00005-0013-00000

Paper No. _____

Filed on behalf of: InfoBionic, Inc.

By: Leslie Bookoff
Dinesh Melwani
Biju Chandran
BOOKOFF McANDREWS, PLLC
2401 Pennsylvania Ave., NW
Suite 450
Washington, DC 20037
Telephone: 202-808-3550
Facsimile: 202-450-5538
E-mail: LBookoff@bookoffmcandrews.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INFOBIONIC, INC.
Petitioner,

v.

BRAEMAR MANUFACTURING, LLC
Patent Owner.

Patent No. 7,907,996

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,907,996

Table of Contents

TABLE OF AUTHORITIES iii

LISTING OF EXHIBITS iv

I. INTRODUCTION 1

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1) 1

III. NOTICE OF FEES PAID UNDER 37 C.F.R. § 42.15(a) 3

IV. CERTIFICATION OF GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104 3

V. IDENTIFICATION OF CHALLENGE AND RELIEF REQUESTED UNDER 37 C.F.R. § 42.104 3

VI. BACKGROUND 4

1. Disclosure of the '996 patent 4

2. Prosecution History of the '996 patent and Earlier Application 9

VII. CLAIM CONSTRUCTION 11

1. "Subset" 12

2. Means-Plus-Function Limitations 14

a) "Means for Identifying Atrial Fibrillation Events" 14

b) "Means for Obtaining Heart Rate Data" 16

c) "Means for receiving a human assessment" 17

d) "Means for Pictographically Presenting" 19

VIII. PETITIONER'S ARGUMENTS RE: APPLIED ART DO NOT CONTRADICT NOR REHASH ANY OF THE EXAMINER'S ASSERTIONS 20

IX. DETAILED DISCUSSION OF UNPATENTABILITY 21

A. Ground 1 - Claims 1, 12, 18, and 23 are obvious over *Bock* in view of *Walker* and *ACC Guidelines* and further in view of *Reinhold* 21

1. Independent Claim 1 21

2. Independent Claim 12 37

3. Independent Claim 18 39

4. Independent claim 23 42

B. Ground 2 - Alternate Theory of Obviousness of Claims 1, 12, 18, and 23 based on *Bock*, *ACC Guidelines*, *Walker*, and *Reinhold* 48

IX. CONCLUSION.....52

TABLE OF AUTHORITIES

Cases

In re Cuozzo Speed Technologies, LLC., No. 2014-1301 (February 4, 2015) .. 11-12

In re Translogic Tech Inc., 504 F.3d 1249, 1257 (Fed. Cir. 2007) 12

KSR Int'l. Co. v. Teleflex, Inc., 550 U.S. 398, 417 (2007) 29, 36, 49, 50

Phillips v. AWH Corp., 415 F.3d 1303, 1312, 1313 (Fed. Cir. 2005) (*en banc*).....12

Federal Statutes

35 U.S.C. § 102 .....3, 4

35 U.S.C. § 103 ..... 1, 3, 4

35 U.S.C. § 112 ..... 11, 14

35 U.S.C. § 311 1

Federal Regulations

37 C.F.R. § 42.100 ..... 1, 11

37 C.F.R. § 42.104 ..... 3, 14

37 C.F.R. § 42.105 52

37 C.F.R. § 42.15 3

37 C.F.R. § 42.6 52

37 C.F.R. § 42.8 1

LISTING OF EXHIBITS[1]

Exhibit	Description
Exhibit 1001	U.S. Patent No. 7,907,996 to Prystowsky et al.
Exhibit 1002	Declaration of Robert T. Stone, Ph.D.
Exhibit 1003	Prosecution History of U.S. Patent No. 7,907,996
Exhibit 1004	U.S. Provisional Application No. 60/525,386
Exhibit 1005	U.S. Patent No. 6,490,479 to Bock
Exhibit 1006	U.S. Patent No. 7,490,085 to Walker
Exhibit 1007	U.S. Patent No. 4,531,527 to Reinhold
Exhibit 1008	ACC/AHA Guidelines for Ambulatory Electrocardiography, Journal of the American College of Cardiology, Vol. 34, No. 3, September 1999, pp. 912-948 ("*ACC Guidelines*")
Exhibit 1009	Definition of "subset" from Merriam-Webster's Collegiate Dictionary, Tenth Edition, Copyright 2001, page 1170.
Exhibit 1010	Prosecution History of U.S. Patent No. 7,212,850

[1] Citations to non-patent publications are to the exhibit page numbers and citations to patent publications are to column:line number of the patents.

Exhibit 1011	Plaintiff CardioNet, Inc.'s Opening Claim Construction Memorandum in CardioNet, Inc. v. The Scottcare Corporation and Ambucor Health Solutions, Inc., Civil Action No. 12-cv-2516 (PBT), United States District Court Eastern District of Pennsylvania dated March 13, 2013.
Exhibit 1012	Plaintiff CardioNet, Inc.'s Opening Claim Construction Memorandum in CardioNet, Inc. v. Mednet Healthcare Technologies, Inc. et al., Civil Action No. 12-cv-2517 (JS), United States District Court Eastern District of Pennsylvania dated January 9, 2013.
Exhibit 1013	Memorandum Opinion in CardioNet, Inc. v. The Scottcare Corporation and Ambucor Health Solutions, Inc., Civil Action No. 2:12-cv-2516, United States District Court Eastern District of Pennsylvania dated October 8, 2014.
Exhibit 1014	Memorandum in CardioNet., et al. v. Mednet Healthcare Technologies, Inc. et al., Civil Action No. 12-2517, United States District Court Eastern District of Pennsylvania dated November 15, 2013.

I. INTRODUCTION

On behalf of InfoBionic, Inc. ("InfoBionic" or "Petitioner") and in accordance with 35 U.S.C. § 311 and 37 C.F.R. § 42.100, Petitioner requests *inter partes* review (IPR) of claims 1, 12, 18, and 23 of U.S. Patent No. 7,907,996 to Prystowsky et al. ("the '996 patent," Ex. 1001). This Petition establishes that there is a reasonable likelihood of prevailing with respect to at least one of the challenged claims. This Petition also establishes by a preponderance of evidence that claims 1, 12, 18, and 23 of the '996 patent are unpatentable under 35 U.S.C. § 103(a). Accordingly, these claims should be cancelled.

II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

Real Party-in-Interest: Pursuant to 37 C.F.R. § 42.8(b)(1), Petitioner, InfoBionic Inc., is the real party-in-interest.

Related Matters: Per 37 C.F.R. § 42.8(b)(2), Petitioner identifies the following related matters. Braemar Manufacturing, LLC ("Braemar" or "Patent Owner"), the alleged owner by assignment of the '996 patent, and CardioNet LLC ("CardioNet"), the alleged exclusive licensee of the '996 patent, have asserted the '996 patent and U.S. Patent Nos. 7,212,850 ("the '850 patent"), 6,225,901 ("the '901 patent"), and 6,940,403 ("the '403 patent") against Petitioner in a civil action titled *CardioNet, LLC et al. v. InfoBionic, Inc.*, Case No. 1:15-cv-11803, at the United States District Court, District of Massachusetts. This action is currently

pending. Petitioner is concurrently filing petitions for *inter partes* review of the '850 patent, the '901 patent, and the '403 patent.

The '850 patent and '996 patent have also been asserted in two additional patent litigation actions in the Eastern District of Pennsylvania: (1) *CardioNet, Inc. et al. v. The Scottcare Corp. et al.*, Case No. 2:12-cv-2516 (pending); and (2) *CardioNet, Inc. et al. v. MedNet Healthcare Tech. Inc. et al.*, Case No. 2:12-cv-02517 (terminated).

U.S. Patent Application No. 14/593,237 claims priority to the '996 patent and is pending before the Patent Office.

Counsel and Service Information: Lead counsel is Leslie Bookoff (Reg. No. 38,084) and back-up counsel are Dinesh Melwani (Reg. No. 60,670), and Biju Chandran (Reg. No. 63,684). Addresses for hand and postal delivery of service is: Bookoff McAndrews, PLLC, 2401 Pennsylvania Ave., NW, Suite 450, Washington, DC 20037. Addresses for e-mail delivery of service are: docketing@bookoffmcandrews.com, lbookoff@bookoffmcandrews.com, dmelwani@bookoffmcandrews.com, and bchandran@bookoffmcandrews.com. Petitioner consents to electronic service. The lead and backup counsel can be reached by phone at (202) 808-3494 and by facsimile at (202) 450-5538.

III. NOTICE OF FEES PAID UNDER 37 C.F.R. § 42.15(a)

Petitioner submits the required fees with this petition. Please charge any additional fees required for this proceeding to Deposit Account No. 50-5906.

IV. CERTIFICATION OF GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(a)

Petitioner certifies that the '996 patent is available for *inter partes* review, and that the Petitioner is not barred or estopped from requesting such review of the '996 patent on the grounds identified in this Petition.

V. IDENTIFICATION OF CHALLENGE AND RELIEF REQUESTED UNDER 37 C.F.R. § 42.104(b)(1)-(3)

As described in more detail in Section IX, claims 1, 12, 18, and 23 of the '996 patent are unpatentable in view of the references and grounds listed below. Therefore, it is respectfully requested that these claims be cancelled.

Reference 1: U.S. Patent No. 6,490,479 ("*Bock*"), filed December 28, 2000, and issued December 3, 2002, qualifies as prior art to the '996 patent under 35 U.S.C § 102(e). Ex. 1005.

Reference 2: U.S. Patent No. 7,490,085 ("*Walker*"), filed December 18, 2002, and issued February 10, 2009, qualifies as prior art to the '996 patent under 35 U.S.C § 102(e). Ex. 1006.

Reference 3: ACC/AHA Guidelines for Ambulatory Electrocardiography, ACC/AHA Practice Guidelines ("*ACC Guidelines*"), Journal of the American

College of Cardiology, Vol. 34, No. 3, September 1999, pp. 912-948. The *ACC Guidelines* qualifies as prior art to the '996 patent under 35 U.S.C § 102(b). Ex. 1008.

Reference 4: U.S. Patent No. 4,531,527 ("*Reinhold*"), issued July 30, 1985, qualifies as prior art to the '996 patent under 35 U.S.C § 102(b). Ex. 1007.

Ground 1: Claims 1, 12, 18, and 23 are unpatentable over *Bock* in view of *Walker* and the *ACC Guidelines* and further in view of *Reinhold* under 35 U.S.C. § 103(a).

Ground 2: Alternate theory of obviousness of claims 1, 12, 18, and 23 based on *Bock*, *Walker*, the *ACC Guidelines, and Reinhold* under 35 U.S.C. § 103(a).

