ and the ‘event generator’ can be *any* ‘data processing device’ that ‘generate[s] an event.” Def.’s Mem. 18 [#37] (quoting ’207 Patent 13 col. 5:15-20, 55-56; 15 col. 9:22-32 [#25-1]).

conventional computer hardware and/or software.”³ Def.’s Mem. 17-18 [#37]. And, InfoBionic argues that the conventional components are not put together so as to add anything inventive by their combination. Rather, the claim elements “merely recite the conventional components that perform their usual functions put together in a standard way to perform a commonplace diagnostic method: collect data, analyze it, and identify medically significant events.” Id. at 14. InfoBionic contends that the claims are therefore lacking an inventive concept and are patent ineligible. Id. at 15-16. For support, InfoBionic cites to FairWarning IP, 839 F.3d 1089, Intellectual Ventures I LLC v. Symantec Corp., 838 F.3d 1307 (Fed. Cir. 2016), and Elec. Power, 830 F.3d 1350.

In FairWarning IP, the Federal Circuit rejected the argument that the claims “solve technical problems unique to the computer environment and thus should be patent eligible” where the claims did not recite “technological advance relating to accessing and combining disparate information sources,” or otherwise “propose a solution or overcome a problem specifically arising in the realm of computer technology.” 839 F.3d at 1091. Instead, the court found that the claims were rather “directed to the broad concept of monitoring audit log data.” (quotation omitted). Similarly, in Intellectual Ventures, the Federal Circuit found no inventive concept where the claimed method of filtering emails to address computer viruses and spam did not “improve the functioning of the computer itself,” but rather “use[d] generic computers to perform generic computer functions.” 838 F.3d at 1315. And in Electric Power, the court found that claims which did not “require a new source or type of information, or new techniques for

³ As InfoBionic points out, the patent itself states that a variety of implementations of conventional computer software can be used to implement these functions. See ’207 Patent 16 col. 11:5-9 [#25-1] (“Various implementations of the systems and techniques described here can be realized in digital electronic circuitry, integrated circuitry, specially designed ASICs (application specific integrated circuits), computer hardware, firmware, software, and/or combinations thereof.”).

analyzing it” or “invoke any assertedly inventive programming” did not “require an arguably inventive set of components or methods, such as measurement devices or techniques[] that would generate new data.” 830 F.3d at 1355. The Electric Power court emphasized that “[m]erely requiring the selection and manipulation of information . . . by itself does not transform the otherwise-abstract processes of information collection and analysis.” Id. (citations omitted).

The court finds InfoBionics’s argument to be correct. Claim 1, the only claim quoted in the Complaint [#25], 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^[4] 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 detector.

’207 Patent 16 col. 12:12-27 [#25-1]. The other asserted claims read as follows:

2. The device of claim 1, wherein the relevance determination logic is to accommodate variability in the beat-to-beat timing caused by ventricular beats by weighting ventricular beats as being negatively indicative of the one of atrial fibrillation and atrial flutter.
3. The device of claim 1, wherein the variability determination logic is to compare times between R-waves in three successive QRS complexes to determine the variability in the beat-to-beat timing.
- ...
7. The device of claim 1, wherein the event generator is to generate an event by performing operations comprising: collecting data associated with the collection

⁴ For purposes of this motion to dismiss, the court adopts Plaintiffs’ construction of the term “ventricular beats” to mean “premature ventricular beats that are irregular beats that interrupt the normal heart rhythm.” Pls.’ Opp’n 6 n.2 [#40].

of beats; and transmitting the data associated with the collection of beats to a remote receiver.

...

10. The device of claim 1, wherein the relevance determination logic comprises logic to identify the relevance of the variability using a non-linear function of a beat-to-beat interval.

11. The device of claim 1, wherein the beat detector comprises a QRS detector.

12. The device of claim 1, further comprising a sensor that includes two or more body surface electrodes subject to one or more potential differences related to cardiac activity.

...

22. The article of claim 20⁵, determining the relevance comprises: identifying a beat of the collection as a ventricular beat, and weighting the beat as being negatively indicative of the one of atrial fibrillation and atrial flutter.

Compl. ¶ 20 [#25]; '207 Patent 16 col. 12:28-17, col. 14:43 [#25-1].

