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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Application Number: 16/952,943
Filing Date: 19 Nov 2020
Appellant(s): Biosense Webster (Israel) Ltd.

Brandon Theiss
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/16/2025.

(1) Grounds of Rejection to be Reviewed on Appeal

Every ground of rejection set forth in the Office action dated 04/01/2025 from which the appeal is taken is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(2) Response to Argument

For the rejection of claims 1-20 and 22-24 under 35 U.S.C. 101, Appellant's arguments in the Brief on appeal have been fully considered but are not persuasive essentially for reasons of record and arguments addressed below.

Appellant asserts that the invention is not a result-oriented command to "detect arrhythmia," but a concrete technique implemented in a particular medical device context that transforms raw catheter signals into a position-registered, emphasized heart map used during the procedure (Appeal Brief, page 12). See Application, ¶¶0020-0025. However, the only structure claimed is a catheter with a plurality of electrodes and that amounts to pre-solution activity of data gathering. Additionally, "a catheter" is recited at a high level of generality and this type of catheter would include all intra-cardiac catheters capable of acquiring electrogram (EGM) signals. Detecting the cardiac arrhythmia is part of the abstract idea.

Appellant asserts that under Step 2A, Prong 2, any mathematical operations are integrated into a practical application: sensor acquisition and pre-processing feed the beat-bounded, derivative-weighted correlation whose thresholded output updates a cardiac map and emphasizes affected anatomy, which is the device's operative output during mapping (Appeal Brief, pages 12-13). See *Diamond v. Diehr*, 450 U.S. 175, 191-92 (1981); *Thales Visionix Inc. v. United States*, 850 F.3d 1343, 1348-

50 (Fed. Cir. 2017). However, the sensor acquisition amounts to pre-solution activity of data gathering. The steps performed after the data gathering amount to the abstract idea itself.

Appellant asserts that claims 15 and 16 in particular, the display and mapping limitations recite a specific user-interface behavior tied to the algorithmic state of the device and aimed at solving an intra-procedural usability problem, which falls squarely within the Federal Circuit's user-interface eligibility decisions (Appeal Brief, page 13). See *Trading Techs. Int'l, Inc. v. CQG, Inc.*, 675 F. App'x 1001, 1004-05 (Fed. Cir. 2017); *Core Wireless Licensing S.A.R.L. v. LG Elecs., Inc.*, 880 F.3d 1356, 1362-63 (Fed. Cir. 2018); *Data Engine Techs. LLC v. Google LLC*, 906 F.3d 999, 1007-10 (Fed. Cir. 2018). In this case, the displaying limitation is insignificant post-solution activity because it amounts to nothing more than displaying the results of steps being performed to detect a cardiac arrhythmia, which is considered abstract.

Appellant asserts that under Step 2B, the Office has not met its evidentiary burden to show that the specific claimed combination was well-understood, routine, and conventional: maximum-slope per-channel weighting applied to a template-bounded, multi-channel correlation within a heartbeat-length window, used to gate a position-registered map update with anatomical emphasis (Appeal Brief, page 13). However, the steps listed are not additional elements. They are part of the abstract idea.

A. Claims 1-20 and 22-24 are directed to a concrete intracardiac mapping system and a rule-bound control sequence for processing multi-electrode intracardiac EGMs, not to an abstract objective of detecting arrhythmia

Appellant asserts that the level of claimed specificity of the prescribed sequence changes how the device processes domain-specific physiological timeseries data, which falls on the eligible side of Step 2A (Appeal Brief, page 15). However, the Examiner disagrees. The steps sequence of processing the data amount to the abstract idea. An improvement to the abstract idea is still an abstract idea.

