In the Supreme Court of the United States

INFOBIONIC, INC.,

Petitioner,

v.

CARDIONET, LLC, BRAEMAR MANUFACTURING, LLC, *Respondents*.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

CHARLES H. SANDERS LATHAM & WATKINS LLP 200 Clarendon Street 27th Floor Boston, MA 02116 GREGORY G. GARRE Counsel of Record GABRIEL K. BELL MAXIMILIAN A. GRANT LATHAM & WATKINS LLP 555 11th Street, NW Suite 1000 Washington, DC 20004 (202) 637-2207 gregory.garre@lw.com Counsel for Petitioner

QUESTION PRESENTED

This Court has long recognized that fundamental concepts and basic mental processes are not patent eligible. This so-called "abstract idea" exception to 35 U.S.C. § 101 is critical to ensuring that patent monopolies do not impede innovation. In this case, the Federal Circuit held—in direct conflict with this Court's decisions—that invoking the abstract idea exception requires a showing that the challenged claims recite a "longstanding" human practice. App. 25a; see id. at 18a-19a.

The question presented is: Whether the Federal Circuit has properly narrowed the scope of the abstract idea exception under 35 U.S.C. § 101.

RULE 29.6 STATEMENT

Pursuant to this Court's Rule 29.6, petitioner InfoBionic, Inc. states that it has no parent corporation and that no publicly held company owns 10% or more of its stock.

RELATED PROCEEDINGS

CardioNet, LLC and Braemar Mfg., LLC v. InfoBionic, Inc., No. 1:17-cv-10445, U.S. District Court for the District of Massachusetts. Judgment pending.

TABLE OF CONTENTS

QUESTION PRESENTED i
RULE 29.6 STATEMENT ii
RELATED PROCEEDINGS ii
TABLE OF AUTHORITIES vi
OPINIONS BELOW1
JURISDICTION1
STATUTORY PROVISIONS INVOLVED1
INTRODUCTION2
STATEMENT OF THE CASE
Section 101 Of The Patent Act3
Patent At Issue5
District Court Proceedings6
Federal Circuit's Decision7
REASONS FOR GRANTING THE PETITION9
I. THIS COURT'S GUIDANCE IS URGENTLY NEEDED ON § 101 BECAUSE THE FEDERAL CIRCUIT IS HOPELESSLY FRACTURED AND UNPREDICTABLE
A. The Federal Circuit's § 101 Jurisprudence Is Hopelessly Confused10
B. The United States And Numerous Commentators Have Urged The Court To Provide Further Guidance As Well15

iii

TABLE OF CONTENTS—Continued

II.	THE FEDERAL CIRCUIT'S DECISION IN THIS CASE DIRECTLY CONFLICTS WITH THIS COURT'S PRECEDENTS		
	A.	This Court Long Ago Established That Mental Steps Are Within The "Abstract Idea" Category Whether "New" Or Not17	
	В.	The Federal Circuit's Holding In This Case That Mental Steps Are Not Within The "Abstract Idea" Category Unless They Are "Longstanding" Directly Conflicts With <i>Benson</i> And <i>Flook</i> 20	
	C.	The Federal Circuit's Decision Also Directly Conflicts With <i>Mayo</i> 23	
III.	TH VE GU	IS CASE PROVIDES AN IDEAL HICLE TO PROVIDE FURTHER IDANCE ON THE SCOPE OF § 10127	
	A.	The Federal Circuit's Decision Addressed A Pure Legal Issue	
	B.	The Federal Circuit's Decision Is Wrong And Impedes Innovation27	
COI	NCL	USION	

TABLE OF CONTENTS—Continued

Page

APPENDIX

VOLUME I

Opinion of the United States Court of Appeals for the Federal Circuit, CardioNet, LLC v. InfoBionic, Inc., No. 2019-1149, 955 F.3d 1358 (Fed. Cir. Apr. 17, 2020).....1a Memorandum and Order of the United States District Court for the District of Massachusetts. CardioNet. LLC v. InfoBionic, Inc., No. 1:17-cv-10445-IT, 348 Order of the United States Court of Appeals for the Federal Circuit Denving Petition for Rehearing, CardioNet, LLC v. InfoBionic, Inc., No. 2019-1149 (Fed. Cir. June 4, 35 U.S.C. § 101......61a

VOLUME II

U.S. Patent No. 7,941,207 B2 (May 10, 2011)62a

TABLE OF AUTHORITIES

Page(s)

CASES

Aatrix Software, Inc. v. Green Shades Software Inc.
890 F.3d 1354 (Fed. Cir. 2018)14
Alice Corp. Pty. Ltd. v. CLS Bank International,
573 U.S. 208 (2014)passim
Amdocs (Israel) Ltd. v. Openet Telecom, Inc.,
841 F.3d 1288 (Fed. Cir. 2016), <i>cert.</i> <i>denied</i> , 138 S. Ct. 469 (2017)13
American Axle & Manufacturing., Inc. v. Neapco Holdings LLC,
F.3d, No. 2018-1763, 2020 WL 6228080 (Fed. Cir. Oct. 23, 2020)2, 9, 10, 14
American Axle & Manufacturing, Inc. v. Neapco Holdings LLC,
966 F.3d 1347 (Fed. Cir. 2020)10, 14
Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282 (Fed. Cir. 2015)14
Association for Molecular Pathology v. Myriad Genetics, Inc
569 U.S. 576 (2013)
Athena Diagnostics, Inc. v. Mayo Collaborative Services, LLC,
927 F.3d 1333 (Fed. Cir. 2019)10, 14

Berkheimer v. HP Inc., 881 F.3d 1360 (Fed. Cir. 2018), cert denied, 140 S. Ct. 911 (2020)2
Berkheimer v. HP Inc., 890 F.3d 1369 (Fed. Cir. 2018)14
Bilski v. Kappos, 561 U.S. 593 (2010)4, 19, 21, 22
Braemar Manufacturing, LLC v. ScottCare Corp., 816 F. App'x 465 (Fed. Cir. 2020)23
Bridge & Post, Inc. v. Verizon Communications, Inc., 778 F. App'x 882 (Fed. Cir. 2019)13
CardioNet, LLC v. InfoBionic, Inc., 816 F. App'x 471 (Fed. Cir. 2020)22
Cleveland Clinic Foundation v. True Health Diagnostics, LLC, 859 F.3d 1352 (Fed. Cir. 2017), cert. denied, 138 S. Ct. 2621 (2018)25
CyberSource Corp. v. Retail Decisions, Inc., 654 F.3d 1366 (Fed. Cir. 2011)19, 22
DDR Holdings, LLC v. Hotels.com, L.P., 773 F.3d 1245 (Fed. Cir. 2014)

Dropbox, Inc. v. Synchronoss Technologies, Inc., 815 F. App'x 529 (Fed. Cir. 2020)12
 EcoServices, LLC v. Certified Aviation Services, LLC, No. 2019-1602, 2020 WL 5949809 (Fed. Cir. Oct. 8, 2020)
Electric Power Group, LLC v. Alstom S.A., 830 F.3d 1350 (Fed. Cir. 2016)4, 10, 11, 23
Ericsson Inc. v. TCL Communication Technology Holdings Ltd., 955 F.3d 1317 (Fed. Cir. 2020)12
<i>Funk Bros. Seed Co. v. Kalo Inoculant Co.,</i> 333 U.S. 127 (1948)
Gottschalk v. Benson, 409 U.S. 63 (1972)passim
Intellectual Ventures I LLC v. Symantec Corp., 838 F.3d 1307 (Fed. Cir. 2016)13, 19, 22, 29
Interval Licensing LLC v. AOL, Inc., 896 F.3d 1335 (Fed. Cir. 2018)10, 13, 16, 19
Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012)passim

viii

MyMail, Ltd. v. ooVoo, LLC, 934 F.3d 1373 (Fed. Cir. 2019)13
Parker v. Flook, 437 U.S. 584 (1978)2, 4, 18, 20, 21
 SAP America, Inc. v. InvestPic, LLC, 898 F.3d 1161 (Fed. Cir. 2018), cert. denied, 139 S. Ct. 2747 (2019)19
Smart Systems Innovations, LLC v. Chicago Transit Authority, 873 F.3d 1364 (Fed. Cir. 2017)13
SRI International, Inc. v. Cisco Systems, Inc., 930 F.3d 1295 (Fed. Cir. 2019)11, 23
Synopsys, Inc. v. Mentor Graphics Corp., 839 F.3d 1138 (Fed. Cir. 2016), cert. denied, 138 S. Ct. 71 (2017)19
<i>TecSec, Inc. v. Adobe Inc.,</i> F.3d, 2020 WL 6228460 (Fed. Cir. Oct. 23, 2020)
Visual Memory LLC v. NVIDIA Corporation, 867 F.3d 1253 (Fed. Cir. 2017)11, 12
STATUTES

28 U.S.C. § 1254(1).....1

ix

Page(s)

35 U.S.C.	§ 101	1.	3
00 0.0.01		-,	~

OTHER AUTHORITIES

2019 Revised Patent Subject Matter
Eligibility Guidance, 84 Fed. Reg. 50
(Jan. 7, 2019)15, 16
Jeremy C. Doerre Is There Any Need to
Resort to a δ 101 Exception for Prior Art
Ideas? 2019 Patently O Pat I. J. 10
(2019)
Shahrokh Falati, To Promote Innovation,
Congress Should Abolish The Supreme
Court Created Exceptions to 35 U.S.
<i>Code</i> §101, 28 Tex. Intell. Prop. L.J. 1
(2019)
John M. Golden, Flook Says One Thing,
Diehr Says Another: A Need for
Housecleaning in the Law of Patentable
Subject Matter, 82 Geo. Wash. L. Rev.
1765 (2014)
Jonathan Stroud & Derek M. Kim,
Debugging Software Patents After Alice.
69 S.C.L. Rev. 177 (2017)

PETITION FOR A WRIT OF CERTIORARI

InfoBionic, Inc. ("InfoBionic") respectfully petitions this Court for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The decision of the court of appeals (App. 1a-37a) is reported at 955 F.3d 1358 (Fed. Cir. 2020). The court's denial of panel rehearing *(id. at 60a)* is not reported. The final decision of the district court *(id. at 38a-59a)* is reported at 348 F. Supp. 3d 87 (D. Mass. 2018).

JURISDICTION

The court of appeals entered judgment on April 17, 2020 (App. 1a-37a), and denied InfoBionic's timely petition for panel rehearing on June 4, 2020 (App. 60a). On March 19, 2020, this Court extended the time within which to file any petition for a writ of certiorari due on or after that date to 150 days from, *inter alia*, the order denying a timely petition for rehearing. Accordingly, the deadline for filing a petition for a writ of certiorari in this case is November 2, 2020. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

35 U.S.C. § 101 is reprinted in the appendix hereto. App. 61a.

INTRODUCTION

Federal Circuit The active judges have "unanimous[ly]" made an "unprecedented plea for guidance" from this Court on § 101. American Axle & Mfg., Inc. v. Neapco Holdings LLC, --- F.3d ----, No. 2018-1763, 2020 WL 6228080, at *3 (Fed. Cir. Oct. 23, 2020) (Moore, J., concurring in denying stay of mandate). The Federal Circuit is "at a loss as to how to uniformly apply § 101" and the doctrine has devolved into an inconsistent, "panel-dependent body of law." *Id.* The confusion is especially great in cases, such as this, involving software-related claims. The calls for this Court to step in have grown to a from crescendo not only judges, but from commentators and the United States alike. Twice last term, the United States filed invitation briefs urging this Court to intervene in an appropriate § 101 case.

This case presents an ideal opportunity to provide needed guidance. First, the decision below addressed a pure legal issue that is emblematic of this confusion-whether invoking the "abstract idea" exception established by this Court's decisions requires a showing that the challenged claims recite a "longstanding" human practice. Second, the Federal Circuit's conclusion that this showing is required directly conflicts with this Court's seminal decisions in Gottschalk v. Benson, 409 U.S. 63 (1972), and Parker v. Flook, 437 U.S. 584 (1978), as well as with Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012). And third, this case has none of the procedural complexities that prompted the United States to recommend against review in Berkheimer v. HP Inc., 881 F.3d 1360 (Fed. Cir. 2018), cert denied, 140 S. Ct. 911 (2020), and,

instead, presents a clean vehicle to provide needed guidance in this critical area.