Nothing in these claims imposes a meaningful limit on the abstract idea of identifying AF by looking at the variability in time between heartbeats and taking into account ventricular beats. Plaintiffs argue that the invention uses “specifically programmed rules, termed ‘determination logic’” to improve the cardiac monitoring, Pls.’ Opp’n 14 [#40],⁶ and that “claims 2, 3, 10, and

⁵ Claim 20 asserts:

An article comprising one or more machine-readable media storing instructions operable to cause one or more machines to perform operations, the operations comprising: determining a beat-to-beat variability in cardiac electrical activity; determining a relevance of the variability over a collection of beats to one of atrial fibrillation and atrial flutter using a non-linear function of a beat-to-beat interval; and identifying one of an atrial fibrillation event and an atrial flutter event based on the determined relevance, the event being a period in time when the information content of the cardiac electrical activity is of increased relevance to the one of atrial fibrillation and atrial flutter.”

'207 Patent 17 [#25-1].

⁶ See also *id.* at 6 (the '207 patent “uses determination logic to identify AF events”); *id.* at 16 (the '207 patent achieves solutions “through the claimed beat detectors and the event generators’ application of the determination logic”); *id.* at 17 (the claims focus on a challenge to computer monitoring “by using determination logic to calculate beat-to-beat variability”); *id.* (“the limitations of the '207 patent . . . require[e] the rules to be applied in a specific way”); *id.* at 18 (“[t]he specificity of the decision logic in taking into account variability in the beat-to-beat

22 (which is dependent upon claim 20) recite additional limitations to the determination logic described in the patent specification.” Id. at 19. But, Plaintiffs do not identify what aspect of “the determination logic described in the patent specification” makes either the patent as a whole, or the specific claims asserted, patent-eligible.

The “determination logic” cited by Plaintiffs is not a limitation set forth in the ’207 patent. Instead, the “determination logic” is undefined and unspecified. Claim 1 broadly claims the use of components with “variability determination logic to determine a variability in the beat-to-beat timing of a collection of beats,” without specifying any limitations to that logic. ’207 Patent 16 col. 12:17-18 [#25-1]. In claim 2, the determination logic “is to accommodate variability in the beat-to-beat timing caused by ventricular beats by weighting ventricular beats as being negatively indicative of the one of atrial fibrillation and atrial flutter.” Id. at col. 12:29-32. In claim 3 “the variability determination logic is to compare times between R-waves in three successive QRS complexes to determine the variability in the beat-to-beat timing.” Id. at col. 12:33-36. And, in claim 10 “the relevance determination logic comprises logic to identify the relevance of the variability using a non-linear function of a beat-to-beat interval.” Id. at 17 col. 13:5-8. The innovation of the ’207 patent may be to use computer equipment and logic to monitor the variability of beats, but nothing in these claims places any limitation on that abstract idea.

Plaintiffs argue that the claims recite the following additional inventive limitations:

[C]laims 2 and 22 specifically require that the determination logic weight premature ventricular beats ‘as being negatively indicative,’ claim 3 specifically

timing . . . provides . . . limitation”); id. at 20 (“the beat detectors and event generator of the ’207 patent work together with the determination logic”); id. (“specific programming is required to perform the claims’ function”); id. at 21 (“[i]t is the combination of . . . elements, together with the determination logic, that solves the prior art cardiac monitoring problem of incorrectly identifying AF events”).

requires analysis of ‘three successive QRS complexes,’ and claims 10 and 20 (not independently asserted) limit the determination logic to a non-linear function. Moreover, claim 7 provides for the additional advantage and monitoring system flexibility of the transmission of data associated with a collection of beats to a remote receiver – similar to the claims already found eligible by the Court in the Related Action.

Pls.’ Opp’n 23 [#40] (citing CardioNet, LLC v. InfoBionic, Inc., 2017 WL 1788650 (D. Mass. May 4, 2017) (order allowing in part and denying in part renewed motion for judgment on the pleadings)).