VI. BACKGROUND

1. Disclosure of the '996 patent

The '996 patent describes systems and techniques for processing arrhythmia events (e.g., atrial fibrillation "AF" events) from physiological data and "selectively presenting atrial fibrillation events to a medical practitioner." Ex. 1001 at 1:23-26: Ex. 1002 at ¶ 15. With reference to FIG. 1 reproduced above,

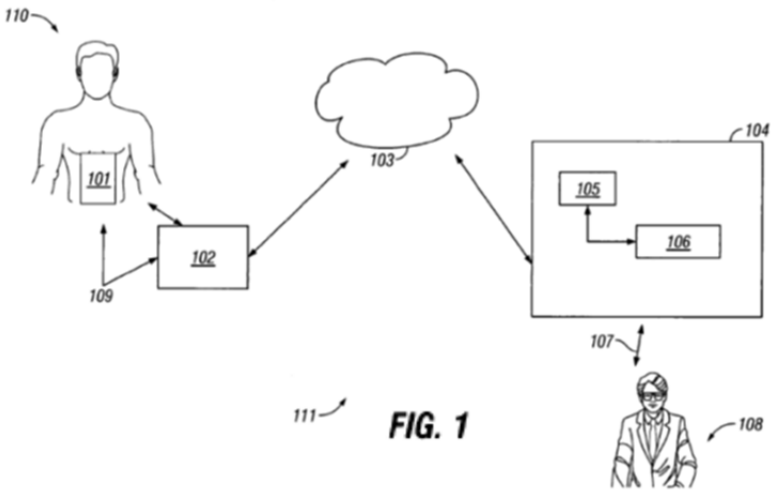


FIG. 1

the ’996 patent discloses a monitoring system 109 that communicates, via devices 101 and 102, physiologic data to monitoring center 104. Ex. 1001 at 2:32-35; Ex. 1002 at ¶ 16. The monitoring center 104 includes a monitoring (or display) station 105 and a processing system 106. Ex. 1001 at 2:58-59. A cardiovascular technician (CVT) uses the monitoring station 105 to evaluate the received physiological data to identify arrhythmia events (such as AF events). *Id.* at 2:60-64. The CVT reports assessments of the physiological data to the processing system 106 which also receives information related to the arrhythmia events identified by the monitoring system 109. *Id.* at 2:64-67. The processing system 106 analyzes the human-assessed data from the CVT and the data reported by the monitoring system 109 and determines whether or not to generate a graph related to these events based on a correlation analysis of the human-assessed data and the data reported from the monitoring system 109. *Id.* at 3:1-5; Ex. 1002 at ¶ 17.

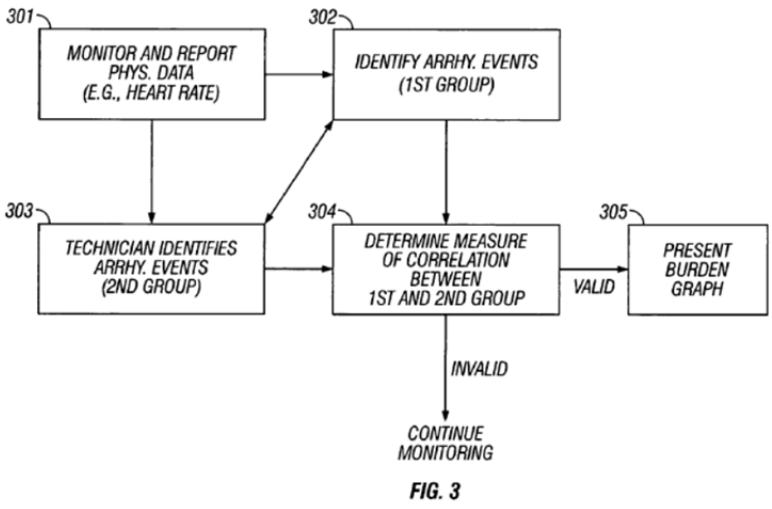
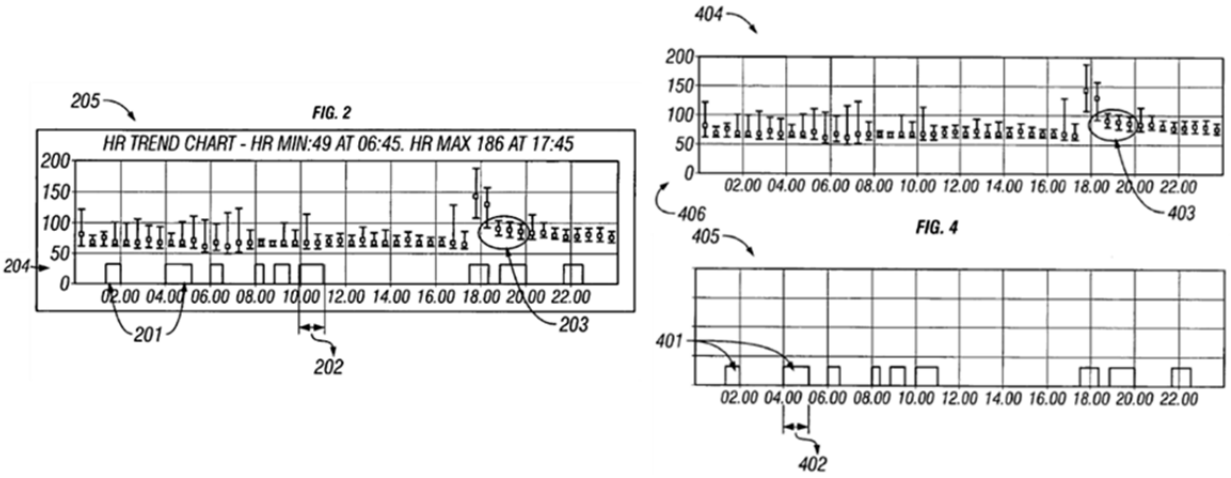


FIG. 3

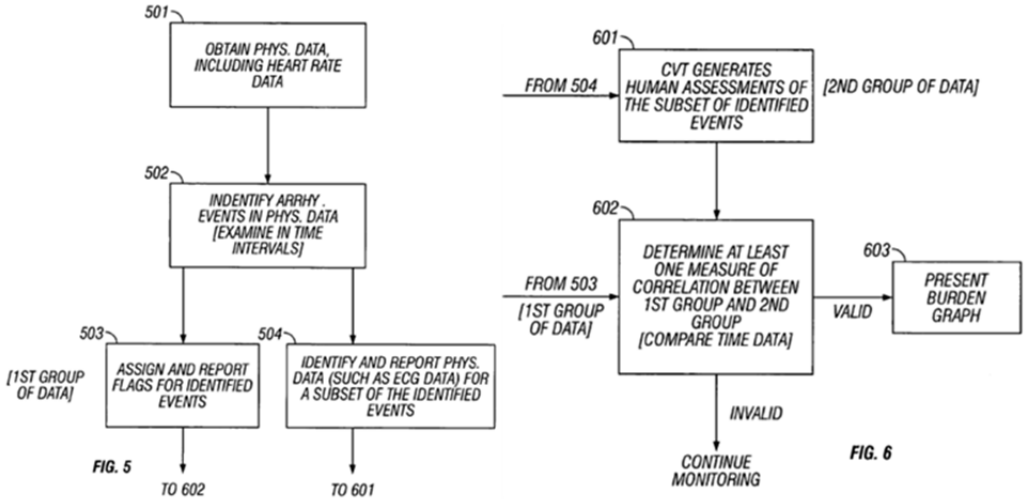
In one embodiment (*see* FIG. 3 reproduced to the right), the monitoring system 109 monitors and reports physiologic data to monitoring

center 104 at step 301. Ex. 1001 at 3:13-15; 2:35-38. The monitoring center 104 analyzes the received physiologic data at step 302 and identifies arrhythmia events. *Id.* at 3:15-18; 2:42-43. These identified arrhythmia events constitute a first group of data. *Id.* at 3:19-20. At step 303, a CVT using station 105 evaluates the physiologic data received from steps 301 and/or 302 and identifies arrhythmia events (human-assessed events). *Id.* at 3:25-28. These human-assessed events constitute a second group of data. *Id.* at 3:28-30; Ex. 1002 at ¶ 18.

At step 304, the processing system 106 analyzes both the first and second group of data and determines a measure of correlation between the two groups of data. Ex. 1001 at 3:32-34. That is, the processing system 106 compares the software identified arrhythmia events to the human identified arrhythmia events. "This process can involve, for example, determining whether a correlation measure exceeds and/or equals a predetermined correlation parameter or whether a correlation measure is less than and/or equals that parameter." *Id.* at 3:34-38. If this correlation analysis indicates that the determined arrhythmia event is valid, the system generates a report relating to heart rate trend and arrhythmia events such as the graph shown in FIG. 2 or FIG. 4 at step 305. *Id.* at 3:38-42. If there is insufficient correlation, the system does not generate a report and continues monitoring. *Id.* at 3:42-44; Ex. 1002 at ¶ 19.



FIGS. 2 and 4, reproduced above, illustrate "example[s] of how to pictographically present [ ] heart rate trend and atrial fibrillation burden on a common time scale." Ex. 1001 at 4:1-3, 15-17. The '996 patent states that the advantage of "pictographic presentations, such as those of FIGS. 2 and 4, [is that] a medical practitioner can see whether a patient is more likely to experience an arrhythmia, such as AF, at certain times of the day." *Id.* at 3:62-66. The heart rate trend and atrial fibrillation burden can be presented on a common time scale using one graph (FIG. 2) or using two graphs (FIG. 4). *Id.* at 4:15-17; Ex. 1002 at ¶ 20.



FIGS. 5 and 6, reproduced above, illustrate another embodiment of presenting data based on a correlation analysis. Ex. 1001 at 4:26-27. At step 501, the monitoring system 109 obtains physiologic data, and at step 502, the system identifies the presence of arrhythmia events (e.g., AF events). *Id.* at 4:27-32. At step 503, the system assigns flags indicating the presence of arrhythmia events and reports those flags (first group of data) to the processing system. *Id.* at 4:32-34. At step 504, the system identifies and reports physiological data, such as ECG data, for a subset of the events identified at 502 and reported at 503. *Id.* at 4:35-37. At step 601, the CVT analyzes this data to determine whether arrhythmia events have occurred, thereby generating a second group of data. *Id.* at 4:42-44. The processing system then determines a measure of correlation between the first and second groups of data, and if enough human-assessed events reported at 601 match the events reported at step 503, the data is pictographically presented "in a form such as FIG. 2 or FIG. 4." *Id.* at 4:44-54; Ex. 1002 at ¶ 21.

In all disclosed implementations of the '996 patent, cardiac data is evaluated both by an algorithm and by a human to identify arrhythmic events such as AF events. *See* steps 302 and 303 in the embodiment of FIG. 3 (Ex. 1001 at 3:14-17, 25-27) and steps 502 and 601 in the embodiment of FIGS. 5 and 6 (*id.* at 4:33-36, 46-48). The algorithm-identified and human-identified arrhythmic events are then compared. *See* step 304 in the embodiment of FIG. 3 (*id.* at 3:32-35) and step 602

in the embodiment of FIGS. 5 and 6 (*id.* 4:48-51). And, if the algorithm-detected arrhythmic event is validated or corroborated by the human assessment, it is presented. Ex. 1001 at 3:39-45; 4:52-56; *see* also Ex. 1004 at p. 8; Ex. 1002 at ¶ 22.