The petition should be granted.

STATEMENT OF THE CASE

Section 101 Of The Patent Act

Section 101 of the Patent Act provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. However, § 101 "contains an important implicit exception" for abstract ideas (such as mental processes or fundamental human activities), natural laws, and natural phenomena. Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 216 (2014) (citation omitted); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012). This Court's two-step framework articulated in *Alice* and *Mayo* governs the determination whether patent claims are directed to patent-eligible subject matter. Under that analysis, a patent claim lacks patent-eligible subject matter if it (1) is directed to an abstract idea (or another ineligible principle), and (2) fails to add an inventive concept. Alice, 573 U.S. at 218-26.

That modern framework built upon, and reaffirmed, this Court's decisions in *Gottschalk v. Benson* and *Parker v. Flook. Benson* and *Flook* established that mentally performable steps and mathematical formula fall within the "abstract idea" category, even if they were never previously performed. As this Court explained in *Alice*, the abstract idea in *Benson* was "an algorithm for converting binary-coded decimal numerals into pure binary form." Alice, 573 U.S. at 218 (discussing Benson, 409 U.S. at 71-72). Although the idea "varie[d] the ordinary arithmetic steps a human would use" and was implemented in a computer processor, it was ultimately something that humans "could" do mentally. Benson, 409 U.S. at 67. And the Flook Court "held that a mathematical formula for computing 'alarm limits' in a catalytic conversion process was also a patent-ineligible abstract idea." Alice, 573 U.S. at 218 (quoting Flook, 437 U.S. at 594-95). As in Benson, it was irrelevant that the formula was new and that the claims purported to limit it to a particular technological field. Flook, 437 U.S. at 595; see also Mayo, 566 U.S. at 80-81, 84-85 (reaffirming, inter alia, Benson and Flook).

This Court and the Federal Circuit have repeatedly recognized that this Court's decisions in Benson and Flook are critical to policing the boundaries of patent eligibility under § 101. See, e.g., Alice, 573 U.S. at 218; Mayo, 566 U.S. at 80-81, 84-85; Bilski v. Kappos, 561 U.S. 593, 612 (2010) (Benson and Flook are key "guideposts"); Electric Power Grp., LLC v. Alstom S.A., 830 F.3d 1350, 1354 (Fed. Cir. 2016) ("analyzing information by steps people go through in their minds" are "essentially mental processes within the abstract-idea category" under Benson and Flook). And this Court has recognized that the "abstract idea" exception to § 101 is critical to ensuring that patents are not used to monopolize scientific concepts or mental processes that are so fundamental that they belong to everyone. Alice, 573 U.S. at 221.

Patent At Issue

Respondents CardioNet, LLC and Braemar Manufacturing, LLC (collectively "CardioNet") own the patent at issue, U.S. Patent No. 7,941,207 ("the '207 patent"), titled "Cardiac Monitoring." App. 62a-78a. The patent describes automated systems and techniques for analyzing heartbeat data to identify certain conditions-atrial fibrillation and atrial flutter (together, "AF"). Id. at 62a (abstract), 71a-72a (1:46-3:48). AF is a well-known condition that involves "loss of synchrony between the atria and the ventricles" leading to "irregular" heart beating, *i.e.*, variability in beat-to-beat timing. Id. at 71a The patent's purported invention is a (1:23-39).device to automatically detect AF by (a) detecting beat-to-beat timing of a patient's cardiac activity, (b) detecting premature ventricular beats (which are irregular beats that interrupt the normal heart rhythm), and (c) "determin[ing] the relevance of the beat-to-beat timing to [AF], taking into account the variability in the beat-to-beat timing caused by premature ventricular beats." Id. at 14a-15a.

Illustrative claim 1 of the patent recites:

1. A device, comprising:

- [(a)] a beat detector to identify a beat-to-beat timing of cardiac activity;
- [(b)] a ventricular beat detector to identify ventricular beats in the cardiac activity;
- [(c)] variability determination logic to determine a variability in the beat-tobeat timing of a collection of beats;
- relevance determination logic to identify a relevance of the variability in the beat-

to-beat timing to at least one of atrial fibrillation and atrial flutter; and

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

Id. at 76a.¹

It is undisputed that collecting heartbeat data (*i.e.*, steps (a) and (b)) was well-known and required only off-the-shelf beat-detecting technology, as the patent specification admits. Id. at 73a, 75a (5:15-20, 9:22-32). It is undisputed that doctors have long identified AF based on the variability in beat-to-beat timing (*i.e.*, by "determin[ing] the relevance of the beat-tobeat timing," id. at 15a)—AF is, by definition, a heart condition characterized by irregular beats. See CardioNet CAFC Opening Br. 10-11; App. 71a (1:23-39). And it is undisputed that doctors are capable of identifying AF in light of ventricular beats (i.e., "taking into account the variability in the beat-to-beat timing caused by premature ventricular beats," App. 15a).

District Court Proceedings

On March 16, 2017, CardioNet sued InfoBionic alleging infringement of the '207 patent. Complaint, No. 1:17-cv-10445-IT (D. Mass. Mar. 16, 2017), ECF

¹ The parties and courts below agreed that the "ventricular beats" in the claims refers to premature ventricular beats, also known as premature ventricular contractions. App. 53a n.4.

No. 1. InfoBionic moved to dismiss the complaint because the asserted claims lack patent-eligible subject matter under § 101. App. 38a. Applying the two-step *Alice* test, the district court held that claim 1 and the other asserted claims (various dependent claims) are ineligible under § 101. *Id.* at 41a-59a.

At Alice step one, the court held the claims are directed to "the abstract idea of identifying AF by looking at the variability in time between heartbeats and taking into account ventricular beats," which are "essentially mental processes" rather than a specific technological improvement. Id. at 55a, 44a-48a (citation omitted). At Alice step two, the court held that the claims fail to add an inventive concept and instead merely use conventional computer and medical technology to automate the data collection and analysis. Id. at 48a-58a. The court determined that, even accepting as true the allegations in CardioNet's complaint, the claims "do not recite any specific implementation improvement or in computerized medical technology," id. at 47a-48a, and "provide no meaningful details on how to implement" the system, *id.* at 57a (citation omitted). The district court, therefore, granted InfoBionic's motion to dismiss.

Federal Circuit's Decision

The Federal Circuit reversed. App. 26a. According to the court, the decisive issue under § 101 was whether doctors had a longstanding practice of performing the claimed diagnostic techniques *i.e.*, identifying AF by looking at the variability in time between heartbeats and taking into account ventricular beats. *Id.* at 14a-21a, 24a-25a; *id.* at 28a-29a. The panel found "no suggestion" in the patent "that doctors were 'previously employing" that technique. *Id.* at 18a; *see id.* ("Nothing in the record in this case suggests that the claims merely computerize pre-existing techniques for diagnosing [AF]."). The Federal Circuit thus held that the district court erred in holding that the claim was patent ineligible on the pleadings. *Id.* at 18a-19a.

In so holding, the court rejected InfoBionic's argument that, "even assuming" those techniques were never previously used, they are still "mental abstract-idea category." within the processes InfoBionic CAFC Br. 49, 20 (citation omitted); see id. at 19 ("Determining the relevance of [premature ventricular beat] information to identify an AFib or AFlut event is ... a mental process"); id. at 49 ("even assuming" techniques were new, "the purported advance is itself just an abstract idea-the concept of identifying AF based on heartbeat variability and premature ventricular beats"); CAFC Oral Arg. 24:54-25:33 ("[L]et's assume this is completely new. Then we're squarely in the realm of Flook"); id. at 21:32-38 ("What this boils down to is the mental processes"—"what a doctor could do"); id. at 22:24-41, 23:09-43.²

The Federal Circuit denied InfoBionic's petition for rehearing. App. $60a.^3$

² Available at http://oralarguments.cafc.uscourts.gov/ default.aspx?fl=2019-1149.MP3.

³ The case is currently on remand before the district court. While it strongly disagrees with the Federal Circuit's ruling that a "longstanding" human practice is necessary to invoke the abstract idea exception, InfoBionic has sought to introduce evidence that doctors did, in fact, have a longstanding practice

REASONS FOR GRANTING THE PETITION

I. THIS COURT'S GUIDANCE IS URGENTLY NEEDED ON § 101 BECAUSE THE FEDERAL CIRCUIT IS HOPELESSLY FRACTURED AND UNPREDICTABLE

The Federal Circuit, by its own admission, is hopelessly fractured on the minimum requirements for patent eligibility under § 101. Different panels routinely reach different outcomes on materially indistinguishable patents. Yet the court has repeatedly denied en banc review, often accompanied by a chorus of disparate opinions. For that reason, the Federal Circuit judges themselves have "unanimous[ly]" called for this Court to intervene. American Axle & Mfg., Inc. v. Neapco Holdings LLC, ---- F.3d ----, No. 2018-1763, 2020 WL 6228080, at *3 (Fed. Cir. Oct. 23, 2020) (Moore, J., concurring in denying stay of mandate). The United States and others have likewise recognized that it is necessary for this Court to revisit § 101. Just as a circuit split warrants review, so too does a fundamental rift in the nation's patent court on the most fundamental of all patent issues—what is patentable to begin with.

of using the claimed diagnostic techniques. CardioNet, however, contends that the Federal Circuit's decision conclusively found the claims patent eligible under § 101. No matter how the district court resolves that issue, it almost certainly will be the subject to an appeal. The issue presented here is the threshold question of whether the Federal Circuit properly held that the abstract idea exception under § 101 *requires* a showing that the claims at issue automate a longstanding human practice. If this Court grants certiorari, InfoBionic intends to seek a stay of proceedings in the district court while the case is pending before this Court, so this Court can resolve this threshold question.

A. The Federal Circuit's § 101 Jurisprudence Is Hopelessly Confused

The Federal Circuit's § 101 decisions applying this Court's precedents have become highly paneldependent, unpredictable crap shoots. Just a few days ago, one judge lamented: "As the nation's lone patent court, we are at a loss as to how to uniformly apply § 101. ... [W]e have struggled to consistently apply the judicially created exceptions to this broad statutory grant of eligibility, slowly creating a paneldependent body of law and destroying the ability of American businesses to invest with predictability." *American Axle & Mfg., Inc.*, 2020 WL 6228080, at *3 (Moore, J., concurring in denying stay of mandate).

Other judges on the Federal Circuit have likewise recognized that its "rulings on patent eligibility have become so diverse and unpredictable as to have a serious effect on the innovation incentive in all fields of technology." *American Axle & Mfg., Inc. v. Neapco Holdings LLC,* 966 F.3d 1347, 1357 (Fed. Cir. 2020) (Newman, J., joined by four judges, dissenting from denial of rehearing en banc); *see also, e.g., Interval Licensing LLC v. AOL, Inc.,* 896 F.3d 1335, 1354-55 (Fed. Cir. 2018) (Plager, J., concurring in part and dissenting in part) (there is "little consensus"); *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC,* 927 F.3d 1333, 1371 (Fed. Cir. 2019) (O'Malley, J., dissenting from denial of en banc reh'g) (per curiam) (§ 101 doctrine is "baffling").

Unpredictability is rampant. For example, in *Electric Power Group, LLC v. Alstom S.A.*, the Federal Circuit held that claims reciting "systems and methods for performing real-time performance monitoring of an electric power grid by collecting data

from multiple data sources, analyzing the data, and displaying the results" were ineligible under *Alice*. 830 F.3d 1350, 1351 (Fed. Cir. 2016). The court recognized that, although the claims were "lengthy" and "use[d] computers as tools," they amounted to "steps people go through in their minds, or by mathematical algorithms"—which are "essentially mental processes within the abstract-idea category." *Id.* at 1354-55 (relying on *Benson* and *Flook*).