But, as InfoBionic responds, claims 2, 3, 10, and 22 “provide additional information relating to the variability or determination logic, but provide no meaningful details on *how* to implement it, and thus add nothing inventive. At most, these claims add generic calculations that humans can perform.” Def.’s Mem. 24 [#37]. And “the addition of a mathematical equation that simply changes the data into other forms of data cannot save it.” RecogniCorp, LLC v. Nintendo Co., Ltd., 855 F.3d 1322, 1328 (Fed. Cir. 2017) (holding that “the presence of a mathematical formula” did not add an inventive concept to transform “the abstract idea of encoding and decoding into patent-eligible subject matter”).

Similarly, claim 7 simply provides that “the event generator collects and transmits data to a remote receiver,” but “collecting, transmitting, and storing data is generic and conventional,” Def.’s Mem. 20 [#37], and therefore does not add an inventive limitation.

See In re TLI Commc’ns LLC Patent Litig., 823 F.3d at 613.⁷

⁷ Claims 11 and 12 do not even include the reference to “determination logic,” and instead simply limit the source and type of data collected to a QRS detector and body surface sensors, both of which are conventional technology. See In re TLI Commc’ns LLC Patent Litig., 823 F.3d at 613 (holding that, at step two of the Alice inquiry, “mere recitation of concrete, tangible components is insufficient to confer patent eligibility to an otherwise abstract idea. Rather, the components must involve more than performance of ‘well-understood, routine, conventional activit[ies]’ previously known to the industry.” (quoting Alice, 134 S. Ct. at 2359)).

In sum, unlike in Bascom, Andocs, or the previous CardioNet litigation, the asserted claims of the '207 patent are broadly described, with no meaningful limitation, so as to preempt other technological systems directed to the abstract idea of monitoring and analyzing ventricular beats to identify AF events.

Plaintiffs argues finally that under the Federal Circuit's decision in Berkheimer, 881 F.3d 1360, the second step of Alice involves factual inquiries, and may overlap with other fact-intensive inquiries such as novelty under § 102. Pls.' Not. Supp. Authorities 2 [#43]. In Berkheimer, the court found on review of a summary judgment record that there were disputed facts to support the nonmovant's claim that the asserted data processing system claims may be directed to an improvement in the computer technology itself. See 881 F.3d at 1360. Here, there are no disputes of fact as the court accepts the Plaintiffs' non-conclusory factual assertions in the complaint and the patent as true. On the facts as alleged, and the patent terms as construed by Plaintiffs, Plaintiffs' asserted claims are not directed to any improvement in the computer technology itself, but rather seek to improve cardiac monitoring instead through the abstract idea of measuring the variability of heartbeats.

Conclusion

For all of the above reasons, the '207 patent is directed to an abstract idea and the asserted claims do not add an inventive elements. Accordingly, Defendant's Motion to Dismiss [#36] is ALLOWED.

IT IS SO ORDERED.

Date: October 16, 2018

/s/ Indira Talwani
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

CARDIONET, LLC, and BRAEMAR
MANUFACTURING, LLC,

Plaintiffs,

v.

INFOBIONIC, INC.,

Defendant.

*
*
*
*
*
*
*
*
*
*

Civil Action No. 17-cv-10445-IT

ORDER OF DISMISSAL

October 17, 2018

TALWANI, D.J.

Having allowed Defendant's Motion to Dismiss [#36], this matter is dismissed. The clerk shall close the case.

IT IS SO ORDERED.

/s/ Indira Talwani
United States District Judge

CERTIFICATE OF SERVICE

I declare that I, Ching-Lee Fukuda, am employed by the firm of Sidley Austin, LLP, located at 787 Seventh Avenue, New York, NY 10019.

I declare that on January 10, 2019, I served a true and correct copy of the **Corrected Opening Brief of Appellants** by electronic means (CM/ECF) and therefore served all counsel of record.

I certify under penalty of perjury under the laws of the United States of America that the foregoing information contained in this Certificate of Service is true and correct.

Dated: January 10, 2019

/s/ Ching-Lee Fukuda
Ching-Lee Fukuda
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, NY 10019
(212) 839-5300
Counsel for Appellant

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). The brief contains 11,581 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Fed. Cir. R. 32(b).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Century Schoolbook font.

This brief complies with the confidentiality requirements of Federal Circuit Rule 28(d) because it contains no words marked as confidential.

Dated: January 10, 2019

/s/ Ching-Lee Fukuda _____
Ching-Lee Fukuda
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, NY 10019
(212) 839-5300
Counsel for Appellant