2. Prosecution History of the '996 patent and Earlier Application

The '996 patent issued from U.S. Patent Application No. 11/739,037 ("the '037 application"), filed on April 23, 2007, and purports to be a continuation of U.S. Application No. 10/760,122 ("the '122 application" or "parent application"), now U.S. Patent No. 7,212,850 ("the '850 patent"), which purports to claim priority to Provisional Application No. 60/525,386, filed on November 26, 2003.

During prosecution of the parent application, the Examiner applied U.S. Patent No. 6,937,887 to Bock (*"*Bock '887*"*), a continuation of the *Bock* reference used in the grounds of this petition.[2] In order to overcome the Bock '887 reference, the Patent Owner amended the rejected claims to require "human-assessment of atrial fibrillation/arrhythmia events." Ex. 1010 at p. 50. The claims were subsequently allowed. *Id.* at pp. 30, 33.

In the continuation application (i.e., the '037 application), the Examiner rejected the independent claims over the *Bock* reference used in the grounds of this petition (i.e., U.S. Patent No. 6,490,479 to Bock). *See* Ex. 1003 at p. 345. In

[2] Bock '887 and the *Bock* reference have the same specification.

response, the Patent Owner substantially amended each of the independent claims to require, among other things, receiving "human assessment of a subset of the identified atrial fibrillation events" and "based on the human assessment of the subset of the identified atrial fibrillation events . . . pictographically presenting information regarding the heart rate data for [ ] multiple time intervals," and requiring that the information for each time interval comprise "a range of heart rates and a heart rate average." *See* Ex. 1003 at p. 302. The Patent Owner argued that *Bock* "is silent regarding receiving a human assessment of identified atrial fibrillation events . . . [and] is also silent regarding pictographically presenting heart rate data and atrial fibrillation activity based on the human-assessment of a subset of identified atrial fibrillation events." *Id.* at p. 315 (emphasis in original).

While the Examiner did not issue subsequent claim rejections of the amended independent claims, the Examiner rejected a new dependent claim that recited "presenting a range of heart rates and a heart rate average for each of multiple time intervals" over a combination of *Bock* and *Heikkila*. *Id.* at p. 311, 243. The Examiner relied on *Heikkila* for the teaching of "a range of heart rates and a heart rate average," and *Bock* for the teaching of "multiple time intervals." *Id.* at p. 243. Despite the Patent Owner's arguments to the contrary (*id.* at p.180), the Examiner maintained the rejection stating that:

> The multiple time intervals are shown by Bock, and hence do not have to be shown again in the device of Heikkila. To provide the average and standard deviation for multiple time intervals, as opposed to only one time interval, would not produce any unexpected results.

Ex. 1003 at p. 171. Accordingly, the Examiner considered the limitation of displaying "a range of heart rates and a heart rate average," for each of the multiple time intervals, to be well-known in the art. The Patent Owner subsequently cancelled the rejected dependent claim and the application proceeded to allowance. Thus, during prosecution of the '996 patent, the Examiner believed that *Bock* taught all aspects of the claims except the aspects related to human assessment.

VII. CLAIM CONSTRUCTION

During an IPR, claim terms should be given their broadest reasonable interpretation in view of the specification in which they appear.[3] *See* 37 C.F.R. § 42.100(b) ; Ex. 1002 at ¶ 23. The United States Court of Appeals for the Federal Circuit recently concluded that the Patent Office properly adopted that standard for construing claims in an IPR. *In re Cuozzo Speed Technologies, LLC*., No. 2014-

[3] Given the different claim construction standards used by the PTO and district courts, Petitioner reserves the right to argue different claim constructions in litigation. Petitioner also reserves all other arguments, such as 35 U.S.C. §112 arguments, for litigation.

1301 (February 4, 2015). Any claim terms not construed herein should be "given their ordinary and customary meaning," which is the meaning that the term would have to a person of ordinary skill in the art (POSITA).[4] *See In re Translogic Tech Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007 (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312, 1313 (Fed. Cir. 2005) (en banc)).

1. "Subset"

Independent claims 1, 12, 18, and 23 recite "receiving a human assessment of a subset of the identified atrial fibrillation events." Under the BRI standard, the term "subset" should be construed to mean "some or all elements of a set." Ex. 1002 at ¶ 24.

The plain and ordinary meaning of "subset" is "a set each of whose elements is an element of an inclusive set." Ex. 1009 at p. 3. This meaning is consistent with the use of "subset" in the specification. Ex. 1002 at ¶ 25. The specification uses the term "subset" when discussing the embodiment illustrated in FIGS. 5 and 6. *See* Ex. 1001 at 4:26-59. In this embodiment, a subset of the system-identified

[4] For the purposes of this Petition, a POSITA is someone who has at least a bachelor's degree in electrical or mechanical engineering, or equivalent proficiency, and at least two to three years of experience in the research and/or development of remote patient monitoring systems, such as cardiac remote patient monitoring systems.

arrhythmia events is sent to a cardiovascular technician (CVT) for assessment. *Id.* at 4:42-47. If at least some of the human-assessed arrhythmia events match the system-identified arrhythmic events, then the system-identified arrhythmia events are deemed valid and the system pictographically presents all the events. *Id.* at 4:48-54. The specification contemplates sending all of the system-identified arrhythmia data to the CVT for assessment and provides that the system "***need only***" send data for the most significant system-identified events to "minimize[e] the data sent to the" technician. *Id.* at 4:54-59 (emphasis added). Thus, the broadest reasonable interpretation of "subset" is "some or all elements of a set." Ex. 1002 at ¶ 25.

The proposed construction is consistent with the construction of "subset" offered by Patent Owner in related litigations. The BRI should encompass Patent Owner's construction. Patent Owner has argued that "subset" should be construed to mean "a set consisting of elements of a given set that can be the same as the given set or smaller." *See* Ex. 1011 at pp. 22-24; Ex. 1012 at pp. 19-21. The Patent Owner has stated that "nothing in the claims, specification or prosecution history states that all data ***cannot*** be reported to the technician" and that "exemplary embodiments make clear that the technician may even 'request additional data,' outside of the event dataset for review, in making an assessment." Ex. 1011 at p. 24 (citing Ex. 1001 at 3:25-31); *see also* Ex. 1012 at pp. 20-21. In view of these

statements, the Board should adopt Petitioner's proposed construction or a construction that is at least as broad as the Patent Owner's construction.

While the court in both litigations ultimately construed the term "subset" narrowly to mean "a set that is less than all the elements of a given set" (Ex. 1013 at p. 15) and "less than all" elements of the set (Ex. 1014 at p. 18), those constructions are not the broadest reasonable interpretations of the term "subset" and should not be adopted by the Board. *See* Ex. 1002 at ¶¶ 24, 25.

2. Means-Plus-Function Limitations

Several claims of the '996 patent include means-plus-function claim terms. The specification does not identify particular structure corresponding to the function of each means-plus-function claim term. However, as required by 37 C.F.R § 42.104 (b)(3), without conceding sufficiency of the claims under 35 U.S.C. § 112, ¶ 6, Petitioner identifies what Patent Owner may argue is the corresponding "structure."[5]

a) "Means for Identifying Atrial Fibrillation Events"

[5] Because the IPR procedure does not permit challenges under 35 U.S.C. § 112, Petitioner has not included any indefiniteness arguments here. Petitioner reserves the right, however, to raise such arguments and/or argue different constructions during litigation.

Independent claim 18 recites "means for identifying atrial fibrillation events in physiological data obtained for a living being." This is a means-plus-function limitation with the function of "identifying atrial fibrillation events in physiological data."

The '996 patent describes a monitoring system 109 with devices 101 and 102. Ex. 1001 at 2:32-34. The '996 patent states that "monitor processing device 102 … can detect arrhythmia events (such as atrial fibrillation events)" from physiologic data. *Id.* at 2:40-43. The '996 patent also states that "a cardiovascular technician (CVT) can use [a] monitoring station 105 to evaluate physiological data received from monitoring system 109, identifying and reporting, among other things, arrhythmia events (such as atrial fibrillation events)." *Id.* at 2:60-64. The Patent Owner may argue that both the monitor processing device 102 and the monitoring station 105 perform the function of "identifying atrial fibrillation events in physiological data."

The Patent Owner also may argue that the '996 patent states that devices 101 and 102 may be in a single device such as, for example, the commercially available "CardioNet Mobile Cardiac Outpatient Telemetry (MCOT) device." *Id.* at 2:45-47. And the Patent Owner may point out that the system and all its functions "can be implemented in digital electronic circuitry, or in computer hardware, firmware, software, or in combinations of the forgoing." *Id.* at 4:60-63. An exemplary

disclosed software product is a computer program and microprocessors are described as exemplary hardware. *Id.* at 4:64-67; 5:1-3.

Thus, for purposes of this proceeding Petitioner has assumed the corresponding structure in the '996 patent for the identified function of "identifying atrial fibrillation events in physiological data" are: CardioNet's Mobile Cardiac Outpatient Telemetry (MCOT) device; digital electronic circuitry; and/or a computer system with software/hardware configured to perform the recited function; or equivalents thereof. Ex. 1002 at ¶ 26.

b) "Means for Obtaining Heart Rate Data"

Claim 18 also recites "means for obtaining heart rate data for the living being." This is a means-plus-function limitation with the function of "obtaining heart rate data for the living being."

In the '996 patent, monitoring system 109 receives physiologic data (including heart rate data) from the patient and sends the data to the monitoring center 104. Ex. 1001 at 2:33-35; 1:56-58; 3:13-15. A technician uses monitoring station 105 to assess the physiological data received from monitoring system 109 and reports these assessments to processing system 106. *Id.* at 2:60-65. The '996 patent states that the processing system 106 "generates a report relating to both heart rate trend and the arrhythmia events" based on a correlation analysis. *Id.* at 3:32-42. The Patent Owner may argue that each of monitoring system 109,

monitoring station 105, and processing system 106 performs the recited function of "obtaining heart rate data for the living being." The Patent Owner also may argue that monitoring system 109 may be the "CardioNet Mobile Cardiac Outpatient Telemetry (MCOT) device." Ex. 1001 at 2:45-47. Further, the Patent Owner may point out that the system and all its functions may be implemented as "digital electronic circuitry, or in computer hardware, firmware, software, or in combinations of the forgoing." *Id.* at 4:60-63. An exemplary disclosed software product is a computer program, and microprocessors are described as exemplary hardware. *Id.* at 4:64-67; 5:1-3.

Thus, for purposes of this proceeding, Petitioner has assumed the corresponding structures for the identified function of "obtaining heart rate data for the living being" are: CardioNet's Mobile Cardiac Outpatient Telemetry (MCOT) device; digital electronic circuitry; and/or a computer system with software/hardware configured to perform the recited function; or equivalents thereof. Ex. 1002 at ¶ 27.

c) "Means for receiving a human assessment"

Claim 18 also recites "means for receiving a human assessment of a subset of the identified atrial fibrillation events." This is a means-plus-function limitation with the function of "receiving a human assessment of a subset of the identified atrial fibrillation events."