1. "Each Case Turns on Its Facts": On These Facts, the Claims Recite a Device-Embedded Technical Improvement, and *Intellectual Ventures* Is Inapposite

Appellant asserts that the claims are directed to a concrete signal-processing improvement to an EP mapping system, aligning with decisions upholding eligibility for similarly specific, domain-tied methods that improve technology rather than claim abstract ends (Appeal Brief, page 16). See *CardioNet, LLC v. InfoBionic*, Inc., 955 F.3d 1358, 1370-73 (Fed. Cir. 2020) (claims "focused on a specific means or method that improves" cardiac monitoring); *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1313-16 (Fed. Cir. 2016) (rule-based processing of time-series data eligible); *Thales*, 850 F.3d at 1348-50 (non-conventional sensor math improving system operation is not abstract). However, the Examiner disagrees. The steps in the sequence of processing the data amount to the abstract idea. An improvement to the abstract idea is still an abstract idea.

Appellant asserts that these claims do not take a preexisting manual method and make it faster; they require a different method-median-filter-derived activity signals, activity-threshold-bounded POIs, and derivative-based per-channel weighting applied to multi-channel correlation-implemented in the specific context of intracardiac EGM acquisition and used to drive device behavior (e.g., thresholded arrhythmia detection and map emphasis in the apparatus/dependents) (Appeal Brief, page 17). However, even if this is a different method, it is still directed to the abstract idea. Additionally, MPEP 2106.05 recites:

> As made clear by the courts, the "'novelty' of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter." *Intellectual Ventures I v. Symantec Corp.*, 838 F.3d 1307, 1315, 120 USPQ2d 1353, 1358 (Fed. Cir. 2016) (quoting *Diamond v. Diehr*, 450 U.S. at 188–89, 209 USPQ at 9). See also *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1151, 120 USPQ2d 1473, 1483 (Fed. Cir. 2016) ("a claim for a new abstract idea is still an abstract idea. The search for a § 101 inventive concept is thus distinct from demonstrating § 102 novelty.").

Appellant asserts that the Office has identified no evidence that this particular combination-template-bounded correlation with derivative-based channel weighting in intracardiac EGMs-was well-

understood, routine, and conventional (Appeal Brief, page 17). However, these steps are not additional elements and are part of the abstract idea itself.

2. The Amended Claims Are Focused On A Technological Improvement To Medical Devices And Are Therefore Patent-Eligible Under *CardioNet, LLC V. InfoBionic, Inc.*

Appellant asserts that accordingly, like in *CardioNet*, the present claims "do not merely collect electronic information, display information, or embody mental processes" and, therefore, "do not fit into the familiar class of claims that focus on certain independently abstract ideas that use computers as tools and instead "they fit into the class of claims that focus on an improvement in computers [and other technologies] as tools" (Appeal Brief, page 22). *CardioNet*, 955 F.3d at 1371. However, each case turns on its own facts. In the case of *CardioNet*, the claims were found to be directed to an improvement to cardiac monitoring technology. Specifically, the written description does not disclose that doctors performed the same techniques as the claimed device in diagnosing atrial fibrillation or atrial flutter. *Id.* at 1370. Indeed, as discussed above, nothing in the record supports the district court's fact finding (and InfoBionic's assertion) that doctors long used the claimed diagnostic processes. *Id.* However, in the case of the instant application, there is not an improvement because the improvement is directed to the abstract idea itself.

Appellant asserts that the claims recite the basic steps that any doctor could (and would) perform to make such diagnoses-collecting and analyzing a patient's heartbeat data" (Appeal Brief, page 23). *Id.* However, this was used because specifically, the written description does not disclose that doctors performed the same techniques as the claimed device in diagnosing atrial fibrillation or atrial flutter. *Id.* Indeed, as discussed above, nothing in the record supports the district court's fact finding (and InfoBionic's assertion) that doctors long used the claimed diagnostic processes. *Id.* Whereas in the present application, processes for detecting cardiac arrhythmias have been done before.

Appellant states that like *CardioNet*, the claims recite a specific rule-bound technique that improves cardiac-signal diagnostics: median filtering → activity threshold → POI → weighted multi-channel correlation (with weights from maximum slope) → thresholded detection. The focus is not the result "detect arrhythmia," but the particular technique implemented in a cardiac device context (Appeal Brief, page 24). However, the Examiner cites Appellant to MPEP 2106.05 recited above. Additionally, the particular technique implemented is directed to the abstract idea itself.