More recently, however, in *SRI International*, *Inc.* v. Cisco Systems, Inc., a different (divided) panel held that claims for "monitor[ing]" a network "in realtime"-again by collecting data from multiple sources, analyzing the data, and presenting the results—were *eligible* under § 101 because they were not directed to an abstract idea at step one of the Alice framework. 930 F.3d 1295, 1303 (Fed. Cir. 2019). That panel majority did not address whether the claims were, at root, directed to essentially mental processes—and did not cite Flook or Benson. In contrast, the dissenting judge in that case stated that the claims are "clearly abstract" and "differ very little from the claims" in *Electric Power*. Id. at 1312-13 (Lourie, J., dissenting).

Likewise, in Visual Memory LLC v. NVIDIA Corporation, a divided panel held that claims reciting a computer memory system that determines the type of data being stored based on a "programmable operational characteristic" were eligible at Alice step one. 867 F.3d 1253, 1257-62 (Fed. Cir. 2017). Although the claims recited a simple choice that could be performed mentally—a far more straightforward "algorithm" than the ineligible multi-step binaryconversion process in Benson—the court did not cite or discuss Benson. Cf. Visual Memory Br. of Appellee 1, 2016 WL 7212231 (Fed. Cir. Dec. 7, 2016) (arguing that "[t]he claims are indistinguishable from those found ineligible by the Supreme Court in ... *Benson*").

In contrast, the dissent concluded that the claims were abstract and ineligible because they were "not specific means or directed to a method of implementing а 'programmable operational characteristic." Visual Memory, 867 F.3d at 1263 (Hughes, J., dissenting). As the dissent explained, "the majority has analyzed step one of *Alice* in a way that is unterthered from the [patent] claims and the specification." *Id.* at 1264. And "[u]nder the majority's reasoning," the dissent continued, "many patent ineligible computer-implemented inventions could be described as non-abstract because they purport to 'improve' a computer despite requiring someone else to provide all the innovation." Id.

The confusion is only worsening. Just this year, in Ericsson Inc. v. TCL Communication Technology Holdings Ltd., a divided panel found that computer data security claims were ineligible, explaining that the court "ha[s] repeatedly found the concept of controlling access to resources via software to be an abstract idea." 955 F.3d 1317, 1327 (Fed. Cir. 2020). Likewise. in Dropbox. Inc. v. **Synchronoss** Technologies, Inc., the court found ineligible claims that recited an apparatus for providing security based on various calculations. 815 F. App'x 529, 531-32 (Fed. Cir. 2020). A few months later, however, the Federal Circuit held that similar data security claims were eligible because they were not directed to an abstract idea at step one. TecSec, Inc. v. Adobe Inc., --- F.3d ---, 2020 WL 6228460, at *14 (Fed. Cir. Oct. 23, 2020). The TecSec panel did not even attempt to distinguish *Ericsson* or *Dropbox*.

Other fractured and inconsistent decisions on the patentability of computer-implemented claims like the claim at issue here abound. See, e.g., Amdocs (Isr.) Ltd. v. Openet Telecom, Inc., 841 F.3d 1288, 1306 (Fed. Cir. 2016) (2-1 decision finding claims patent eligible), cert. denied, 138 S. Ct. 469 (2017); EcoServices, LLC v. Certified Aviation Servs., LLC, No. 2019-1602, 2020 WL 5949809, at *15 (Fed. Cir. Oct. 8, 2020) (same); DDR Holdings, LLC v. Hotels.com, L.P., 773 F.3d 1245, 1263 (Fed. Cir. 2014) (same); MyMail, Ltd. v. ooVoo, LLC, 934 F.3d 1373, 1381 (Fed. Cir. 2019) (2-1 decision vacating district court's ineligibility ruling); Bridge & Post, Inc. v. Verizon Commc'ns, Inc., 778 F. App'x 882, 894 (Fed. Cir. 2019) (2-1 decision finding computer claims ineligible); Interval Licensing LLC, 896 F.3d at 1348 (same); Smart Sys. Innovations, LLC v. Chicago Transit Auth., 873 F.3d 1364, 1374 (Fed. Cir. 2017) (same); Intellectual Ventures I LLC v. Symantec Corp., 838 F.3d 1307, 1311 (Fed. Cir. 2016) (same, generating three separate opinions).

One judge (who was also on the panel below in the present case) has wholesale "dissent[ed] from [the Federal Circuit's] continued application of this incoherent body of doctrine" and opined that there is "no need, and indeed no place in today's patent law, for this abstract (and indefinable) doctrine." *Interval Licensing LLC*, 896 F.3d at 1348, 1355 (Plager, J., concurring in part and dissenting in part); *see also Smart Sys. Innovations, LLC*, 873 F.3d at 1376 (Linn, J., dissenting in part and concurring in part) ("[T]he abstract idea exception—if it is to be applied at all—must be applied narrowly"). To say that this body of law is muddled and unpredictable is an understatement.

Yet the Federal Circuit has repeatedly declined to revisit § 101 en banc, often in remarkably fractured and candid opinions underscoring the discord. See American Axle & Mfg., Inc., 966 F.3d at 1347-48 (six separate opinions); Athena Diagnostics, LLC, 927 F.3d at 1334 (eight separate opinions); Aatrix Software, Inc. v. Green Shades Software, Inc., 890 F.3d 1354, 1354-55 (Fed. Cir. 2018) (per curiam) (three separate opinions); Berkheimer v. HP Inc., 890 F.3d 1369, 1370 (Fed. Cir. 2018) (per curiam) (same); Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282, 1284 (Fed. Cir. 2015) (per curiam) (same).

Instead, the Federal Circuit repeatedly has urged this Court to provide additional guidance. As one judge explained, although "[t]here is very little about which all twelve [active Federal Circuit judges] are unanimous, especially when it comes to § 101," they are "unanimous in [their] unprecedented plea for guidance." American Axle & Mfg., Inc., 2020 WL 6228080, at *3 (Moore, J., concurring in denying stay of mandate) (emphasis added); see also, e.g., Berkheimer, 890 F.3d at 1374 (Lourie, J., joined by Newman, J., concurring in denial of en banc reh'g) ("I believe the law needs clarification by higher authority Section 101 issues certainly require attention beyond the power of this court."); Athena *Diagnostics*, 927 F.3d at 1340 (Fed. Cir. 2019) (Dyk, J., joined by Hughes and Chen, JJ., concurring in denial of en banc reh'g) ("[I]t would be desirable for Supreme the Court to refine the [§ 101] framework").

This "irreconcilable split in the nation's only patent court" cries out for this Court's intervention. *American Axle & Mfg., Inc.*, 2020 WL 6228080, at *3 (Moore, J., concurring in denying stay of mandate).

B. The United States And Numerous Commentators Have Urged The Court To Provide Further Guidance As Well

The United States has also recognized that this Court's intervention is needed. Last term, this Court called for the Solicitor General's views in two § 101 cases. See HP Inc. v. Berkheimer, No. 18-415; Hikma Pharmaceuticals USA Inc. v. Vanda Pharmaceuticals Inc., No. 18-817. In response, the Solicitor General observed that there is "substantial uncertainty in the lower courts concerning the scope of the [§ 101] exceptions" and urged the Court to "grant review in an appropriate case to clarify the substantive Section 101 standards." Berkheimer U.S. Invitation Brief 12-13, 10 (Dec. 6, 2019); see also Vanda U.S. Invitation Br. 8 (Dec. 6, 2019). Nevertheless, because of wrinkles in each of these cases, the Solicitor General ultimately recommended that the Court deny review in them, which it did.⁴

The PTO's guidance to its more than 8,500 patent examiners and administrative judges likewise recognized that "[p]roperly applying the *Alice/Mayo* test in a consistent manner has proven to be difficult"; "has caused uncertainty in this area of the law"; has made it difficult for "inventors, businesses, and other patent stakeholders to reliably and predictably determine what subject matter is patent-eligible"; and "poses unique challenges for the USPTO" itself. 2019 Revised Patent Subject Matter Eligibility

⁴ The Solicitor General recommended against review in *Berkheimer* because of certain procedural issues in that case, and recommended against review in *Vanda* because the government agreed with the underlying finding of eligibility.

Guidance, 84 Fed. Reg. 50, 50 (Jan. 7, 2019); see also id. at 52.

Commentators. too, have recognized that additional clarity is needed. Indeed, "[t]here is almost criticism among commentators universal and academicians," and "[t]he testimonials in the blogs and elsewhere to the current mess regarding our § 101 jurisprudence have been legion." Interval Licensing LLC, 896 F.3d at 1353-54 (Plager, J., concurring in part and dissenting in part). For example, a former Chief Judge of the Federal Circuit has urged this Court to provide additional guidance on § 101 because "[t]he Federal Circuit's menagerie of patent-eligibility decisions over the past decade are devoid of any semblance of consistency." Amicus Br. of Former Chief Judge Michel 3, Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, No. 19-430, 2019 WL 5784718 (Nov. 1, 2019). In stark terms, former Chief Judge Michel wrote:

> During my twenty-two years on the bench, I do not recall any other legal issue ... that created such disharmony, disagreement, and inconsistency. ... One cannot distinguish eligible subject matter from ineligible, with any reasonable certainty.

Id. at 4; see also id. ("[T]he utter doctrinal confusion has created a legal quagmire").⁵

⁵ See also, e.g., Shahrokh Falati, To Promote Innovation, Congress Should Abolish the Supreme Court Created Exceptions to 35 U.S. Code §101, 28 Tex. Intell. Prop. L.J. 1, 30 (2019) (noting "wide disparity in the post-Alice decisions" as to "what is considered 'abstract"); Jeremy C. Doerre, Is There Any Need to

In short, this Court's guidance is urgently needed.

II. THE FEDERAL CIRCUIT'S DECISION IN THIS CASE DIRECTLY CONFLICTS WITH THIS COURT'S PRECEDENTS

This case is emblematic of how far the Federal Circuit's § 101 jurisprudence has fallen off the rails. This case concerns the central issue of the scope of the "abstract idea" exception recognized by this Court's precedents. The Federal Circuit's eligibility decision in this case improperly narrows the scope of the abstract idea exception, in direct conflict with this Court's seminal decisions in *Benson* and *Flook*, as well as the Court's more recent decision in *Mayo*.

A. This Court Long Ago Established That Mental Steps Are Within The "Abstract Idea" Category Whether "New" Or Not

Under this Court's two-step framework articulated in *Alice*, claims that merely purport to automate abstract ideas (including longstanding economic activities such as intermediated settlement) using conventional computer technology are not eligible under § 101. *Alice*, 573 U.S. at 225-26. However, this Court expressly declined to "delimit the precise contours of the 'abstract ideas' category," and instead made clear that it includes the types of ideas and concepts previously found abstract. *Id.* at 221.

Resort to a § 101 Exception for Prior Art Ideas?, 2019 Patently-O Pat. L.J. 10, 15 n.50 (2019) (noting "uncertain[ty] as to when to apply the implicit exception ... for abstract ideas"); John M. Golden, Flook Says One Thing, Diehr Says Another: A Need for Housecleaning in the Law of Patentable Subject Matter, 82 Geo. Wash. L. Rev. 1765, 1770 (2014) ("[T]he law of subject-matter eligibility has plunged into a seemingly ever widening maelstrom of uncertainty.").

For example, in *Benson* and *Flook*, this Court long ago established that mentally-performable steps and mathematical formula fall within the abstract ideas category, even if those steps and formula were entirely new—not longstanding.

In Benson, this Court held that the claims were directed to ineligible subject matter because they merely automated calculations (conversions from binary-coded decimal numbers to pure binary) that "can be done mentally." 409 U.S. at 67. That was so even though humans had not previously used those steps-indeed, the "method sought to be patented varie[d] the ordinary arithmetic steps a human would use." Id. (emphasis added). Likewise, in Flook, the applicant sought a patent on a process for updating "alarm limits" in petrochemical processes, to detect "the presence of an abnormal condition indicating either inefficiency or perhaps danger." 437 U.S. at 585. The claims recited a specific formula and steps for calculating the updated alarm limits to be used in a computer-automated process. Id. at 585-86, 596-98. This Court "assume[d] that [the applicant's] formula [wa]s novel and useful," but nonetheless found the claims ineligible under § 101 because such "mental processes, and abstract intellectual concepts are not patentable." Id. at 588-89. In no uncertain terms, this Court stated: "Very simply, our holding today is that an improved method of calculation, even when tied to a specific end use, is unpatentable subject matter under § 101." Id. at 595 n.18.