In the ’996 patent, a cardiovascular technician uses “the monitoring station 105 to evaluate physiological data received from monitoring system 109, identifying and reporting, among other things, arrhythmia events (such as atrial fibrillation events).” Ex. 1001 at 2:60-64; *see* also *id.* at 3:25-50. The ’996 patent states that “[t]o provide for interaction with a user (such as the CVT), the system can be implemented on a computer system having a display device such as a monitor or LCD (liquid crystal display) screen for displaying information to the user and a keyboard and a pointing device such as a mouse or a trackball by which the user can provide input to the computer system. The computer system can be programmed to provide a graphical user interface through which computer programs interact with users.” *Id.* at 5:34-42. The Patent Owner may argue that the computer system performs the recited function of “receiving a human assessment.” The Patent Owner may point out that the system and all its functions “can be implemented in digital electronic circuitry, or in computer hardware, firmware, software, or in combinations of the forgoing.” *Id.* at 4:60-63. An exemplary disclosed software product is a computer program, and microprocessors are described as exemplary hardware. *Id.* at 4:64-67; 5:1-3.

Thus, for purposes of this proceeding, Petitioner has assumed the corresponding structures for the identified function of “receiving a human assessment” of the identified atrial fibrillation events are: digital electronic

circuitry; and/or a computer system with a monitor or an LCD screen and software/hardware configured to perform the recited functions; or equivalents thereof. Ex. 1002 at ¶ 28.

d) "Means for Pictographically Presenting"

Claim 18 also recites "means for pictographically presenting" information. This is a means-plus-function limitation having the function of "pictographically presenting" the recited information.

In the '996 patent, the processing system 106 performs a correlation analysis, and "[i]f, based on the correlation analysis, the information related to the arrhythmia events is determined to be valid, then the system generates a report relating to both heart rate trend and the arrhythmia events at 305, such as the graph shown in FIG. 2 or the graphs shown in FIG. 4." Ex. 1001 at 3:32-42. FIGS. 2 and 4 illustrate examples of "how to pictographically present both heart rate trend and atrial fibrillation burden on a common time scale." *Id.* at 4:1-3, 15-17. The Patent Owner may argue that processing system 106 performs the function of "pictographically presenting" the recited data. The Patent Owner may point out the system and all its functions "can be implemented in digital electronic circuitry, or in computer hardware, firmware, software, or in combinations of the forgoing." *Id.* at 4:60-63. An exemplary disclosed software product is a computer program, and microprocessors are described as exemplary hardware. *Id.* at 4:64-67; 5:1-3.

Further, the Patent Owner may point out that the disclosed system can be implemented on a computer system with a monitor or an LCD screen. *Id.* at 4:64-67; 5:34-42.

Thus, for purposes of this proceeding, Petitioner has assumed the corresponding structures for the identified function of "pictographically presenting" the recited information are: digital electronic circuitry; and/or a computer system with a monitor or an LCD screen and software/hardware configured to perform the recited functions; or equivalents thereof. Ex. 1002 at ¶ 29.

VIII. PETITIONER'S ARGUMENTS RE: APPLIED ART DO NOT CONTRADICT NOR REHASH ANY OF THE EXAMINER'S ASSERTIONS

This Petition relies on previously unapplied combinations. While *Bock* was considered during prosecution, the combination of *Bock* and the *ACC Guidelines* and *Walker*, both of which were not cited or considered by the Examiner, demonstrate that the claimed features that the Examiner considered to be novel were, in fact, known in and obvious from the prior art. As discussed above in Section VI.2, the claims of the '996 patent were allowed after the feature requiring human-assessment of identified atrial fibrillation events was added to the claims rejected over *Bock*. This feature was known, described in, and practiced in the art well before the '996 patent, as evidenced by the *ACC Guidelines*, which explains

that human-assessment of algorithm-detected arrhythmias was critical to ensure accuracy (*see* Ex. 1008 at pp. 913, 914, 917), and *Walker*, which teaches incorporating human-assessment into an algorithm-based medical event (including arrhythmia) detection system such as *Bock* (*see generally* Ex. 1006). Additionally, this Petition is supported by the declaration of Robert Stone (Ex. 1002), an expert in the field of the prior art and the '996 patent. Thus, the arguments presented in this Petition establish a reasonable likelihood that the Petitioner will prevail with respect to at least one challenged claim and should not preclude institution of this IPR. *See e.g.*, *Fresenius-Kabi USA LLC*, v. *Cubist Pharmaceuticals, Inc*., IPR2015-00223, Paper No. 13 (instituting IPR based on a ground applying the same prior art reference that a patent owner had successfully argued over during prosecution). *See also* IPR2015-00227; IPR2014-01043; IPR2013-00066.

IX. DETAILED DISCUSSION OF UNPATENTABILITY

A. Ground 1 - Claims 1, 12, 18, and 23 are obvious over *Bock* in view of *Walker* and *ACC Guidelines* and further in view of *Reinhold*

1. Independent Claim 1

i. "A machine-implemented method comprising:"

Bock discloses systems and methods to detect irregularities, such as arrhythmias and atrial fibrillation ("AF") in animal heartbeat. Ex. 1005 at 1:6-10. *Bock* states that the disclosed method "is intended to be implemented in software

running on a computer." *Id.* at 3:65-67. That is, the method is "machine-implemented." Ex. 1002 at ¶ 30.

ii. "identifying atrial fibrillation events in physiological data obtained for a living being, wherein identifying atrial fibrillation events comprises examining the physiological data in multiple time intervals, and identifying intervals in which at least one atrial fibrillation event has occurred;"

Bock "monitor[s] ECG signals in adults and paced patients . . . [and] has particular application in detecting atrial fibrillation." Ex. 1005. at 1:38-41; 4:10-13. *Bock* identifies atrial fibrillation (AF) events in ECG data of patients. *Id.* at 2:28-31; 1:38-41, 6-8; Ex. 1002 at ¶ 31.

In system 20 of *Bock*, ECG data is input into a classification module 22 "where the beats are detected and correlated to templates based on morphology." Ex. 1005 at 5:15-20; FIG. 2. A beat refers to an ECG signal from one complete heartbeat (for e.g., from a P wave to a second P wave, *see id.* at 1:15-32). Ex. 1002 at ¶ 32. "The beat classification module determines whether the heart beat being analyzed falls within classifications that are suitable for use in analyzing whether an AF condition exists. If the beat falls within a class suitable for analysis, the ECG information is fed to an interval calculator [24]." Ex. 1005 at 2:33-38. "The interval calculator determines the time interval between successive R waves (the 'RR interval')." *Id.* at 2:38-39; *see* also 5:29-30. The RR interval output from the "the interval calculator [24] is provided to a probability engine [40] and to a

contextual analysis module [30]." *Id.* at 2:39-41. The probability engine 40 "receives the beat classification data and RR interval value generated by modules 22 and 24 and calculates a probability that the ***current beat or rhythm is an AF arrhythmia***" and outputs a state variable indicating whether or not AF is present in that beat. *Id.* at 5:46-52; 6:53-55 (emphasis added). That is, system 20 of *Bock* identifies AF states by examining ECG data in multiple time intervals (i.e., multiple beats), and identifying intervals (beats) in which at least one AF state has occurred. *See* Ex. 1005 at 11:8-9. Ex. 1002 at ¶ 32.

iii. "obtaining heart rate data for the living being;"

System 20 of *Bock* obtains heart rate data from the ECG data of the patient. *Id.* at Abstract; 11:57-62; 12:9 – 11; 2:38-39. Specifically, *Bock* states that the "method … detect[s] irregular heart activity" and includes a "beat classification module [that] determines whether the heart beat being analyzed falls within classifications" for detecting an irregular condition. *Id.* at Abstract. *Bock* also states that "[t]he interval calculator [24] determines the time interval between successive R waves (the 'RR interval')" of the ECG. *Id.* at 2:38-39. The time interval between successive R waves of the ECG is related to the patient's heart rate and is heart rate data. Ex. 1002 at ¶ 33.

iv. "receiving a human assessment of a subset of the identified atrial fibrillation events; and"

As discussed in the claim construction section, "subset" should be construed as "some or all elements of a set." *See Supra* VII.1. Therefore, this limitation requires receiving human assessments of some or all of the identified atrial fibrillation events. Ex. 1002 at ¶ 34.

The probability engine 40 determines and outputs a state variable that indicates whether AF is present in a beat to both a state evaluation module 50 and contextual analysis module 30. Ex. 1005 at 5:46-52; 6:36-39, 53-55. The contextual analysis module 30 performs multiple tests to check if an AF state identified by the probability engine 40 is a true AF event or a false alarm. *Id.* at 2:46-52; 9:41-45. In one test, module 30 compares the physiological data associated with the identified AF state with common beat patterns (or block maps) that appear irregular but are not as a result of an AF event. *Id.* at 9:42-46. The results of these tests are provided to the state evaluation module 50. *Id.* at 6:42-43; *see also id.* at 2:47-54; 5:64-65; 9:63 – 10:28. Thus, module 30 assesses the validity of the AF states identified by the probability engine 40 and provides this information to the state evaluation module 50. *See id.* at 2:46-52; 9:41-45; Ex. 1002 at ¶ 35.

The output from the contextual analysis module 30 to the state evaluation module 50 is an algorithm-based assessment of the AF states identified by the probability engine 40. Ex. 1002 at ¶ 36. It would have been obvious to a POSITA

to modify *Bock* to incorporate "human" assessment based on the knowledge of one of ordinary skill in the art and the disclosure of *Walker*. *Id.* At the time of the alleged invention, a POSITA was well aware that it was important for arrhythmias detected by computer algorithms to be validated by technicians for accuracy. *Id.* For instance, the *ACC Guidelines* explain that "[i]t is critical that each classification of arrhythmia morphology and each ischemic episode be reviewed by an experienced technician or physician to ensure accurate diagnosis because AECG [ambulatory electrocardiography] recordings during routine daily activities frequently have periods of motion artifact of baseline wander that may distort the [ ] QRS morphology." Ex. 1008 at 913, 914, 917. Thus, based at least on these 1999 guidelines, at the time of the alleged invention (in late 2003), a POSITA would have known that it was "critical" to have algorithm-detected arrhythmias (such as *Bock*) validated by an experienced technician for accurate diagnosis especially when the method of *Bock* is used for ambulatory electrocardiography (AECG) recordings during Holter monitoring. Ex. 1002 at ¶ 36; *see* Ex. 1005 at 1:59-61.

Walker discloses techniques for "enhancing performance of computer-assisted data operating algorithms in a medical context." Ex. 1006 at Abstract. *Walker* contemplates the use of the disclosed technique for detecting arrhythmias in ECG signals. *Id*. at 17:29-32, 61-67. In *Walker*, diagnosis made by a computer

algorithm is iteratively improved by modifying the algorithm based on validation and feedback from human experts. *Id.* at Abstract. In *Walker*, physiological data (such as ECG data) from sensors 114 on a patient are processed and transmitted to a processing module 120 for analysis and then sent to a display/user interface 122 for output. *Id.* at 16:5-9, 18-31; 17:29-32; FIG. 9. Computer algorithms are used for analysis of the data in processing module 120. *Id.* at 46:35-44; Ex. 1002 at ¶ 37.