3. The Amended Claims Are Not Directed To An Abstract Idea And Are Therefore Patent-Eligible Under *Thales Visionix, Inc. V. United States*.

Appellant states that similar to the patent-eligible claims in *Thales*, the amended claims also use sensors (i.e., a first sensor respective one or more electrodes arranged for insertion into a heart of the patient for acquiring unipolar pattern intra-cardiac (IC) electrogram (EGM) signals from an area of the heart) in an unconventional manner to solve a problem that originates from attempting to use data that originates from different sources (i.e. detect the cardiac arrhythmia) (Appeal Brief, page 26). However, the Examiner disagrees. The plurality of electrodes of a catheter is a well-understood, routine, and conventional structure as shown in US 20040059237 (¶79), US 9259165 (col. 4 and lines 8-9), and US 10271758 as cited in the IDS (col. 7 and lines 36-38).

Appellant asserts that the inertial sensors are conventional, and clearly, mounting sensors on an object is conventional. However, the Court ruling was based on how the data was used to solve a technical problem: the orientation of the frames of reference. Just like in *Thales*, the present invention uses the sensor data to solve a technical problem, namely the detection of cardiac arrhythmia. Accordingly, like in *Thales*, the present claims are patent-eligible (Appeal Brief, page 28). However, in Thales, "the claims use inertial sensors in a non-conventional manner." *Thales*, 850 F.3d at 1348-49. The sensors in the present application are used in a conventional way. As previously stated, it is known to gather data using a catheter with electrodes.

4. The Present Claims Are Patent-Eligible Under *Ex Parte Fautz* and *Thales* as They Provide a Technological Improvement in Medical Diagnostics

Appellant asserts that the PTAB in *Ex Parte Fautz* found the claims were not directed to abstract ideas but practical applications that enhanced the functionality of a medical device. Similarly, the present claims utilize mathematical analysis of biometric data to improve cardiac mapping accuracy during electrophysiology procedures, addressing the real-world issue of erroneous heart mapping (Appeal Brief, page 29). However, in *Ex Parte Fautz*, the independent claims recite a practical application, as the results improve the output by reconstructing image data of the examination subject on the basis of the sum signal. *Ex Parte Fautz* (Appeal No. 2019-000106) (PTAB May 15, 2019). In the instant application, detecting an arrhythmia is known in the prior art.

Appellant asserts that *Thales* supports claims that use sensors in a non-conventional manner to improve how a system determines a physical condition (there, pose; here, arrhythmia activation across electrode positions). *Ex Parte Fautz* (informative) confirms that mathematical operations embedded in, and improving, a medical device's operation are not abstract under Step 2A, Prong 2. Here, the derivative-based weighting of template channels and POI-bounded correlation improve sensitivity/specificity of real-time mapping, i.e., operation of the EP system itself (Appeal Brief, page 34). However, unlike in *Thales* where the sensors were used in a conventional manner, there is no criticality in the specification indicating that the electrodes on the catheter are used in a way that is not well-understood, routine, and conventional. Unlike in *Ex Parte Fautz* where there was an improvement, the instant application is directed to an improvement of the abstract idea itself.

5. Like The Hypothetical Patent-Eligible Example In The MPEP, The Present Claims Measure Physiological Parameters And Are, Therefore, Similarly Patent-Eligible Under 35 U.S.C. §101

Appellant asserts that example claims "an earring comprising a sensor for taking periodic blood glucose measurements and a memory for storing measurement data from the sensor" do not recite an abstract idea. Like that hypothetical example, the present claims are also directed to a method of measuring physiological parameters (Appeal Brief, page 36). However, unlike the earring with a sensor and memory where there was no judicial exception, there is an abstract idea in the instant application.

Appellant asserts that the Examiner cites no evidence that the claimed particular combination of steps was well-understood, routine, and conventional (Appeal Brief, page 37). However, these steps are directed to the abstract idea itself and are not additional elements.