This Court reaffirmed and relied upon those decisions in setting forth its analytical framework in *Alice*, 573 U.S. at 218, and *Mayo*, 566 U.S. at 80-81, 84-85. As this Court explained, "[p]henomena of nature, though just discovered, mental processes, and

abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." Mayo, 566 U.S. at 70 (quoting Benson, 409 U.S. at 67); see also Bilski, 561 U.S. at 612 (looking to "the guideposts in Benson, Flook, and Diehr"). Similarly, in other contexts, this Court has recognized that ineligible concepts do not satisfy § 101 even if they are "hitherto unknown," Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948), or, indeed, "[g]roundbreaking, innovative, or even brilliant," Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 591 (2013).⁶

⁶ See also, e.g., SAP Am., Inc. v. InvestPic, LLC, 898 F.3d 1161, 1163 (Fed. Cir. 2018) ("We may assume that the [computer-implemented] techniques claimed are '[g]roundbreaking, innovative, or even brilliant,' but that is not enough for eligibility." (quoting Myriad, 569 U.S. at 591)), cert. denied, 139 S. Ct. 2747 (2019); Interval Licensing LLC, 896 F.3d at 1347 ("[A] claim for a new abstract idea is still an abstract idea."" (alteration in original) (quoting Synopsys, Inc. v. Mentor Graphics Corp., 839 F.3d 1138, 1151 (Fed. Cir. 2016), cert. denied, 138 S. Ct. 71 (2017))); Intellectual Ventures I, LLC, 838 F.3d at 1318 ("[W]ith the exception of generic computerimplemented steps, there is nothing in the claims themselves that foreclose them from being performed by a human, mentally or with pen and paper."); CyberSource Corp. v. Retail Decisions, Inc., 654 F.3d 1366, 1371, 1375 (Fed. Cir. 2011) ("methods which can be performed mentally, or which are the equivalent of human mental work, are unpatentable abstract ideas" "even when performed by a computer").

B. The Federal Circuit's Holding In This Case That Mental Steps Are Not Within The "Abstract Idea" Category Unless They Are "Longstanding" Directly Conflicts With *Benson* And *Flook*

The Federal Circuit held that the claims in this case were not ineligible unless they were directed to automating "longstanding" human activity. App. 25a; see id. at 18a-19a, 24a. In resolving the § 101 issue, the court stressed that there was no evidence "that doctors *long used* the claimed diagnostic processes" and that "[n]othing in the record in this case suggests that the claims merely computerize pre-existing techniques for diagnosing" AF. Id. at 19a (emphasis added); see also id. at 18a (finding no evidence "that doctors were 'previously employing' the techniques performed on the claimed device"); id. at 19a ("[T]he written description does not disclose that doctors performed the same techniques as the claimed device in diagnosing [AF].") (emphases added). That led the Federal Circuit to reject ineligibility.

That decision directly conflicts with *Benson* and *Flook* because automating mentally performable steps is abstract, even if the steps are new. *See Benson*, 409 U.S. at 67; *Flook*, 437 U.S. at 585; *supra* at 17-19. If a patent claim is directed to longstanding human activity, that may be *sufficient* to show an abstract idea (like the ineligible economic concepts of intermediated settlement in *Alice* and risk hedging in *Bilski*), but, as a matter of law, that showing is not *necessary* under *Benson* and *Flook*. Far from insisting on evidence that the claimed techniques were "long used," as the Federal Circuit did here, App. 19a, this Court expressly held that the claims in those cases were ineligible *even though* they were *not* previously

used. Benson, 409 U.S. at 67; Flook, 437 U.S. at 588-89; supra at 17-19. The Federal Circuit's decision also runs afoul of this Court's refusal to artificially restrict the "abstract idea" category. See, e.g., Alice, 573 U.S. at 221 (expressly declining to "delimit the precise contours of the 'abstract ideas' category"); Bilski, 561 U.S. at 609 (rejecting "categorical rules that might wide-ranging and unforeseen have impacts"). Therefore, the Federal Circuit's insistence that claims for automating mentally performable diagnostic practices are not directed to an abstract idea absent evidence that performing those mental diagnostic steps was a longstanding medical practice cannot be squared with this Court's precedent.⁷

That direct conflict warrants this Court's review. Indeed, understanding the contours of *Benson* and *Flook* is critical to understanding the scope of the

⁷ As noted, InfoBionic has sought to present evidence to the district court on remand that the automated technique at issue is, in fact, not new at all. See note 3, supra. CardioNet has opposed InfoBionic's request on the ground that the Federal Circuit's decision conclusively resolves the § 101 issue. See CardioNet's Mem. in Support of its Mot. for Judgment on InfoBionic's Section 101 Defense 5-6, No. 1:17-cv-10445-IT (D. Mass. Oct. 8, 2020), ECF No. 96. The district court has yet to resolve that dispute. But this petition presents the threshold legal question of whether such a showing is necessary at all to establish that a claim falls within the abstract idea exception. If the answer to that question is no, as this Court's precedents establish, then the claims here are ineligible without further evidentiary inquiry. Adding an unnecessary evidentiary inquiry on this issue will only further muddle the law and reliance interests in this critical area, and unnecessarily add to the time and expense of litigating the threshold issue of patent eligibility. Accordingly, this Court should hold, as a matter of law, that there is no requirement that a practice be "longstanding" in order to invoke the abstract idea exception.

abstract idea exception generally, as this Court has repeatedly recognized by discussing those decisions in explaining the scope of this exception. *See, e.g., Alice,* 573 U.S. at 218; *Mayo,* 566 U.S. at 80-81, 84-85; *Bilski,* 561 U.S. at 612. And the Federal Circuit has split over the proper reading of *Benson* and *Flook* and their critical role in excluding claims that merely automate mental steps, such as the mentally performable diagnostic determinations here.

Indeed, in another case between the same parties here, where Cardionet asserted another of its heartcondition-detection patents against InfoBionic, the same district court again found the claims ineligible. In that case, a different Federal Circuit panel affirmed the finding of ineligibility. CardioNet, LLC v. InfoBionic, Inc., 816 F. App'x 471, 476-77 (Fed. Cir. 2020). That panel recognized and applied the relevant principle (which should have governed here too): "Even assuming that measuring the atrial fibrillation burden is a new metric as CardioNet claims, it is at most a mathematical computation performed on a general-purpose computing device, which *could* otherwise be 'performed by a human, mentally or with pen and paper." Id. (emphases added) (quoting Intellectual Ventures I LLC, 838 F.3d at 1318, which cites the application of *Benson* and Flook in CyberSource Corp. v. Retail Decisions, Inc., 654 F.3d 1366, 1371-72 (Fed. Cir. 2011)). In other words, even if the claims recited automatically calculating a "new metric" for diagnosing a heart condition based on a patient's heartbeats, it was still an abstract idea because that calculation "could" be performed mentally by a human. Id. In contrast, here, the panel incorrectly insisted on evidence that the mental concepts were "long standing." Supra at $20\text{-}21.^8$

And to take another example (discussed above), one Federal Circuit panel (applying Benson and *Flook*) held that computer-implemented claims for collecting, analyzing, and presenting data to monitor a system for anomalies were ineligible because they were "essentially mental processes within the abstract idea category," Electric Power, 830 F.3d at 1354, whereas another panel (ignoring *Benson* and *Flook*) reached the opposite conclusion on materially indistinguishable claims, SRI Int'l, 930 F.3d at 1303; see id. at 1312-13 (Lourie, J., dissenting); supra at 10-11. The Federal Circuit's disparate evaluations of patent eligibility under § 101 and panel-dependency in inconsistently applying *Benson* and *Flook* further underscores the need for the Court to address the conflict in this case.

C. The Federal Circuit's Decision Also Directly Conflicts With Mayo

The Federal Circuit's decision in this case also conflicts with this Court's own decisions building on *Benson* and *Flook*, including this Court's decision in *Mayo*. The mental activity at the heart of these

⁸ Underscoring the panel's departure here from settled principles, the Federal Circuit also has held ineligible other CardioNet patent claims for automatically identifying "relevance" of cardiac signals using a "new algorithm," reasoning that it was "no more than a mental process, capable of performance in the human mind or with pen and paper, and is therefore itself an abstract idea." Braemar Mfg., LLC v. ScottCare Corp., 816 F. App'x 465, 469-70 (Fed. Cir. 2020).

claims is far more abstract than the natural law and mental steps found ineligible in *Mayo*.

In *Mayo*, the patent claims recited a medical method for calibrating a patient's dosage of certain thiopurine drugs based on a correlation between specific levels of certain metabolites in a patient's blood and the efficacy or toxicity of the drugs. 566 U.S. at 73-75; *see id.* at 86 (recited medical principles were "narrow" with "limited applications").⁹ That specific correlation—recited in the claims as mental steps for "indicat[ing]" the need to increase or decrease the drugs—was not longstanding medical activity. *See id.* at 74 ("[T]hose in the field did not know the precise correlations between metabolite levels and likely harm or ineffectiveness."); *id.* at 73

wherein the level of 6-thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

566 U.S. at 74-75 (quoting patent).

⁹ A representative patent claim in *Mayo* recited:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

⁽a) administering a drug providing 6thioguanine to a subject having said immunemediated gastrointestinal disorder; and

⁽b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

("[T]he steps in the claimed processes (*apart from the natural laws themselves*) involve well-understood, routine, conventional activity previously engaged in by researchers in the field." (emphasis added)). Nonetheless, this Court recognized that it reflected a patent ineligible concept.¹⁰

Here, the claims do not even purport to quantify a specific correlation between the patient's heartbeats (including premature ventricular beats) and the existence of the AF conditions. Illustrative claim 1 recites. purelv functional merelv in terms. determining whether there is some unspecified "relevance" between those medical phenomena. App. 76a (cl. 1). The only other meaningful difference from the ineligible Mayo claims is that, here, the (far abstract) "relevance" determination more is automated. But the claimed automation is expressly described in results-oriented terms, with no pretense of any improved technology. At the outset, claim 1 recites collecting the patient's physiological measurement (heartbeats) using well-known, off-theshelf devices (id. at 76a (cl. 1); see id. at 73a, 75a (5:15-20, 9:22-32))—just like the claimed "methods for determining metabolite levels were well known" in Mayo, 566 U.S. at 79. Claim 1 here then recites nonspecific functional components to perform the diagnostic steps that medical professions otherwise could perform: "determination logic" (with no details specified) to determine whether the variability in

¹⁰ The Federal Circuit has applied *Mayo* in finding other specific natural laws ineligible under § 101. *See, e.g., Cleveland Clinic Found. v. True Health Diagnostics, LLC,* 859 F.3d 1352, 1361 (Fed. Cir. 2017) (correlation between myeloperoxidase in a bodily sample and cardiovascular disease risk), *cert. denied,* 138 S. Ct. 2621 (2018).
heartbeats is "relevan[t]" to AF and an "event generator" to generate an event if it is, indeed, relevant. App. 76a (cl. 1); *see id*. (11:5-12:9) (can use "any combination" of "general purpose" components, "any computer program product[s] ... to provide machine instructions and/or data to a programmable processor," "any form of sensory feedback," and "any form or medium of digital data communication").

In effect, therefore, the Federal Circuit's decision in this case means that adding generic automation to the Mayo patent claims would have made them eligible under § 101. Suppose, for example, the Mayo claims recited (a) conventional devices for collecting the patient's metabolite levels, (b) "determination logic" to determine whether they are "relevant" to efficacy or toxicity (*i.e.*, because they exceed certain numerical amounts), and (c) an "event generator" to indicate that a change in dosage is warranted. Under the Federal Circuit's reasoning in this case, those hypothetical claims would have survived § 101 because. although doctors could perform the determinations mentally, there was no evidence "that doctors long used the claimed diagnostic processes" (id. at 19a (emphasis added))-i.e., no evidence doctors had long relied on the particular metabolite levels to assess efficacy or toxicity. See Mayo, 566 U.S. at 73-74.