In *Walker*, with reference to FIG. 26 reproduced to the right, both an expert (step 400) and the algorithm (step 404) analyzes patient data (such as ECG data) for diagnostic events (e.g., arrhythmias). Ex. 1006 at 3:15-17; 71:60-62; 72:9-12; 11:3-6, 18-23; 17:55-67; 6:5-7. After analysis, the expert produces a dataset labeled D1 (step 402) and the algorithm produces a dataset labeled D2 (step 406). *Id.* at 72:3-5, 21-23. Optionally, the expert produced dataset D1 may be verified by an algorithm (step 408) to produce

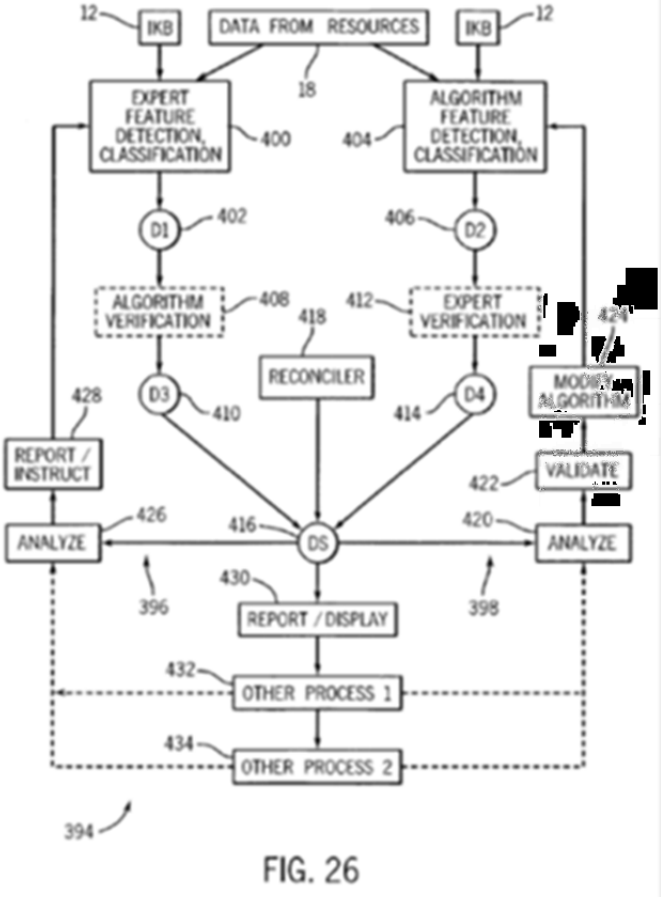


FIG. 26

dataset D3 (step 410), and the algorithm produced dataset D2 may be verified by an expert (step 412) to produce dataset D4 (step 414). *Id.* at 72:24-28, 45-46, 51-54, 62-63; Ex. 1002 at ¶ 38.

Walker discloses that dataset D4 may include "***changes*** made to [dataset D2] by the expert or medical professional." Ex. 1006 at 72:62-67 (emphasis added). When changes are made to the dataset D2 by the expert in step 412, the reconstructed dataset D4 would necessarily include some algorithm-identified events of dataset D2. Ex. 1002 at ¶ 39. Because of the changes made to dataset D2 by the expert, dataset D4 includes a subset of dataset D2. *Id.* Moreover, if no changes are made to dataset D2 by the expert in step 412, then dataset D4 includes all elements of dataset D2 (i.e., subset is less that all elements of a set), and if changes are made by the expert, then dataset D4 includes some elements of dataset D2 (i.e., subset is less that all elements of a set). *Id.*

A reconciler 418 (a medical professional) receives dataset D4 (a subset of identified events). Ex. 1006 at 73:1-2, 5-7, 10-14, 61-63. The discrepancies in datasets D3 (produced by the expert and verified by the algorithm) and D4 (produced by the algorithm and verified by the expert human) are then resolved by reconciler 418 to produce a dataset D5 (step 416) which is then reported and displayed (step 430). *Id.* at 73:1-2, 5-7, 10-14, 61-63; Ex. 1002 at ¶ 40. A person of ordinary skill would have recognized that the dataset D4 reviewed by the

reconciler 418 in this step includes a subset of the algorithm-produced dataset D2 because of the changes made by the expert in step 412. *Id.* at ¶ 41. In *Walker* "the clinicians [ ] interact with the data processing system [ ] through conventional input devices such as keyboards, computer mice, touch screens, portable or remote input and reporting devices." Ex. 1006 at 6:51-55. A POSITA would have recognized that reconciler 418 receives on a computer or other device dataset D4, which is a human assessment of a subset of the algorithm-identified events of dataset D2. Ex. 1002 at ¶ 41.

The changes made by the expert to the algorithm-produced dataset are used to modify parameters of the algorithm to improve future diagnosis. Ex. 1006 at 73:15-28. That is, in *Walker*, diagnosis (such as, arrhythmia, *see id.* at 3:15-17; 17:67) made a computer algorithm (dataset D2) is assessed and modified by a human in steps 412 and 418, and the modifications are used to refine the disclosed algorithm to improve its diagnostic capabilities. *See Id.* at 72:62-67; 73:5-7, 10-14, 21-28; Ex. 1002 at ¶ 42. *Walker* also states that, by using this iterative approach, the algorithm "may be specifically tailored for [a] patient by altering parametric settings to enhance the utility of future application of the algorithm." Ex. 1005 at 74:25-27; Ex. 1002 at ¶ 42.

Note that this claim limitation recites "receiving a human assessment of a subset of the identified atrial fibrillation events." This limitation <u>does not</u> recite

receiving human assessment of **only** a subset of the identified atrial fibrillation events. Therefore, under a broad and reasonable interpretation, the recited limitation will be satisfied if human assessments of **some or all** of the identified atrial fibrillation events are received, because receiving human assessments of all events necessarily satisfies receiving some human assessments of some events.

Based on the teachings of *Walker* and the *ACC Guidelines*, a POSITA would have recognized that modifying the contextual module 30 of *Bock* to assess, with human assistance, the AF states identified by probability engine 40 will improve accuracy of AF detection in *Bock*. Ex. 1002 at ¶ 43. *Bock* recognizes the difficulty of identifying AF over other irregular heart rhythms using computer algorithms and the importance of ensuring accurate AF diagnosis. Ex. 1005 at 2:4-17. The *ACC Guidelines* teach the importance of having algorithm-detected arrhythmias validated by an experienced technician to ensure accuracy of diagnosis especially during ambulatory cardiac monitoring. Ex. 1008 at 913, 914, 917. *Walker* teaches a technique of using human assessment to improve the accuracy of the diagnosis made by computer algorithms and to tailor the computer-based diagnosis for specific patients. Ex. 1006 at *Id.* 2:16-22; 74:21-29. Based on the *ACC Guidelines* and *Walker*, a POSITA would have recognized that modifying *Bock* to include human-assessment would assist in improving the accuracy of diagnosis especially during Holter monitoring where an ECG of an ambulatory patient is monitored.

See Ex. 1005 at 1:59-61; Ex. 1002 at ¶ 43. A POSITA also would have recognized that incorporating the human-assessment feature in *Bock* would assist the device in distinguishing AF rhythms in the physiological data from other irregular rhythms. Ex. 1002 at ¶ 43. A POSITA also would have recognized that incorporating this feature of *Walker* in *Bock* would enable the system to be tailored for AF diagnosis for different patients. Moreover, one of ordinary skill in the art would have appreciated that modifying system 20 of *Bock* by adding human-assessment as taught by *Walker* would have amounted to nothing more than the use of a known technique to improve a similar device that yields nothing more than predictable results. *See KSR Int'l. Co. v. Teleflex, Inc.*, 550 U.S. 398, 417 (2007).

v. "based on the human assessment of the subset of the identified atrial fibrillation events, pictographically presenting, using a common time scale, information regarding the heart rate data for the multiple time intervals during a defined time period in alignment with indications of atrial fibrillation activity for the identified intervals, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden,

In *Bock*, based on a correlation between each AF state identified by the probability engine 40 and the information from contextual analysis module 30 regarding the validity of this AF state, the state evaluation module 50 determines if a true AF event exists, and graphically presents it on a display. Ex. 1005 at 2:66-3:2; 6:6-13; 6:42-46.

In *Walker*, a reconciler 418 resolves the discrepancies in datasets D3 (produced by the expert) and D4 (produced by the algorithm) to produce a dataset (D5) which is then reported and displayed (step 430). Ex. 1006 at 73:1-2, 5-7, 10-14, 61-63. *Walker* reports and displays data based on a human assessment of a subset of the data identified by the algorithm. *See supra* Section IX.A.1.iv. As explained above, based at least on the teachings of *Walker* and the *ACC Guidelines*, it would have been obvious to a POSITA to incorporate the human assessment feature of *Walker* in *Bock* to enhance AF detection. *Id*. Thus, in *Bock* as modified by *Walker* and the *ACC Guidelines*, the state evaluation module 50 graphically displays the identified AF events based on human assessment of a subset of the identified AF events. Ex. 1002 at ¶ 44.

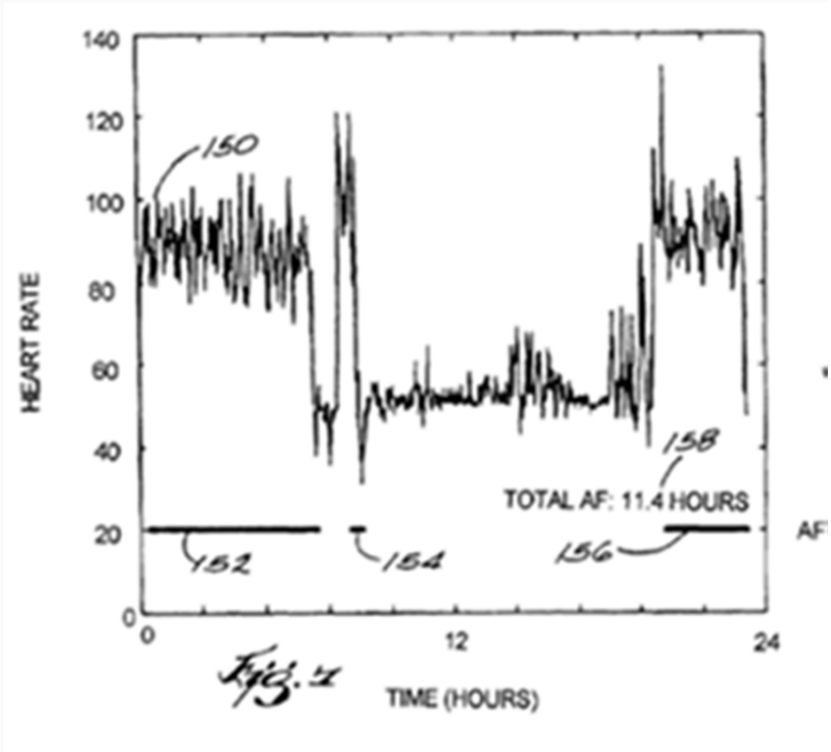


Fig. 7

The graphical display includes a trend line of heart rate (y-axis) over time (x-axis) for a defined time period. *See* Ex. 1005 at FIG. 7 reproduced above. Since the displayed trend line is a continuous waveform, the presented heart rate data includes heart rate data for the multiple time intervals (i.e., beats) of the ECG data examined by system 20. Ex. 1002 at ¶ 45. In the graph, "portions of the waveform during which an AF condition exists are marked with horizontal bars 152, 154, and 156, respectively." Ex. 1005 at 12:8-12. The width of each horizontal bar represents the duration of an AF event. Ex. 1002 at ¶ 45.