6. Like Example 4 In The 2019 Patent Eligibility Guidance, When Viewed In Combination, The Claims Amount To Significantly More Than The Judicial Exception (Step 2B)

Appellant cites to Example 4 of the Subject Matter Eligibility Examples and states that the claim is patent-eligible as it includes specific components and interactions that improve GPS technology by enhancing signal acquisition and accuracy in weak-signal environments, thus providing significantly more than the abstract idea alone (Appeal Brief, page 40). Appellant adds that the present claim includes specific components and interactions that improve the accuracy of the detection of cardiac arrhythmias (Appeal Brief, page 40). However, unlike in Example 4, where the combination of elements (the programmed CPU acts in concert with the recited features of the mobile device to enable the mobile device to determine and display its absolute position through interaction with a remote server and multiple remote satellites), the instant application including one or more electrodes on one or more catheters does not amount to an improvement.

7. The Claims Do Not Merely "Measure" as Pre-Solution Data Gathering; They Integrate Physiological Acquisition with a Specific Processing Pipeline That Controls Device Behavior

Appellant asserts that the claims are not mere "measuring"; they are a rule-bound pipeline that changes the state of the system by converting signals into a thresholded correlation score used to make the detection decision and to select the best alignment by phase-shifting a moving template window (e.g., within ±40 ms in 1 ms increments)-operations a clinician cannot practically perform mentally or on paper (Application, ¶67) (Appeal Brief, page 42). However, this was not indicated as a measurement step. It is the abstract idea itself of making a determination based on the correlation score.

Appellant asserts that acquisition is functionally coupled to filtering, thresholding, template formation, derivative-based weighting, correlation, thresholded decision, and map update-an integrated practical application, not pre-solution data gathering (Application,¶¶11, 20, 25, 29-30, 36-37, 67) (Appeal Brief, page 43). However, the Examiner disagrees. There is pre-solution activity of gathering the data and the remaining steps amount to the abstract idea.

8. The present claims improve the operation of a cardiac sensor and are therefore eligible under Step 2A Prong 2.

Appellant asserts that in the present case, the Examiner bears the initial burden to provide evidence that the specific sequence recited------(a) median-filter "activity signal," (b) activity-threshold-defined POI spanning a heartbeat's WOI, and (c) derivative-based channel weighting applied to multi-channel correlation to detect arrhythmia with a thresholded score driving a map update-was well-understood, routine, and conventional in EP mapping systems at the relevant time. The Final Action cites general catheters/electrodes but no evidence that derivative-based per-channel weighting for template-matching intracardiac EGMs-in the claimed real-time, multi-electrode context-was conventional. Under Berkheimer and Aatrix, this is a dispositive factual question; in the absence of particularized evidence, Step 2B cannot sustain the rejection (Appeal Brief, page 45). However, the Examiner indicated these steps are part of the abstract idea. See MPEP 2106.07(a) which recites:

> The court does not require "evidence" that a claimed concept is a judicial exception, and generally decides the legal conclusion of eligibility without resolving any factual issues.

FairWarning IP, LLC v. Iatric Sys., 839 F.3d 1089, 1097, 120 USPQ2d 1293, 1298 (Fed. Cir. 2016) (citing *Genetic Techs. Ltd. v. Merial LLC*, 818 F.3d 1369, 1373, 118 USPQ2d 1541, 1544 (Fed. Cir. 2016)); *OIP Techs.*, 788 F.3d at 1362, 115 USPQ2d at 1092; *Content Extraction & Transmission LLC v. Wells Fargo Bank, N.A.*, 776 F.3d 1343, 1349, 113 USPQ2d 1354, 1359 (Fed. Cir. 2014).

9. The Office Action Has Failed To Meet Its Burden Of Establishing That The Claims Are Ineligible Under 35 U.S.C. §101

Appellant asserts that the claims are not directed to an abstract idea under Step 2A, prong one. They do not merely announce a result ("detect arrhythmia") or claim unconstrained data analysis. Rather, they recite a specific, rule-bound signal-processing technique embedded in a cardiac mapping system (Appeal Brief, page 46). However, the Examiner disagrees. The claims amount to pre-solution activity of data gathering and the abstract idea.