That makes no sense. *Mayo* itself held that adding conventional technology (in that case, routine medical measuring technology) to an ineligible principle does not convert it to a patent eligible application. *Id.* at 79-80. And *Alice* confirmed that automating an ineligible principle using generic computer technology does not confer eligibility. 573 U.S. at 212, 221-27. The Federal Circuit's decision, therefore, also conflicts with those decisions and that additional conflict warrants this Court's review.

III. THIS CASE PROVIDES AN IDEAL VEHICLE TO PROVIDE FURTHER GUIDANCE ON THE SCOPE OF § 101

A. The Federal Circuit's Decision Addressed A Pure Legal Issue

The appeal before the Federal Circuit raised a clean legal issue—the patent eligibility of a single patent that purports to automate medical diagnostic techniques. The Federal Circuit squarely held, as a matter of law, that proof of a longstanding practice (of the claimed techniques) was necessary to find the claims abstract and ineligible, in direct conflict with Benson and Flook. Supra at 20-22. In addition, as discussed, the Federal Circuit's insistence on evidence of a longstanding human practice stands in stark contrast to the principles and holdings announced in Mayo as well. Supra at 23-26. Moreover, this case is not clouded by any of the procedural issues—*i.e.*, whether there are fact issues at step two of the *Alice* analysis—that prompted the government torecommend against granting review in *Berkheimer*. Berkheimer U.S. Invitation Brief See at 10(addressing the "procedural question is . . . premature"). Instead, this case focuses squarely, and solely, on the "substantive standard for assessing patent-eligibility under [§] 101" that. as the "fostered government acknowledged. has uncertainty" and warrants review. Id.

B. The Federal Circuit's Decision Is Wrong And Impedes Innovation

The Federal Circuit's decision is also wrong and, if allowed to stand, will impede innovation. As the district court concluded, under a straightforward application of the two-step *Alice* framework—in view of a proper reading of *Benson* and *Flook*—the '207 patent claims are ineligible because they merely purport to automate activities that doctors can perform mentally—the very substance of medical judgment and practice. *See* App. 41a-59a; *supra* at 6-7, 17-19. That is true regardless of whether these automated processes are deemed longstanding or new.

At *Alice* step one, the claims plainly center on an abstract concept. It was undisputed below that the claims' focus-*i.e.*, determining the "relevance" of a patient's heartbeat data, including certain irregular beats (premature ventricular beats), in diagnosing certain heart conditions (AF)—is something that doctors *can* do mentally. As the district court correctly held, the claims are directed to "the abstract idea of identifying AF by looking at the variability in time between heartbeats and taking into account ventricular beats," id. at 55a, which are "essentially mental processes," id. at 46a (citation omitted). The Federal Circuit only found the claims non-abstract because, in that court's view, there was no evidence that doctors had long done so. Id. at 18a-19a, 25a. But under *Benson* and *Flook*, as reaffirmed in *Mayo* and *Alice*, claims are ineligible even if they are directed to mental processes that are not longstanding.

And, at *Alice* step two, the claims add nothing inventive. Instead, they merely purport to automate the mentally performable abstract concept using medical generic computer components and technology, with no explanation for how the "relevance" determination diagnosis or is

See supra at 25-26; App. 76a-77a. accomplished. Indeed, the claims provide far less detail about the computer components than the computerimplemented claims that this Court found ineligible in Benson and Alice. See Benson, 409 U.S. at 73-74 (multi-step claims for performing conversion, storing binary digits in "reentrant shift register[s]" and shifting signals to the left and right in specific ways); Alice, 573 U.S. at 224 (multi-step claims for creating updating "shadow records" and and issuing instructions to exchange institutions). The district court correctly found the claims failed step two of the Alice analysis, App. 48a-58a, and the Federal Circuit did not hold otherwise; its analysis ended at step one, id. at 21a.

Holding that the kind of abstract concept at issue in this case is patent eligible would impede scientific progress in developing new medical processes and treatments through the use of mental concepts owned by all. Moreover, software patents like these are especially prone to abuse because "their scope is ... disproportionate vastly to their technological disclosure"-they "do not include any actual code developed by the patentee, but instead describe, in intentionally vague and broad language, a particular goal or objective." Intellectual Ventures I LLC, 838 F.3d at 1326-27 (Mayer, J., concurring); see also, e.g., Jonathan Stroud & Derek M. Kim, Debugging Software Patents After Alice, 69 S.C.L. Rev. 177, 205 (2017) ("[S]oftware patents, by their very nature, generally have broad, ambiguous claims"). As discussed, the claims here are purely results-oriented, with no disclosure of any inventive technology or concepts. They instead leave to others the hard work of programming a computer or manufacturing hardware to actually make the desired diagnostic determinations. If invoking the "abstract idea" exception requires proof of longstanding human activities—as the Federal Circuit held here—then parties may seek to secure monopolies on fundamental concepts available to all by couching claims in intentionally vague terms to automate purportedly new mentally performable activities—as the claims at issue here do.

This case illustrates precisely danger to innovation and competition. An established market player (CardioNet) is wielding an intentionally vague and functional set of patents-many of which were correctly found ineligible by a different Federal Circuit panel—to smother an upstart competitor in the crib with litigation costs and the assertion of bogus patent monopolies. The principal suggestion here is not that InfoBionic copied any of CardioNet's actual technology-the hardware and software that CardioNet developed and deployed in the marketplace. Rather, the contention is that InfoBionic is precluded from developing competing (and, InfoBionic's view, better) technology because CardioNet "owns" the concept of automatically diagnosing certain heart conditions by determining the relevance of a certain type of heartbeats-no how matter that automation is actually implemented—merely because that abstract diagnostic idea was purportedly not longstanding. That is anathema to this Court's § 101 precedents and opens the door to widespread abuse.

If the Federal Circuit judges themselves cannot find a consistent approach to § 101—even on similar computer claims asserted by the same patentee against the same defendant—then the public, innovators, and investors stand little chance of predicting the outcome for any given software patents. The longer the Federal Circuit is allowed to flounder, the greater the uncertainty, and the greater the risk patent monopolies will be abused to thwart innovation. This Court understandably cannot retool the law in this area in one broad stroke. But granting review in this case would be a first, and undeniably important, step to providing much needed guidance in this critical area of law, and reinforcing that it means what it has already said.

CONCLUSION

The petition for a writ of certiorari should be granted.

CHARLES H. SANDERS LATHAM & WATKINS LLP 200 Clarendon Street 27th Floor Boston, MA 02116 Respectfully submitted, GREGORY G. GARRE *Counsel of Record* GABRIEL K. BELL MAXIMILIAN A. GRANT LATHAM & WATKINS LLP 555 11th Street, NW Suite 1000 Washington, DC 20004 (202) 637-2207 gregory.garre@lw.com *Counsel for Petitioner*

November 2, 2020

APPENDIX VOLUME I OF II

TABLE OF CONTENTS

Page

VOLUME I

VOLUME II

U.S. Patent No. 7,941,207 B2 (May 10, 2011)62a

UNITED STATES COURT OF APPEALS, FOR THE FEDERAL CIRCUIT

CARDIONET, LLC, Braemar Manufacturing, LLC, Plaintiffs-Appellants

v.

INFOBIONIC, INC, Defendant-Appellee

2019-1149

Decided: April 17, 2020

955 F.3d 1358

Before DYK, PLAGER, and STOLL, Circuit Judges.

Opinion dissenting in part and concurring in the result filed by Circuit Judge DYK.

STOLL, Circuit Judge.

CardioNet, LLC and Braemar Manufacturing, LLC (collectively, "CardioNet") appeal the district court's dismissal of their patent infringement complaint against InfoBionic, Inc. The district court held that the asserted claims of CardioNet's U.S. Patent No. 7,941,207 are ineligible under 35 U.S.C. § 101, and therefore the complaint failed to state a claim under Federal Rule of Civil Procedure 12(b)(6). We conclude instead that the asserted claims of the '207 patent are directed to a patent-eligible improvement to cardiac monitoring technology and are not directed to an abstract idea. Accordingly, we reverse the district court and remand for further proceedings.

BACKGROUND

Ι

Anomalies in the electrical activity of a patient's heart can indicate the presence of certain physiological conditions ranging from benign to lifethreatening. Among those conditions are various different types of cardiac arrythmias (abnormal heart rhythms), including atrial fibrillation, atrial flutter, normal sinus rhythm irregularity, irregularity from various types of heart blocks, irregularity associated with premature ventricular contractions, and ventricular tachycardia.

Atrial fibrillation and atrial flutter involve "the loss of synchrony between the atria and the ventricles" of the heart. '207 patent col. 1 ll. 24-25, 34 - 35.A patient may experience "short" or "sustained" episodes of atrial fibrillation or atrial flutter. Short episodes "generally include between two and 20 [heart]beats and may or may not have clinical significan[ce]." Id. at col. 5 ll. 33-35. By contrast, sustained episodes "generally include more than 20 beats and may have relatively greater clinical significance." Id. at col. 5 ll. 35-37. Atrial fibrillation "can lead to irregular ventricular beating as well as blood stagnation and clotting in the atria." Id. at col. 1 ll. 27–28. Both atrial fibrillation and atrial flutter are "associated with stroke, congestive heart failure, and cardiomyopathy." Id. at col. 1 ll. 31-32, 40-42.

Ventricular tachycardia, or V-TACH, is another form of cardiac arrythmia and is characterized by "a rapid succession of ventricular contractions (e.g., between 140 and 220 per minute) generally caused by an abnormal focus of electrical activity in a ventricle." Id. at col. 9 ll. 41–44. Ventricular beats "are irregular beats that interrupt the normal heart rhythm" and that "may be precipitated by factors such as alcohol, tobacco, caffeine, and stress." Id. at col. 9 ll. 10–12, 19–20. The "occurrence of ventricular beats can be used to identify ventricular tachycardia (e.g., when there are three or more consecutive ventricular beats)." Id. at col. 9 ll. 16–19. V-TACH "can last from a few seconds to several days and can be caused by serious heart conditions such as a myocardial infarction." Id. at col. 9 ll. 44–46.

The '207 patent is titled "Cardiac Monitoring" and claims priority to an application filed on January 21, 2004. The '207 patent describes cardiac monitoring techniques for systems and detecting and distinguishing atrial fibrillation and atrial flutter from other various forms of cardiac arrythmia. Electrical signals of the heart can be measured by placing electrodes on a patient's skin. Id. at col. 1 ll. 17–20, col. 5 ll. 1–7. The patent teaches that its systems and techniques determine the beat-to-beat variability in heart rate over a series of successive heartbeats. Specifically, they determine the variability in heart rate "over a series of between 20 and 200 of the recent R to R intervals," or the timing between "R-waves." Id. at col. 2 ll. 4-6, 47-49. An Rwave is the peak of what is referred to as the "QRS complex" of an electrocardiogram signal, as illustrated in Figure 2 below. The QRS complexes (items 215, 220, and 225 of Figure 2) of the signal correspond to the contractions of the ventricles. Id. at col. 4 ll. 53-58.



Id. Fig. 2. A schematic of the '207 patent's cardiac monitoring system is shown below in Figure 8:



FIG. 8

Id. Fig. 8. The written description explains that in detecting atrial fibrillation and atrial flutter, the systems and techniques include accounting for the presence of irregular ventricular beats, which are "negatively indicative" of atrial fibrillation and atrial flutter. *Id.* at col. 1 ll. 61–65, col. 2 ll. 53–61. The patent recognizes that the "occurrence of ventricular beats is generally unrelated to" atrial fibrillation and

atrial flutter, whereas it is indicative of VTACH. *Id.* at col. 9 ll. 15–19. The patent's systems and techniques also analyze information regarding the time period between ventricular contractions (i.e., the R to R interval) to detect atrial fibrillation and atrial flutter using non-linear statistical approaches. *Id.* at col. 1 ll. 49–54, col. 5 ll. 40–44. Figure 10 depicts an embodiment of the '207 patent's system employing these techniques:



FIG. 10

Id. Fig. 10.