The '996 patent defines "atrial fibrillation burden" as "the overall amount of time that a patient is in atrial fibrillation (or arrhythmia) over a specified time period, taking into account the number and duration of episodes." Ex. 1001 at

3:58-62; *see* also FIGS. 2 and 4 which purportedly shows examples "of how to pictographically present both heart rate trend and atrial fibrillation burden on a common time scale." *Id.* at 4:1-3, 15-17. In FIGS. 2 and 4, the width of each bar represents the duration of an AF event. *Id.* at 4:6, 21. The only way of obtaining the "overall amount of time that a patient is in atrial fibrillation" for the illustrated time period (i.e., AF burden) from FIGS. 2 and 4 is by summing up the durations of each identified AF event. Ex. 1002 at ¶ 46. Similarly, summing up the durations (or widths) of the bars 152, 154, and 156 will yield AF burden from FIG. 7 of *Bock*. Ex. 1002 at ¶ 46. Additionally, the total AF time for the time period (24 hrs.) (i.e., AF burden) is displayed in FIG. 7 ("158" in FIG. 7). Ex. 1005 at 11:49-50; FIG. 7. Therefore, in FIG. 7 of *Bock*, heart rate trend is presented with atrial fibrillation burden. *Id.* at FIG. 7; Ex. 1002 at ¶ 46.

vi. "wherein pictographically presenting information regarding the heart rate data comprises displaying for each of the multiple time intervals a range of heart rates and a heart rate average."

FIG. 7 of *Bock* appears to display a continuous heart rate trend. As noted by the Examiner during prosecution, "a skil[l]ed artisan could easily determine the maximum and minimum heart rate for the given interval when looking at figure 7." Ex. 1003 at p. 171. Further, it would have been obvious to a POSITA to modify the heart rate display of *Bock* to display a range of heart rates and an average value

of the heart rate for a time interval based at least on common knowledge in the art and the teachings of *Reinhold*. Ex. 1002 at ¶ 47.

Reinhold discloses a remote cardiac monitoring system for monitoring patients using patient-worn units and remotely located office units. Ex. 1007 at Abstract. The patient-worn unit acquires the patient's physiological data and analyzes the data (using R-R intervals) in real time to determine heart rate and other arrhythmias. *Id.* at Abstract; 27:55-66. The analyzed data is sent by telemetry to the remotely located office unit. *Id.* at Abstract; 24:55-56. The office unit prepares a patient report for a physician. *Id.* at Abstract; *see* "Patient Report" at 29:60 – 32:15. This patient report includes FIG. 8 reproduced below. *Id.* at 30:49; Ex. 1002 at ¶ 48.

FIG. 8 plots the heart rate (*see* "R-R Rate" on the x-axis) in BPM (beats per minute) and other arrhythmic events (such as the frequencies of supraventricular extrasystole (SVE), premature ventricular contraction (PVC), etc.) which were recorded over the monitored time. Ex. 1007 at FIG. 8; 26:1-26; 27:55-66; 31:35-54; Ex. 1002 at ¶ 49. In FIG. 8, the heart rate is displayed as an average value for each hour (time interval). Ex. 1007 at FIG. 8. The range of heart rates (shown in FIG. 8 as a line between minimum ("MIN") and maximum ("MAX") heart rates) for each time interval is also displayed. *Id.*

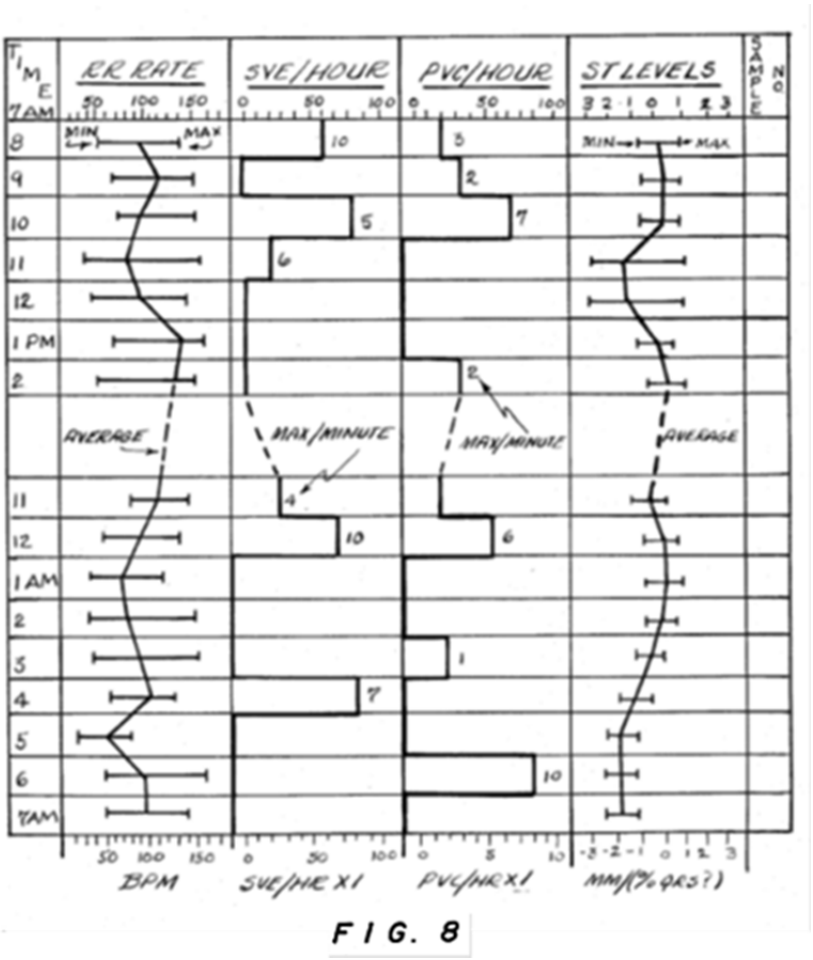


FIG. 8

Based at least on this teaching of *Reinhold*, it would have been obvious to a POSITA to modify the heart rate trend of FIG. 7 of *Bock* to show average values and ranges for different time intervals to allow a physician (or another medical professional who views the graph) to quickly determine the heart rate at any time and its variability. Ex. 1002 at ¶ 49.

In FIG. 7 of *Bock*, AF is displayed in one minute time intervals. *See* Ex. 1005 at 11:36-45. Specifically, the displayed bars 152, 154, and 156 (of AF) are "calculated by summing up the number of five-second time intervals in the one minute AF history and determining if the total time is greater than thirty seconds.

When there is more than thirty seconds of AF in a minute, then the trend variable is positive, if not, then the trend variable is zero for that minute." *Id.* at 11:40-44. A POSITA would have recognized that presenting heart rate also as an average over this (or any other) time interval, and indicating its range for the time interval, would enable the physician to quickly obtain heart rate and its variability from the graph. Ex. 1002 at ¶ 50. A POSITA would have recognized that, due to the noisy appearance of the heart rate waveform in *Bock* (*see* Ex. 1005 at FIG. 7), a physician would have to spend time and effort to determine the patient's heart rate at any particular time. Ex. 1002 at ¶ 50. For example, the POSITA would have known that it would be difficult for the physician to quickly determine the patient's heart rate accurately at a time of, for example, 2.4 hours after monitoring began (i.e., at the first indicator mark on the x-axis to the right of time = 0 in FIG. 7 of *Bock*) because the heart rate in this region appears to vary from about 80-100. Ex. 1005 at FIG. 7. Based at least on the teaching of *Reinhold*, a POSITA would have recognized that presenting the heart rate as an average value for a time interval and showing its range (as in FIG. 8 of *Reinhold*) would allow the physician to quickly determine the patient's average heart rate for this time interval and its variability (max-min). Ex. 1002 at ¶ 50. A POSITA would also have known that variability of the heart rate is an indicator of the patient's cardiac health (*see* Ex. 1008 at p. 18) and therefore would have been motivated to make this modification in the

heart rate trend in FIG. 7 of *Bock*. Ex. 1002 at ¶ 50. Such a modification would have amounted to nothing more than applying known techniques to a known method to yield predictable results. *See KSR*, 550 U.S. at 417.

2. Independent Claim 12

i. "An article comprising a machine-readable medium embodying information indicative of instructions that when performed by one or more machines result in operations comprising:"

As discussed with reference to claim 1, *Bock* discloses methods to detect arrhythmias, such as atrial fibrillation ("AF"). Ex. 1005 at 1:6-10; *see supra* Section IX.A.1.i. *Bock* states that the method "is intended to be implemented in software running on a computer … capable of executing instructions and having such common hardware components as a central processor, memory, and input and output devices." Ex. 1005 at 4:3:65-67. A memory of the computer that stores this software is the recited "article comprising a machine-readable medium." Ex. 1002 at ¶ 51.

ii. "identifying atrial fibrillation events in physiological data obtained for a living being, wherein identifying atrial fibrillation events comprises examining the physiological data in multiple time intervals, and identifying intervals in which at least one atrial fibrillation event has occurred;"

As discussed with reference to claim 1, the method of *Bock* identifies AF events from physiological data of a patient by examining the physiological data in multiple time intervals (beats), and identifying intervals in which at least one atrial

AF event has occurred. Ex. 1005 at 2:28-31; 1:38-41, 6-8; 5:46-52; 6:53-55; *supra* Section IX.A.1.ii; Ex. 1002 at ¶ 52.

iii. "obtaining heart rate data for the living being;"

As discussed with reference to claim 1, system 20 of *Bock* obtains heart rate data from the ECG data of the patient. Ex. 1005 at Abstract; 11:57-62; 12:9-11; 2:38-39; *supra* Section IX.A.1.iii; Ex. 1002 at ¶ 53.

iv. "receiving a human assessment of a subset of the identified atrial fibrillation events; and"

As discussed with reference to claim 1, in system 20 of *Bock* as modified by *Walker* and the *ACC Guidelines*, the state evaluation module 50 receives human assessments of a subset the AF states identified by probability engine 40. *Supra* Section IX.A.1.iii; Ex. 1002 at ¶ 54.

v. "based on the human assessment of the subset of the identified atrial fibrillation events, pictographically presenting, using a common time scale, information regarding the heart rate data for the multiple time intervals during a defined time period in alignment with indications of atrial fibrillation activity for the identified intervals, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden,

As discussed with reference to claim 1, in *Bock* as modified by *Walker* and the *ACC Guidelines*, heart rate trend and duration of AF activity for a defined time period is presented on a common time scale such that heart rate trend is presented with AF burden based on human assessment of a subset of the identified AF states. Ex. 1005 at 11:45-49; FIG. 7; *supra* Section IX.A.1.v; Ex. 1002 at ¶ 55.

vi. "wherein pictographically presenting information regarding the heart rate data comprises displaying for each of the multiple time intervals a range of heart rates and a heart rate average."