Appellant argues that even assuming arguendo that some sub-steps could be characterized as mathematical, the claims are integrated into a practical application (Step 2A, prong two) (Appeal Brief, page 47). However, the Examiner disagrees. The alleged improvement is directed to the abstract idea itself.

Appellant argues that the record here is silent on conventional use of maximum-slope-derived channel weights in the claimed template-matching pipeline (and on the disclosed thresholding and moving-window alignment granularity). (Application, ¶¶36-37, 67). Absent such evidence, Step 2B cannot sustain ineligibility (Appeal Brief, page 48). However, the Examiner indicated these steps are part of the abstract idea. See the recitation to MPEP 2106.07(a) above, where the court does not require "evidence" that a claimed concept is a judicial exception.

Appellant argues that the Examiner's reliance on the "speed/efficiency" maxim from *Intellectual Ventures I LLC v. Capital One Bank (USA)*, 792 F.3d 1363, 1367-69 (Fed. Cir. 2015), is misplaced (Appeal Brief, page 48). However, the Examiner disagrees. This was used because Appellant states that "the claims improve upon existing technology by providing specific and tangible technological advancements,

particularly in real-time monitoring and analysis of cardiac signals" (Remarks filed 2/12/25, page 9). Therefore, arguing "real-time monitoring" is not an improvement.

B. Claims 15 and 16 Are Patent-Eligible Under §101 and Align With Federal Circuit UI Precedent

Appellant argues that claims 15 and 16 recite a specific medical-device user interface and mapping workflow that is integrated with, and conditioned on, the output of the claimed intracardiac signal-processing pipeline (Appeal Brief, page 49). However, claims 15 and 16 amount to post-solution activity. See the example below in MPEP 2106.05(a) which was found to not be sufficient to show an improvement:

> Instructions to display two sets of information on a computer display in a non-interfering manner, without any limitations specifying how to achieve the desired result, Interval Licensing LLC v. AOL, Inc., 896 F.3d 1335, 1344-45, 127 USPQ2d 1553, 1559-60 (Fed. Cir. 2018).

Appellant asserts that the Office Action's treatment of the display and map features as mere post-solution presentation also conflicts with Federal Circuit decisions holding that user interfaces are patent-eligible when they implement specific functionalities that resolve identified technological problems (Appeal Brief, page 51). However, the Examiner disagrees. A user interface is not recited in the claims, only a display screen.

Appellant asserts that prescribed interface functionality corresponds to, and solves, the identified problem by surfacing only clinically significant activity and by visually emphasizing the affected anatomy at the moment it is detected, thereby reducing cognitive load and improving intraprocedural decision making (Appeal Brief, page 52). However, the Examiner disagrees. The result of the abstract idea determination is what is displayed, which does not result in an improvement.

Appellant asserts that even if Step 2B were reached, the record contains no evidence that this particular combination was well-understood, routine, and conventional in EP mapping systems: computing maximum-slope per-channel weights for a heartbeat-bounded, template-based multi-

channel correlation and then automatically incorporating only threshold-exceeding results into a position-registered cardiac map with emphasized regions (Appeal Brief, page 53). Application, ¶¶0042, 0054-0057, 0060. However, the Examiner indicated these steps are part of the abstract idea. See the recitation to MPEP 2106.07(a) above, where the court does not require "evidence" that a claimed concept is a judicial exception.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/L.N.H./
Examiner, Art Unit 3792

Conferees:

/UNSU JUNG/
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/JOSEPH A STOKLOSA/
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Requirement to pay appeal forwarding fee. In order to avoid dismissal of the instant appeal in any application or ex parte reexamination proceeding, 37 CFR 41.45 requires payment of an appeal forwarding fee within the time permitted by 37 CFR 41.45(a), unless appellant had timely paid the fee for filing a brief required by 37 CFR 41.20(b) in effect on March 18, 2013.