Claims 1–3, 7, 10–12, and 22 are at issue on appeal. The claims are drawn to a device for detecting and reporting the presence of atrial fibrillation or

atrial flutter in a patient. Specifically, the device detects beat-to-beat timing of cardiac activity, detects premature ventricular beats (irregular beats that interrupt the normal heart rhythm),¹ and determines the relevance of the beat-to-beat timing to atrial fibrillation or atrial flutter, taking into account the variability in the beat-to-beat timing caused by premature ventricular beats.

Independent claim 1 recites:

1. A device, comprising:

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

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

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

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

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

¹ For purposes of the motion to dismiss, the district court adopted CardioNet's construction of the term "ventricular beats" to mean "premature ventricular beats that are irregular beats that interrupt the normal heart rhythm." *CardioNet, LLC v. InfoBionic, Inc.*, 348 F. Supp. 3d 87, 96 n.4 (D. Mass. 2018) (citation omitted).

beat-to-beat timing caused by ventricular beats identified by the ventricular beat detector.

Id. at col. 12 ll. 12–27.

Dependent claims 2, 3, 7, and 10–12 depend from claim 1 and further define the features of the device or its operation:

2. The device of claim 1, wherein the relevance determination logic is to accommodate variability in the beat-to-beat timing caused by ventricular beats by weighting ventricular beats as being negatively indicative of the one of atrial fibrillation and atrial flutter.

3. The device of claim 1, wherein the variability determination logic is to compare times between R-waves in three successive QRS complexes to determine the variability in the beat-to-beat timing.

7. The device of claim 1, wherein the event generator is to generate an event by performing operations comprising: collecting data associated with the collection of beats; and transmitting the data associated with the collection of beats to a remote receiver.

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

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

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

Id. at col. 12 ll. 28–36, 52–56, col. 13 ll. 5–13.

Similar to claim 2, dependent claim 22 recites "weighting" ventricular beats as being negatively indicative of atrial fibrillation or atrial flutter:

22. The article of claim $20,^2$ determining the relevance comprises: identifying a beat of the collection as a ventricular beat, and weighting the beat as being negatively indicative of the one of atrial fibrillation and atrial flutter.

Id. at col. 14 ll. 39–43.

The '207 patent describes a number of advantages achieved by the claimed cardiac monitoring device. For instance, by analyzing the beat-to-beat timing for atrial fibrillation or atrial flutter while also taking into account the variability in the beat-to-beat timing caused by premature ventricular beats, the device can

Id. at col. 14 ll. 12-24.

² Claim 20 recites:

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

more accurately distinguish atrial fibrillation and atrial flutter from other types of arrythmias and has "improved positive predictability" of atrial fibrillation and atrial flutter. Id. at col. 3 ll. 6-16. The written description states that when the device was used to analyze the MIT-BIH arrhythmia database in Cambridge, Massachusetts, "a sensitivity to [these two arrhythmias] in excess of 90% and a positive predictivity in excess of 96% were obtained." Id. at col. 3 ll. 21–26. In other words, the device reports few false negatives and false positives when used to detect atrial fibrillation or atrial flutter. In addition, the device is able to identify "sustained" episodes of atrial fibrillation and atrial flutter, which have "increased clinical significance" compared to "short" episodes. Id. at col. 3 ll. 16–20. Moreover, the device is "welladapted to monitoring cardiac signals of ambulatory patients who are away from controlled environments such as hospital beds or treatment facilities," and whose cardiac signals "may be noisier and otherwise strongly impacted by the patients' heightened levels of activity." Id. at col. 3 ll. 27–34. The device is also "well-adapted to real-time monitoring of arrhythmia patients, where minimal delays in distinguishing between different types of cardiac arrhythmia can speed the delivery of any urgent medical care." Id. at col. 3 ll. 35–39. Lastly, the device is advantageous in that it "require[s] minimal computational resources" and "do[es] not require training before different types of cardiac arrhythmia can be distinguished." Id. at col. 3 ll. 39-43.

Π

InfoBionic filed a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), arguing that the asserted claims are directed to patent-ineligible subject matter under § 101. The district court determined that the '207 patent claims are ineligible under § 101, applying the Supreme Court's two-step framework for determining patent eligibility. *See Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 134 S.Ct. 2347, 189 L.Ed.2d 296 (2014).

At step one, the district court concluded that the claims are directed to the abstract idea that atrial fibrillation and atrial flutter "can be distinguished by focusing on the variability of the irregular heartbeat." CardioNet, LLC v. InfoBionic, Inc., 348 F. Supp. 3d 87, 93 (D. Mass. 2018) (District Court Op.); see also id. at 97 (further defining the abstract idea as "identifying" atrial fibrillation or atrial flutter "by looking at the variability in time between heartbeats and taking into account ventricular beats"). The district court rejected CardioNet's argument that the claimed invention "represents an improvement to the function of cardiac monitoring devices," including "more accurate and clinically significant" detection of atrial fibrillation and atrial flutter. Id. at 93 (citation omitted). The district court concluded that although the "idea of using a machine to monitor and analyze heart beat variability and interfering beats so as to alert the user of potential [atrial fibrillation or atrial flutter] events may well improve the field of cardiac telemetry." CardioNet "d[id] not identify improvements to any particular computerized technology." Id.

CardioNet appeals. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

We apply regional circuit law when reviewing the district court's dismissal of a complaint for failure to

Athena Diagnostics, Inc. v. Mayo state a claim. Collaborative Servs., LLC, 915 F.3d 743, 749 (Fed. Cir. 2019). The First Circuit reviews such dismissals de novo, accepting as true all well-pleaded facts alleged in the complaint and drawing all reasonable inferences in favor of the non-moving party. In re Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 549 (1st Cir. 2016). Patent eligibility under § 101 is a question of law that may contain underlying issues of fact. See Aatrix Software, Inc. v. Green Shades Software, Inc., 882 F.3d 1121, 1125 (Fed. Cir. 2018); Berkheimer v. HP Inc., 881 F.3d 1360, 1365 (Fed. Cir. 2018). We review de novo a determination that a claim is patent-ineligible subject directed to matter. Berkheimer, 881 F.3d at 1365.

Ι

Section 101 provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor." 35 U.S.C. § 101. The Supreme Court has identified three types of subject matter that are not patent-eligible: "Laws of nature, natural phenomena, and abstract ideas are not patentable." *Alice*, 573 U.S. at 216, 134 S.Ct. 2347 (quoting *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589, 133 S.Ct. 2107, 186 L.Ed.2d 124 (2013)).

In *Alice*, the Supreme Court articulated a two-step test for examining patent eligibility when a patent claim is alleged to involve one of these three types of subject matter. The "abstract ideas" category, the subject matter at issue in this case, embodies "the longstanding rule that '[a]n idea of itself is not patentable.'" *Id.* at 218, 134 S.Ct. 2347 (alteration in original) (quoting Gottschalk v. Benson, 409 U.S. 63, 67, 93 S.Ct. 253, 34 L.Ed.2d 273 (1972)). The Supreme Court recognized, however, that "[a]t some level, 'all inventions ... embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." Id. at 217, 134 S.Ct. 2347 (alteration in original) (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 71, 132 S.Ct. 1289, 182 L.Ed.2d 321 (2012)). "Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept." Id. Rather, "applications" of abstract concepts "to a new and useful end ... remain eligible for patent protection." Id. (quoting Benson, 409 U.S. at 67, 93 S.Ct. 253).

At step one, we consider the claims "in their entirety to ascertain whether their character as a whole is directed to excluded subject matter." McRO, Inc. v. Bandai Namco Games Am. Inc., 837 F.3d 1299, 1312 (Fed. Cir. 2016) (quoting Internet Patents Corp. v. Active Network, Inc., 790 F.3d 1343, 1346 (Fed. Cir. 2015)); see also Elec. Power Grp., LLC v. Alstom S.A., 830 F.3d 1350, 1353 (Fed. Cir. 2016) ("[W]e have described the first-stage inquiry as looking at the 'focus' of the claims, their 'character as a whole.'" (citations omitted)). We also consider the patent's written description, as it informs our understanding of the claims. See Chamberlain Grp., Inc. v. Techtronic Indus. Co., 935 F.3d 1341, 1346 (Fed. Cir. 2019) ("[T]he specification [is] helpful in illuminating what a claim is 'directed to.'" (alterations in original) (citation omitted)). "If the claims are not directed to a patent-ineligible concept under Alice step 1, 'the claims satisfy § 101 and we need not proceed to the second step.'" Data Engine Techs. LLC v. Google LLC, 906 F.3d 999, 1007 (Fed. Cir. 2018) (quoting

Core Wireless Licensing S.A.R.L. v. LG Elecs., Inc., 880 F.3d 1356, 1361 (Fed. Cir. 2018)).

"If the claims are directed to a patent-ineligible concept, however, we next consider Alice step two." *Id.* In this step, we consider "the elements of each individually and 'as an ordered claim both combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." Alice, 573 U.S. at 217, 134 S.Ct. 2347 (quoting Mayo, 566 U.S. at 78–79, 132 S.Ct. 1289). This second step is "a search for an 'inventive concept'—*i.e.*, an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." Id. at 217–18, 134 S.Ct. 2347 (alteration in original) (quoting Mayo, 566 U.S. at 72–73, 132 S.Ct. 1289).

Π

We begin our analysis with *Alice* step one. In doing so, we look to whether the claims "focus on a specific means or method that improves the relevant technology or are instead directed to a result or effect that itself is the abstract idea and merely invoke generic processes and machinery." *McRO*, 837 F.3d at 1314 (citations omitted). We hold that the asserted claims of the '207 patent are directed to patenteligible subject matter.

А

When read as a whole, and in light of the written description, we conclude that claim 1 of the '207 patent is directed to an improved cardiac monitoring device and not to an abstract idea. In particular, the language of claim 1 indicates that it is directed to a device that detects beat-to-beat timing of cardiac activity, detects premature ventricular beats, and determines the relevance of the beat-to-beat timing to atrial fibrillation or atrial flutter, taking into account the variability in the beat-to-beat timing caused by premature ventricular beats identified by the device's ventricular beat detector. In our view, the claims "focus on a specific means or method that improves" cardiac monitoring technology; they are not "directed to a result or effect that itself is the abstract idea and merely invoke generic processes and machinery." McRO, 837 F.3d at 1314 (citations omitted).

The written description confirms our conclusion. It explains that, by identifying "variability in the beat-to-beat timing . . . as relevant to the at least one of atrial fibrillation and atrial flutter in light of the variability in the beat-to-beat timing caused by ventricular beats identified by the ventricular beat detector," the claimed invention achieves multiple technological improvements. First and foremost, the device more accurately detects the occurrence of atrial fibrillation and atrial flutter-as distinct from V-TACH and other arrhythmias-and allows for more reliable and immediate treatment of these two medical conditions. '207 patent col. 3 ll. 6-16, 21-26, 35–39. Indeed, the written description reports that when analyzing real-world arrythmia data, the device demonstrated both high "positive predictivity" of, and high "sensitivity" to, atrial fibrillation and atrial flutter, meaning that it effectively avoids false positives and false negatives, respectively, in detecting these two conditions. Id. at col. 3 ll. 21–26. In addition, the device is able to identify sustained episodes of atrial fibrillation and atrial flutter that have "increased clinical significance." Id. at col. 3 ll. 16 - 20.

The dependent claims are similarly directed to patent-eligible subject matter, as they further specify the physical features or operation of the device of claim 1. For instance, claim 2 additionally requires "weighting" ventricular beats "as being negatively indicative of the one of atrial fibrillation and atrial flutter." Claim 22, which depends from independent claim 20, recites a similar limitation. Claim 3 is additionally directed to "compar[ing] times between R-waves in three successive QRS complexes to determine the variability in the beat-to-beat timing." Claim 7 is additionally directed to "transmitting the data associated with the collection of beats to a remote receiver." Claim 10 additionally requires "using a non-linear function of a beat-to-beat interval." Claim 11 is additionally directed to the use of a "QRS detector." Finally, claim 12 is additionally directed to using "a sensor that includes two or more body surface electrodes subject to one or more potential differences related to cardiac activity." Thus, each of these dependent claims narrows the device's specific technical features or operations.