As discussed with reference to claim 1, in system 20 of *Bock* as modified by *Walker* and the *ACC Guidelines* and further modified by *Reinhold*, presenting information regarding the heart rate data includes displaying a range of heart rates and a heart rate average for each time interval. Ex. 1005 at FIG. 7; Ex. 1007 at FIG. 8; *supra* Section IX.A.1.vi; Ex. 1002 at ¶ 56.

3. Independent Claim 18

i. "An apparatus comprising:"

Bock discloses "[a] method and apparatus to detect irregular heart activity" of a patient. Ex. 1005 at Abstract; *id.* at 1:6-8, 52-56; Ex. 1002 at ¶ 57.

ii. "means for identifying atrial fibrillation events in physiological data obtained for a living being based on examination of the physiological data in multiple time intervals to identify intervals in which at least one atrial fibrillation event has occurred;"

As discussed with reference to claim 1, system 20 of *Bock* receives ECG data from a patient and outputs "a state variable, which indicates … a minute-by-minute … state of AF" (atrial fibrillation) based on examination of the ECG data in multiple time intervals (beats) to identify intervals in which at least one atrial fibrillation event has occurred. Ex. 1005 at 1:6-8, 52-56; 5:15-16, 46-52; 6:53-55; 11:36-39; *supra* Section IX.A.1.ii. Thus, system 20 of *Bock* performs the recited function of "identifying atrial fibrillation events in physiological data obtained for

a living being." *Bock* discloses that system 20 can "be implemented in software running on a computer," or may be "created using hard-wired circuits." Ex. 1005 at 3:65-67; 4:8-9. The structures of system 20 of *Bock* form the recited "means for identifying atrial fibrillation events" as construed in the claim construction section. *See supra* Section VII.2.a; Ex. 1002 at ¶ 58.

iii. "means for obtaining heart rate data for the living being;"

In *Bock*, heart rate of the living being is obtained. Ex. 1005 at Abstract; 1:6-8, 52-56; 11:57-62; 12:9-11; *see supra* Section IX.A.1.iii. Specifically, *Bock* states that "[t]he interval calculator 24 determines intervals between R waves and outputs an RR interval value," to contextual analysis module 30. Ex. 1005 at 5:29-32. "The probability engine 40 also receives [ ] the RR interval value." *Id.* at 5:42-43; *see also id.* at 6:32-35. Thus both contextual analysis module 30 and probability engine 40 of *Bock* perform the recited function of "obtaining heart rate data for the living being." *Bock* discloses that system 20 (including the contextual analysis module 30 and the probability engine 40) can "be implemented in software running on a computer," or may be "created using hard-wired circuits." *Id*. at 3:65-67, 4:8-9. Therefore, the structures of the contextual analysis module 30 and the probability engine 40 of *Bock* form the recited "means for obtaining heart rate data" as construed in the claim construction section. *See supra* Section VII.2.b; Ex. 1002 at ¶ 59.

iv. "means for receiving a human assessment of a subset of the identified atrial fibrillation events; and"

As discussed with reference to claim 1, in *Bock* as modified by *Walker* and the *ACC Guidelines*, the state evaluation module 50 receives human assessments of a subset of the AF states identified by probability engine 40. *Supra* Section IX.A.iv. Thus, the state evaluation module 50 of *Bock* performs the recited function of "receiving a human assessment" of a subset of the identified atrial fibrillation events. *Bock* discloses that system 20 (including the state evaluation module 50) can "be implemented in software running on a computer," or may be "created using hard-wired circuits." Ex. 1005 at 3:65-67; 4:8-9. The structures of the state evaluation module 50 of *Bock* form the recited "means for receiving a human assessment" as construed in the claim construction section. *See supra* Section VII.2.c; Ex. 1002 at ¶ 60.

v. "means for pictographically presenting, based on the human assessment of the subset of the identified atrial fibrillation events, information regarding the heart rate data for the multiple time intervals during a defined time period in alignment with indications of atrial fibrillation activity for the identified intervals, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden, and"

As discussed with reference to claim 1, in *Bock* as modified by *Walker* and the *ACC Guidelines*, the state evaluation module 50 (of *Bock*) graphically displays information regarding heart rate data and AF activity in the recited manner based

on human assessment of a subset of the identified AF events. *Supra* Section IX.A.1.v. Thus, the state evaluation module 50 of *Bock* performs the recited function of "pictographically presenting" the recited information in the recited manner. *Bock* discloses that system 20 (including the state evaluation module 50) can "be implemented in software running on a computer," or may be "created using hard-wired circuits." Ex. 1005 at 3:65-67; 4:8-9. The structures for the state evaluation module 50 of *Bock* form the recited "means for pictographically presenting" as construed in the claim construction section. *See supra* Section VII.2.d; Ex. 1002 at ¶ 61.

vi. "a range of heart rates and a heart rate average are displayed for each of the multiple time intervals"

As discussed with reference to claim 1, in *Bock* as modified by *Walker* and the *ACC Guidelines* and further modified by *Reinhold*, a range of heart rates and a heart rate average are displayed for each of the multiple time intervals. *Supra* Section IX.A.1.vi; Ex. 1002 at ¶ 62.

4. Independent claim 23

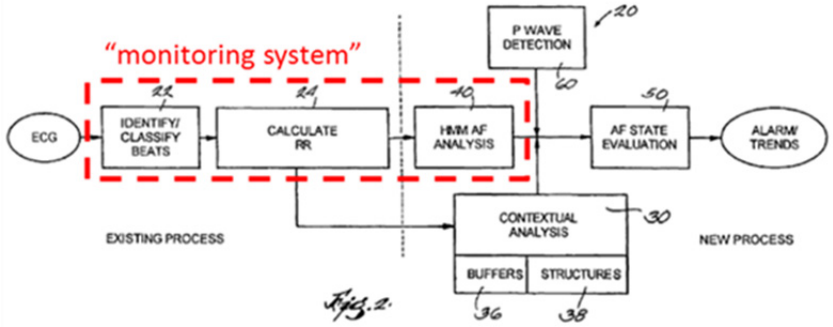
i. "A system for reporting information related to arrhythmia events comprising:"

Bock discloses "methods and devices used to detect irregularities in the beating of an animal heart, generally known as 'arrhythmias.' " Ex. 1005 at 1:6-8. More particularly, *Bock* discloses "a method and an apparatus to detect atrial

fibrillation ('AF')." *Id*. at 1:8-10. In *Bock*, information related to the detected arrhythmias is reported as a graph. Ex. 1005 at 11:45-49; FIG. 7; Ex. 1002 at ¶ 63.

ii. "a monitoring system configured to process and report physiological data, including heart rate data, for a living being, configured to identify atrial fibrillation events from the physiological data, and"

FIG. 2 of *Bock* is reproduced to the right and annotated with a dashed box to indicate the "monitoring system." As



illustrated in this FIG. 2, the classification module 22, interval calculator 24, and the probability engine 40 of system 20 form the recited "monitoring system" that is configured to process and report physiological data, including "heart rate data" (RR intervals), for a living being and configured to identify arrhythmia events from the physiological data. Ex. 1002 at ¶ 64.

In system 20 of *Bock*, physiological data in the form of ECG from a living being is input into a classification module 22 which determines whether the heartbeat is suitable for use in analyzing whether an AF condition exists. Ex. 1005 at 2:33-36. If it is, the ECG information is directed to an interval calculator 24. *Id.* at 2:36-38. "The interval calculator determines the time interval between successive R waves (the 'RR interval')," and provides the RR interval output to a

probability engine 40 and a contextual analysis module 30. *Id.* at 2:38-41; *see* also 5:29-30. The probability engine 40 "receives the beat classification data and RR interval value generated by modules 22 and 24 and calculates a probability that the current beat or rhythm is an AF arrhythmia" and outputs a state variable indicating whether or not an AF (atrial fibrillation) event is present in that beat. *Id.* at 5:46-52; 6:53-55. Atrial fibrillation is a form of arrhythmia. Ex. 1002 at ¶ 65; *see also* Ex. 1005 at 1:6-10. *Bock* states that the components of FIG. 2 may be software components or hard-wired circuits. *Id.* at 4:5-9.

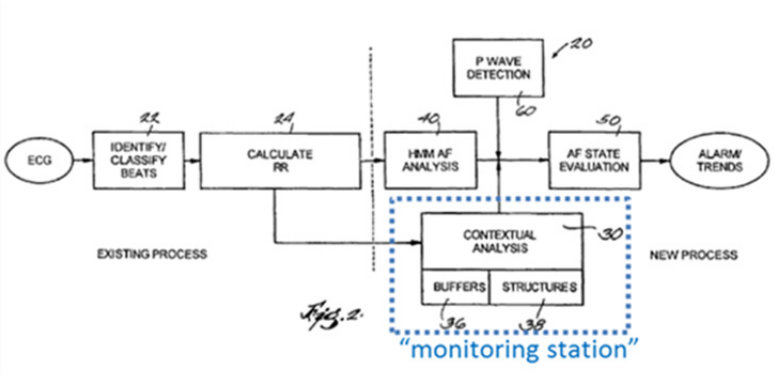
iii. "configured to examine the physiological data in multiple time intervals to identify intervals in which at least one atrial fibrillation event has occurred;"

As discussed above, in *Bock*, ECG data is input into the classification module 22 "where the beats are detected and correlated to templates based on morphology." *Id.* at 5:15-20; FIG. 2. A beat refers to an ECG signal from one complete heartbeat (e.g., from a P wave to a second P wave, *see id.* at 1:15-32). Ex. 1002 at ¶ 66. "The beat classification module determines whether the heart beat being analyzed falls within classifications that are suitable for use in analyzing whether an AF condition exists. If the beat falls within a class suitable for analysis, the ECG information is fed to an interval calculator [24]." Ex. 1005 at 2:33-38. The interval calculator determines the time interval between successive R waves in the signal (the 'RR interval') and directs it to output to the probability engine 40

and the contextual analysis module 30. *Id.* at 2:38-41; *see also* 5:29-30. The probability engine 40 "receives the beat classification data and RR interval value generated by modules 22 and 24 and calculates a probability that the ***current beat or rhythm is an AF arrhythmia***" and outputs a state variable indicating whether or not AF is present in that beat. *Id.* at 5:46-52; 6:53-55 (emphasis added). Thus, probability engine 40 of the monitoring system identifies AF states by examining ECG data in multiple time intervals (i.e., multiple beats), and identifying intervals (beats) in which at least one AF state has occurred. *See id.* at 11:8-9; Ex. 1002 at ¶ 66.

iv. "a monitoring station for receiving the physiological data from the monitoring system; and"

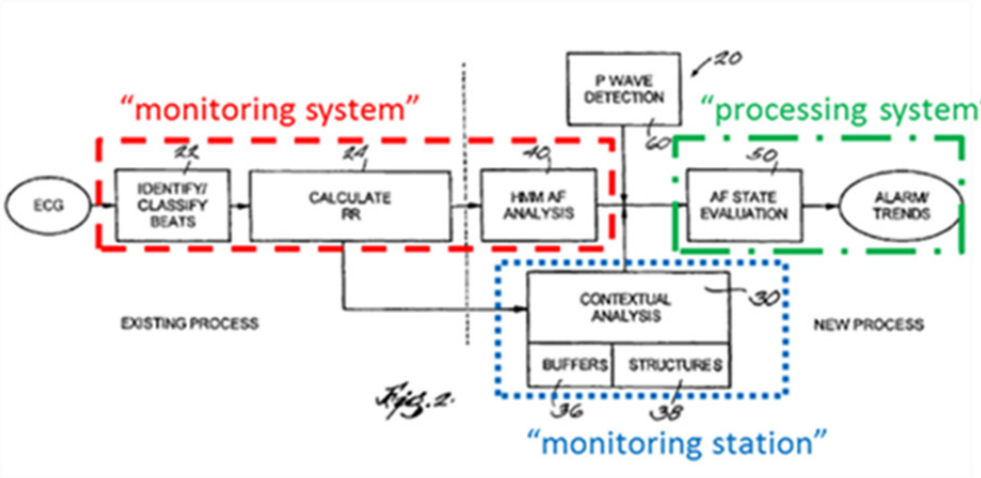
FIG. 2 of *Bock* is reproduced below and annotated with a dashed box to indicate the "monitoring station." As discussed above, the classification module 22, interval calculator 24, and the probability engine 40 of system 20 form the recited "monitoring system." *See supra* Section IX.A.4.ii. The AF detected by the probability engine 40 and the RR interval values from interval calculator 24 are output to a contextual analysis module 30. Ex. 1005 at 6:32-38. "The contextual



analysis module matches predefined maps to the running map of the current ECG information. The contextual analysis module also determines the similarity between consecutive RR intervals." *Id.* at 2:46-49. In system 20, the contextual analysis module 30 is the recited "monitoring station" that receives the physiological data from the monitoring system. Ex. 1002 at ¶ 67

v. "a processing system configured to:

System 20 of *Bock* includes a "processing system." FIG. 2 of *Bock* reproduced below is annotated with dashed boxes to indicate the "monitoring station," the "monitoring system," and the "processing system."



vi. "receive a human assessment of a subset of the identified atrial fibrillation events, and"

With reference to FIG. 2 of *Bock* annotated and reproduced above (*supra* Section IX.A.4.v.), state evaluation module 50 of system 20 receives the state variable that indicates whether an AF condition is present from the probability engine 40. Ex. 1005 at 2:41-45; 5:51-53; 6:53-55. The AF state from the

probability engine 40 and the RR interval values from interval calculator 24 are also output to the contextual analysis module 30. *Id.* at 6:32-38; Ex. 1002 at ¶ 69.

The contextual analysis module 30 performs multiple tests to check if the AF state detected by the probability engine is a true AF event or a false alarm. Ex. 1005 at 2:46-52; 9:41-45. In one test, module 30 compares the physiological signal associated with the detected AF state with common beat patterns (or block maps) that appear irregular but are not as a result of an AF event. *Id.* at 9:42-46. The results of these tests are provided to the state evaluation module 50. Ex. 1005 at 6:42-43; *see also id.* at 2:47-54; 5:64-65; 9:63 – 10:28; Ex. 1002 at ¶ 70.

As discussed with reference to claim 1, the assessments of the AF states by module 30 are analyzed by an algorithm. It would have been obvious to a POSITA to incorporate "human" assessment in *Bock* in light of the knowledge of one of ordinary skill in the art and the disclosure of *Walker* and the *ACC Guidelines* to improve the accuracy of *Bock*'s algorithm-based diagnostics. *See supra* Section IX.A.1.iv; Ex. 1002 at ¶ 71.

vii. "pictographically present based on the human assessment of the subset of the identified atrial fibrillation events, information regarding the heart rate data for the multiple time intervals during a defined time period in alignment with indications of atrial fibrillation activity for the identified intervals, according to the identified atrial fibrillation events, during the defined time period such that heart rate trend is presented with atrial fibrillation burden, and"

As discussed with reference to claim 1, in *Bock* as modified by *Walker* and the *ACC Guidelines*, the state evaluation module 50 (of *Bock*) ("processing system") graphically displays information regarding heart rate data and AF activity in the recited manner based on human assessment of a subset of the identified AF events. *Supra* Section IX.A.1.v; Ex. 1002 at ¶ 72.

viii. "a range of heart rates and a heart rate average are displayed for each of the multiple time intervals."

As discussed with reference to claim 1, in *Bock* as modified by *Walker* and the *ACC Guidelines* and further modified by *Reinhold*, a range of heart rates and a heart rate average are displayed for each of the multiple time intervals. *Supra* Section IX.A.1.vi; Ex. 1002 at ¶ 73.

B. Ground 2 - Alternate Theory of Obviousness of Claims 1, 12, 18, and 23 based on *Bock*, *ACC Guidelines*, *Walker*, and *Reinhold*

As discussed in Ground 1, *Bock*, *ACC Guidelines*, *Walker*, and *Reinhold* render claims 1, 12, 18, and 23 obvious. Ground 2 is presented in the event that the Board (a) interprets "subset" in claims 1, 12, 18, and 23 to mean a set that is "less than all" the elements of a given set (as construed by the courts in the related litigations (*see Supra* Section VII.1)), (b) interprets the recited limitation of "receiv[ing] a human assessment of a subset of" atrial fibrillation events (as recited in these claims) to require receiving human assessment **of only** some elements of the set, and (c) finds that *Walker* does not teach this feature. Petitioner notes that,

for the analysis of Ground 1 to be invalid, the Board needs to find all three of (a), (b), and (c) above to be true. As explained below, a POSITA would have recognized that contextual analysis module 30 of the combined device of *Bock*, *ACC Guidelines*, *Walker*, and *Reinhold* could be modified (if necessary) to receive human assessment of a set of AF states less than all AF states output from probability engine 40. Ex. 1002 at ¶¶ 74, 75.

A person or ordinary skill in the art would have recognized that reducing the amount of events assessed by the human would (1) increase the efficiency and decrease cost of the system and (2) be an inevitable result of the system. Ex. 1002 at ¶ 74. A person of ordinary skill in the art would have realized that having a human assess all the algorithm-detected events would be a slow, time consuming, and costly process because an algorithm can process data significantly faster and at less expense than a human. Ex. 1002 at ¶ 74. Based at least on this knowledge, a person of ordinary skill in the art would have been motivated to modify the combined system of *Bock*, *ACC Guidelines*, *Walker*, and *Reinhold* to have the human technician review only a portion of the events detected by probability engine 40. *Id*.

Walker describes an iterative process whereby the parameters of the algorithm are modified so that the algorithm's assessments conform to the technician's assessments. Ex. 1006 at 73:25-28; Ex. 1002 at ¶ 75. A person of

ordinary skill in the art would have recognized that, as the algorithm-assessments begin to conform to the technician's assessments, the technician's assessments (i.e., human assessments) can be carried out on less than all of the algorithm-assessments without sacrificing accuracy. Ex. 1002 at ¶ 75. A person of ordinary skill in the art would appreciate that reviewing a portion of the algorithm-identified AF states identified by probability module 40 would still ensure accurate diagnosis and would be an efficient and effective method of evaluating the algorithm-based AF states identified by probability module. *Id.* That is, the combined system of *Bock*, *ACC Guidelines*, *Walker*, and *Reinhold* could be modified to receive a human assessment of less than all of the algorithm-based AF states identified by probability engine 40. Ex. 1002 at ¶ 75. Indeed, doing so would have amounted to nothing more than the use of a known technique to improve a similar device that yields nothing more than predictable results. *See KSR*, 550 U.S. at 417.

It was well-known at the time of the alleged invention to have algorithm-identified atrial fibrillation events "reviewed by an experienced technician or physician to ensure accurate diagnosis because AECG [ambulatory electrocardiography] recordings during routine daily activities frequently have periods of motion artifact of baseline wander that may distort the [ ] QRS morphology." Ex. 1008 at 913, 914, 917; *see* Ex. 1002 at ¶ 36. One of ordinary skill at the time of the alleged invention would have understood that the combined

device of *Bock*, *ACC Guidelines*, *Walker*, and *Reinhold* could be modified to have a technician review some of, rather than all of, the algorithm-identified atrial fibrillation events. Ex. 1002 at ¶¶ 74-75. A POSITA would appreciate that reviewing a portion of the algorithm-identified AF states identified by probability module 40 would still ensure accurate diagnosis and would be an efficient and effective method of evaluating the algorithm-based AF states identified by probability engine 40. *Id.* To a POSITA, such a modification of the operation of the device of *Bock*, *ACC Guidelines*, *Walker*, and *Reinhold* would constitute no more than an obvious design choice—one of a "finite number of identified, predictable solutions"—to one skilled in the art. *Id*; *see also KSR*, 550 U.S. at 402-3 ("[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a POSITA has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense."). Thus, the combined device of *Bock*, *ACC Guidelines*, *Walker*, and *Reinhold* could be modified to receive a human assessment of less than all of the algorithm-based AF states identified by probability module 40, thus satisfying a narrow claim construction of "subset." Ex. 1002 at ¶¶ 74-75.

IX. CONCLUSION

For all of the foregoing reasons, the Petition for *Inter Partes* Review should be granted.

Respectfully submitted,

Dated: August 10, 2015

/Leslie Bookoff/

Leslie Bookoff (Reg. No. 38,084)
Bookoff McAndrews, PLLC
2401 Pennsylvania Ave., N.W.
Washington, D.C. 20037
(202) 808-3550

Attorneys for Petitioner
InfoBionic Inc.

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), I hereby certify that on August 10, 2015, I caused to be served a true and correct copy of the foregoing "PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 7,907,996" and INFOBIONIC EXHIBITS 1001-1014 by Federal Express on the Patent Owner at the following correspondence address of record for Patent No. 7,907,996, and at the following correspondence address for the Patent Owner's litigation counsel:

ROPES & GRAY LLP
IPRM - Floor 43
PRUDENTIAL TOWER
800 BOYLSTON STREET
BOSTON, MA 02199-3600

JOHN P. BUEKER, ESQ.
ROPES & GRAY LLP
PRUDENTIAL TOWER
800 BOYLSTON STREET
BOSTON, MA 02199-3600

Dated: August 10, 2015

Respectfully submitted,

By: */Leslie Bookoff/*
Leslie Bookoff
Reg. No. 38,084