We agree with CardioNet that the claims of the '207 patent are akin to claims we have previously determined are directed to technological improvements. For instance, the asserted claims are similar to those we held eligible in *Visual Memory* LLC v. NVIDIA Corp., 867 F.3d 1253 (Fed. Cir. 2017). There, the claims recited a "computer memory system" that used "programmable operational characteristics" of a computer's cache memory based on the type of processor connected to the memory system. Id. at 1257. On appeal from a dismissal under Rule 12(b)(6), we held under Alice step one that the claims were "directed to an improved computer

memory system, not to the abstract idea of categorical data storage." Id. at 1259. Important to our determination was the fact that the written description described technical "advantages offered by" the claimed memory system. Id. at 1259-60. In particular, the written description explained that the claimed system was able to accommodate "different of processors ... without significantly types compromising their individual performance" and "outperform[ed] a prior art memory system . . . armed with 'a cache many times larger than the cumulative size of the subject caches." Id. at 1259 (citations omitted). Weighing "all factual inferences drawn from the specification . . . in favor of Visual Memory, the non-moving party," we reversed the district court's decision that the claims were ineligible. Id. at 1262.

here. the '207 patent's Similarly, written description identifies a number of advantages gained by the elements recited in the claimed cardiac monitoring device. By analyzing the "variability in the beat-to-beat timing" for "atrial fibrillation and atrial flutter in light of the variability in the beat-tobeat timing caused by ventricular beats identified by the ventricular beat detector," the claimed invention more accurately detects the occurrence of atrial fibrillation and atrial flutter, as distinct from V-TACH and other arrhythmias. '207 patent col. 3 ll. 6-16, 21–26, 35–39. We accept those statements as true and consider them important in our determination that the claims are drawn to a technological improvement.

The '207 patent claims are also similar to those we held eligible in McRO. The patent at issue in McRO claimed a "method for automatically animating lip

synchronization and facial expression of threedimensional characters." 837 F.3d at 1307. We reversed the district court's grant of judgment on the pleadings under Federal Rule of Civil Procedure 12(c) that the claims were directed to an abstract idea. We held under Alice step one that the claims were directed to "a specific asserted improvement in computer animation, i.e., the automatic use of rules of a particular type." *Id.* at 1314. The written description confirmed that the "claimed improvement" was "allowing computers to produce accurate and realistic lip synchronization and facial expressions in animated characters that previously could only be produced by human animators." Id. at 1313 (internal quotation marks and citation omitted). We rejected the argument that the claims "simply use a computer as a tool to automate conventional activity" because there was no evidence in the record that "the process previously used by animators [wa]s the same as the process required by the claims." Id. at 1314. The specification made "no suggestion that animators were previously employing the type of rules required by" the claims. Id. In fact, the evidence in the record showed that the traditional process and claimed method produced realistic animations of facial movements in fundamentally different ways. Id.

In this case, there is likewise no suggestion in the '207 patent's written description that doctors were "previously employing" the techniques performed on the claimed device. Nothing in the record in this case suggests that the claims merely computerize preexisting techniques for diagnosing atrial fibrillation and atrial flutter. Moreover, as in McRO, the written description of the '207 patent confirms that the asserted claims are directed to a specific technological improvement—an improved medical device that achieves speedier, more accurate, and clinically significant detection of two specific medical conditions out of a host of possible heart conditions.

В

At the heart of the district court's erroneous step one analysis is the incorrect assumption that the claims are directed to automating known techniques. See District Court Op., 348 F. Supp. 3d at 93. InfoBionic reiterates this argument on appeal, asserting that "the claims are drawn to automating basic diagnostic processes that doctors have long used." Appellee's Br. 2; see also id. at 11 ("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."); id. at 12 ("[T]he claims use computers as mere tools to automate basic human steps."); *id.* at 20 ("[C]laim 1 is nothing more than a computerized version of a doctor's approach to diagnosis."). But the written description does not disclose that doctors performed the same techniques as the claimed device in diagnosing atrial fibrillation or atrial flutter. 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. The district court's assumption also seems incongruous with the claimed subject matter. For example, it is difficult to fathom how doctors mentally or manually used "logic to identify the relevance of the variability [in the beat-to-beat timing] using a non-linear function of a beat-to-beat interval" as required by claim 10. For all these

reasons, the district court erred by holding that the claims are abstract based on this erroneous finding.

Likewise, the district court erred by disregarding the written description's recitation of the advantages of the claimed invention. In opposing InfoBionic's motion, CardioNet had argued that, based on the patent's disclosure, the claimed invention "achieve[s] more accurate and clinically significant" detection of atrial fibrillation and atrial flutter, and thereby constitutes an improvement to cardiac monitoring technology as opposed to an abstract idea. *District* Court Op., 348 F. Supp. 3d at 93 (citation omitted). The district court dismissed this argument. concluding that CardioNet did "not identify improvements to any particular computerized technology." Id. On a motion to dismiss under Rule 12(b)(6), however, the district court must construe all facts and draw all reasonable inferences in favor of CardioNet, the non-moving party. See Athena, 915 F.3d at 749. Here, there is no record evidence undermining the statements in the written description concerning the benefits of the claimed device. The district court's finding is contrary to fact and fails to draw all reasonable inferences in CardioNet's favor.

Furthermore, the district court erred in analogizing the '207 patent claims to certain ineligible "computer-implemented claims for collecting and analyzing data to find specific events." District Court Op., 348 F. Supp. 3d at 92–93. In particular, the district court found comparable our decisions in Berkheimer and FairWarning IP, LLC v. Iatric Systems, Inc., 839 F.3d 1089 (Fed. Cir. 2016). Generalizing the asserted claims as being directed to analyzing, collecting, and reporting data is

inconsistent with our instruction that courts "be careful to avoid oversimplifying the claims' by looking at them generally and failing to account for the specific requirements of the claims." McRO, 837 F.3d at 1313 (citations omitted). In stark contrast to the claims in *Berkheimer* and *FairWarning IP*, the claims of the '207 patent do not merely collect electronic information, display information, or embody mental processes. Indeed, the claims of the '207 patent do not "fit into the familiar class of claims that" focus on "certain independently abstract ideas that use computers as tools." SAP Am., Inc. v. InvestPic, LLC, 898 F.3d 1161, 1168 (Fed. Cir. 2018) (quoting *Elec*. *Power*, 830 F.3d at 1354). Rather, as discussed above, they fit into the class of claims that focus on "an improvement in computers [and other technologies] as tools." Id. Accordingly, the district court's and InfoBionic's reliance on these cases was misplaced.

Because we conclude under *Alice* step one that the asserted claims of the '207 patent are not directed to an abstract idea, we do not reach *Alice* step two. *See Data Engine*, 906 F.3d at 1011; *Visual Memory*, 867 F.3d at 1262. The claims are patent eligible under § 101.

С

Finally, we turn to a dispute raised in the parties' briefs and oral argument, namely, whether we can resolve this *Alice* step one issue at the Rule 12(b)(6) stage without remanding to assess the state of the art as of the invention date to determine whether the asserted claims are directed to automating a practice long used by doctors. *Compare* Appellants' Br. 47 (noting the absence of prior art or expert testimony in the record demonstrating that the claims fail to improve cardiac monitoring technology) *and* Oral Arg.

at 9:16–48, http://oralarguments.cafc.uscourts.gov/ default.aspx?fl=2019-1149.mp3 ("There are factual determinations that need to be made here on what was done by doctors . . . Did they negatively weight this premature ventricular beats in their diagnosis of atrial fibrillation?") with Appellee's Br. 49 ("Here . . . the intrinsic record is dispositive."). We conclude that a remand is unnecessary. Alice step one presents a legal question that can be answered based on the intrinsic evidence.

The analysis under *Alice* step one is whether the claims as a whole are "directed to" an abstract idea, regardless of whether the prior art demonstrates that the idea or other aspects of the claim are known, unknown, conventional, unconventional, routine, or not routine. See Diamond v. Diehr, 450 U.S. 175, 188-89, 101 S.Ct. 1048, 67 L.Ed.2d 155 (1981) ("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."); Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 939 F.3d 1355, 1362 n.3 (Fed. Cir. 2019) ("[I]t makes no difference to the section 101 analysis whether the use of [ineligible subject matter] was known in the prior art."); Data Engine, 906 F.3d at 1011 ("The eligibility question is not whether anyone has ever used tabs to organize information. That question is reserved for §§ 102 and 103. The question of abstraction is whether the claim is 'directed to' the abstract idea itself.").

Indeed, subject matter eligibility under § 101 ordinarily is merely the first step in determining the patentability of a claim. A patent claim must meet other statutory criteria to be valid, including that its claimed invention be novel and nonobvious over the prior art, as well as described adequately to enable its use. See 35 U.S.C. §§ 102, 103, 112. While "it may later be determined that [CardioNet's claimed invention] is not deserving of patent protection because it fails to satisfy the statutory conditions of novelty under § 102 or nonobviousness under § 103," *Diehr*, 450 U.S. at 191, 101 S.Ct. 1048, based on prior art not yet part of the record, the novelty or nonobviousness of the invention has little to no bearing on the question of what the claims are "directed to."

It is true, as the dissent contends, that the Supreme Court in *Alice* and *Bilski v. Kappos* identified as abstract claims directed to performing on a computer "fundamental economic practice[s] long prevalent in our system of commerce." *Alice*, 573 U.S. at 219, 134 S.Ct. 2347 (holding ineligible patent claims directed to the concept of "intermediated settlement," i.e., the use of a third party to mitigate the risk that only one party to an agreed-upon financial exchange will satisfy its obligation); *Bilski v. Kappos*, 561 U.S. 593, 611, 130 S.Ct. 3218, 177 L.Ed.2d 792 (2010) (holding ineligible claims of a patent application directed to the "basic concept of hedging, or protecting against risk," in the field of commodities trading).

But, in neither *Bilski* nor *Alice* did the Court rely on an examination of the prior art as part of its step one inquiry. This is consistent with the other cases cited by the dissent. In determining what the claims are directed to and whether they are directed to an abstract idea, a court may well consult the plain claim language, written description, and prosecution history and, from these sources, conclude that the claims are directed to automating a longstanding or fundamental practice.

Similarly, the court may consult the intrinsic evidence and conclude that the claims are directed to improving the functionality of a computer or network. The court need not consult the prior art to see if, in fact, the assertions of improvement in the patent's written description are true. Rather, "[t]he § 101 patent-eligibility inquiry is only a threshold test," *Bilski*, 561 U.S. at 602, 130 S.Ct. 3218, and we reserve for §§ 102 and 103 purposes our comparison of the prior art and the claims to determine if the claims are, in fact, an improvement over the prior art.

This court's decision in Enfish, LLC v. Microsoft Corp., 822 F.3d 1327 (Fed. Cir. 2016), confirms this point. In *Enfish*, we stated that "the first step in the *Alice* inquiry . . . asks whether the focus of the claims is on the specific *asserted* improvement in computer capabilities" or, instead, on an abstract idea "for which computers are invoked merely as a tool." Id. at 1335–36 (emphasis added). In making this inquiry, we examined the patents' shared written description, including its teachings of the "multiple benefits flow[ing] from th[e] design" of the claimed selfreferential table for a computer database. *Id.* at 1333. Our conclusion that the claims were directed to a patent-eligible invention was based on the patents' teachings that the claimed "self-referential table functions differently than conventional database structures" and "achieves other benefits over conventional databases, such as increased flexibility, faster search times. and smaller memory requirements." Id. at 1337; see also id. at 1339 ("The specification's disparagement of conventional data structures, combined with language describing the

'present invention' as including the features that make up a self-referential table, confirm that our characterization of the 'invention' for purposes of the § 101 analysis has not been deceived by the 'draftsman's art.' "); BASCOM Global Internet Servs., Inc. v. AT&T Mobility LLC, 827 F.3d 1341, 1348 (Fed. Cir. 2016) (concluding that, based on the claim language and written description, the claims were directed to the abstract idea of filtering content on the Internet); FairWarning IP, 839 F.3d at 1093-95 (concluding that, based on the claims, written description, and the patentee's failure to contend that the claims were "directed to an improvement in the way computers operate," the claims were directed to an abstract idea of "collecting and analyzing information to detect misuse and notifying a user when misuse is detected" (citation omitted)). Thus, the Alice step one inquiry in Enfish and our other decisions began, and ended, with the patent itself.

Contrary to the dissent's suggestions, we do not hold today that it is impermissible for courts to "look[] outside the intrinsic evidence" as part of their Alice step one inquiry, Dissent Op. 1379, or that all evidence presented by the parties that doctors have long used the claimed techniques would be irrelevant to the inquiry in this case. It is within the trial court's discretion whether to take judicial notice of a longstanding practice where there is no evidence of such practice in the intrinsic record. But there is no basis for requiring, as a matter of law, consideration of the prior art in the step one analysis in every case. If the extrinsic evidence is overwhelming to the point of being indisputable, then a court could take notice of that and find the claims directed to the abstract idea of automating a fundamental practice, see Bilski,

561 U.S. at 611, 130 S.Ct. 3218—but the court is not required to engage in such an inquiry in every case.

Thus, we simply clarify that step one of the *Alice* framework does not require an evaluation of the prior art or facts outside of the intrinsic record regarding the state of the art at the time of the invention. Neither Bilski, Alice, nor this court's precedent endorses such an analysis. The dissent also contends that "numerous cases decided by our court held that claims were abstract because thev claimed Dissent Op. 1377. longstanding practices." That unqualified statement is simply incorrect. Accordingly, our analysis at *Alice* step one involves examining the patent claims in view of the plain claim language, statements in the written description, and the prosecution history, if relevant. See, e.g., Athena, 915 F.3d at 750 ("To determine whether a claim is directed to an ineligible concept, we have frequently considered whether the claimed advance improves upon a technological process or merely an ineligible concept, based on both the written description and the *claims.*" (emphasis added) (citations omitted)); Chamberlain Grp., 935 F.3d at 1346 ("[W]hile the specification may help illuminate the true focus of a claim, when analyzing patent eligibility, reliance on the specification must always yield to the claim language in identifying that focus." (citation omitted)). The analysis does not require a review of the prior art or facts outside of the intrinsic record regarding the state of the art at the time of the invention. Based on our review of the intrinsic record, the '207 patent claims are not directed to a patentineligible abstract idea. Therefore, reversal is appropriate.

CONCLUSION

For the foregoing reasons, we reverse the district court's determination that the asserted claims of the '207 patent recite patent-ineligible subject matter and remand for further proceedings.

REVERSED AND REMANDED

COSTS

Costs to Appellants.

DYK, Circuit Judge, dissenting in part and concurring in the result.

This is a routine case easily resolved by existing precedent. Under that approach, I agree with the majority that the claims have not been shown to be patent ineligible under section 101. I dissent in part because the majority addresses issues never argued by the parties and appears to suggest approaches not consistent with Supreme Court and circuit authority.

Ι

The '207 patent is directed to an improved cardiac monitoring device. Defendant contended that the device is section 101 ineligible because it amounts to nothing more than using a computer to analyze heart function data in the same way that had long been done by physicians without a computer. See Appellee's Br. 2 ("[T]hose claims are directed to the abstract idea of identifying commonplace heart conditions in the same way doctors have long done \dots ."). The district court agreed, relying on the patent specification to find the claims directed to an abstract idea. Our court has repeatedly held that simply computerizing data analysis previously performed without a computer does not give rise to a patenteligible invention at *Alice* step one. As we explained in *Intellectual Ventures I LLC v. Capital One Bank (USA)*, 792 F.3d 1363 (Fed. Cir. 2015), "our precedent is clear that merely adding computer functionality to increase the speed or efficiency of the process does not confer patent eligibility on an otherwise abstract idea." *Id.* at 1370.

On appeal, the patentee argues that "[t]he key factual dispute is . . . whether the claims are directed to an improvement to existing technology and contain an inventive concept . . . or whether the claims are 'nothing more than a computerized version of a doctor's approach to diagnosis,' as [defendant] contends." Reply Br. 34. It concludes that "the record lacks <u>any</u> evidence that supports the district court's key factual finding." Appellant's Br. 49.

The majority concludes, and I agree, that the patentee is correct: the defendant has not established that the patent simply computerizes the use of longstanding data analysis. On appeal, the defendant does not argue that the case should be remanded to allow the defendant to develop a fuller record. See, e.g., Appellee's Br. 47 ("There are no relevant factual disputes."); Oral Arg. at 22:25-41 (stating that "it doesn't matter" that the record does not clearly show that the claimed technique was long prevalent). Instead the defendant argues only that the intrinsic evidence shows that "the claims are drawn to automating basic diagnostic processes that doctors have long used." Appellee's Br. 2; see also id. at 19-20; id. at 49 ("Here ... the intrinsic record is dispositive "); *id.* at 50 (same). Since the intrinsic
record does not establish this, I agree that no remand is required, and that the asserted claims have not been shown to be patent ineligible.

Π

My problem with the majority opinion is that, after determining in Parts II.A and II.B that the record does not support the defendant's contentions, it goes beyond this simple resolution in Part II.C. The majority states that it is "not hold[ing] ... that it is impermissible for courts to 'look[] outside the intrinsic evidence' as part of their Alice step one inquiry, or that all evidence presented by the parties that doctors have long used the claimed techniques would be irrelevant to the inquiry in this case," but the majority concludes that "step one of the Alice framework does not require an evaluation of the prior art or facts outside of the intrinsic record regarding the state of the art at the time of the invention." Maj. Op. 1374 (citation omitted) (quoting Dissent Op. 1378-79). At the same time, the majority states "[i]t is within the trial court's discretion whether to take judicial notice of a longstanding practice where there is no evidence of such practice in the intrinsic record. But there is no basis for requiring, as a matter of law, consideration of the prior art in the step one analysis in every case." Id.

Thus, on the one hand, the majority recognizes that establishing that a practice is longstanding is clearly relevant, but on the other hand seems to suggest undefined limits on the use of extrinsic evidence to determine whether a practice was longstanding in the prior art at the time of the invention. I agree that the § 101 inquiry is different from § 102/103 analysis, and the mere fact that a prior art reference discloses an idea does not make it longstanding. But limiting the use of extrinsic evidence to establish that a practice is longstanding would be inconsistent with authority. No case has ever said that the nature of a longstanding practice cannot be determined by looking at the prior art. I respectfully dissent from the majority's inclusion of this confusing dicta in Part II.C of the opinion.

First, the majority's views are dicta. As discussed above, neither party in the briefing before this court requested a remand to the district court to make the determination of whether the doctors had long practiced the claimed process.¹ The parties' focus was almost entirely on whether the existing record showed this was a longstanding practice.²

¹ The only reference concerning a possible remand was made by the patent owner at oral argument. See Oral Arg. at 9:16-48 ("There are factual determinations that need to be made here on what was done by doctors Did they negatively weight th[ese] premature ventricular beats in their diagnosis of atrial fibrillation?").

 $[\]mathbf{2}$ See also Appellant's Br. 49 ("[T]he record lacks any evidence that supports the district court's key factual finding."); Appellee's Br. 29 ("[T]he specification makes plain that the purported advantages [of the claimed device] ... are rooted in the abstract idea itself-the ability to distinguish [atrial fibrillation and atrial flutter] from other cardiac irregularities by accounting for premature ventricular beats, which is the type of mental process doctors long performed."); Reply Br. 23 ("InfoBionic . . . falsely asserts without evidentiary support that the '207 patent merely computerized routine diagnostic methods, [and] erroneously ignores the specification's teachings about the benefits of the invention"); id. at 1 ("In addition to lacking any evidence that proves the '207 patent merely computerizes conventional techniques, InfoBionic ignores or dismisses evidence that proves the '207 patent discloses inventive concepts that improved existing cardiac monitoring."); Appellant's Br. at 55 ("[N]othing in the patent says that the

Second, both parties agreed that longstanding practice was relevant to the *Alice* step one analysis. Oral Arg. at 9:16-37("There are factual determinations that need to be made here on what was done by doctors." (Appellant) (emphasis added)); Reply 34 ("The key factual dispute is . . . whether the claims are directed to an improvement to existing technology and contain an inventive concept ... or whether the claims are 'nothing more than a computerized version of a doctor's approach to diagnosis,' as InfoBionic contends."). Neither party argued that extrinsic evidence of the prior art is irrelevant to determining whether a practice is Indeed, the patentee repeatedly longstanding. recognized that extrinsic evidence of the prior art is relevant. See Appellant's Br. 47 ("[The defendant] did not rely on any prior art that discloses negatively weighting premature ventricular beats or the use of non-linear statistics to identify [atrial fibrillation and atrial flutter]. Nor did [the defendant] rely on an demonstrating that expert declaration either technique, individually or in combination with the other elements of the asserted claims, was known.").³

claims merely computerize a routine diagnostic method."); *id.* at 56–57 ("[N]othing in the patent suggests that the claims merely computerize pre-existing techniques for diagnosing [atrial fibrillation and atrial flutter].").

³ See also Reply 26 ("InfoBionic has not and cannot identify any <u>prior art device</u>—conventional or otherwise—that used this combination of components and algorithms. Nor has InfoBionic identified any pre-existing approach by doctors to diagnosing [atrial fibrillation and atrial flutter] that used this combination of components and algorithms."); *id.* at 10 ("Aside from the patent, the district court does not cite any <u>prior art</u>, physician, expert, treatise, article, or concession that supports

Moreover, the parties both discussed a prior art in their briefing evidence document as of longstanding practice of doctors. Appellee's Br. 19 (citing to U.S. Patent Pub. 2002/0065473 as evidence that "medical professionals have long been able to discern ventricular beats in an electrocardiogram" and that "[d]octors have long understood the need to identify and take ventricular beats into account."); Reply 10 (arguing that the document "does not show or even suggest that doctors used that identification to improve AF diagnosis"). There was, in short, agreement that the prior art was relevant.

Third, any limitation on the use of extrinsic evidence would be inconsistent with binding authority. The Supreme Court and our cases have consistently held that whether a practice is "longstanding" or "long prevalent" is central to the step one inquiry and have never suggested that prior art is irrelevant to that question. In Bilski v. Kappos, 561 U.S. 593, 130 S.Ct. 3218, 177 L.Ed.2d 792 (2010), the Court held that "[t]he concept of hedging . . . is an unpatentable abstract idea" because "'[h]edging is a fundamental economic practice long prevalent in our system of commerce." Id. at 611, 130 S.Ct. 3218 (emphasis added) (quoting In re Bilski, 545 F.3d 943, 1013 (Fed. Cir. 2008) (Rader, J., dissenting)). In Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 134 S.Ct. 2347, 189 L.Ed.2d 296 (2014), the Supreme Court explained that "the concept of intermediated settlement at issue" was "squarely within the realm of 'abstract ideas,'" id. at 221, 134 S.Ct. 2347, because, "[l]ike the risk hedging in *Bilski*, the concept

its holding that the patent fails to improve cardiac monitoring technology.").

of intermediated settlement [in Alice] [wa]s "a fundamental economic practice long prevalent in our system of commerce,"'" id. at 219, 134 S.Ct. 2347 (emphasis added) (quoting Bilski v. Kappos, 561 U.S. 593, 611, 130 S.Ct. 3218, 177 L.Ed.2d 792 (2010)). "hedging The Court emphasized that is longstanding commercial practice," id. at 220, 134 S.Ct. 2347 (emphasis added) and "that the mere recitation of a generic computer cannot transform [this] patent-ineligible abstract idea into a patenteligible invention," id. at 223, 134 S.Ct. 2347. As discussed below, numerous cases decided by our court held that claims were abstract because they claimed longstanding practices.

In making the determination that practices are longstanding in the section 101 step one analysis, the Supreme Court and our cases have also repeatedly recognized the relevance of extrinsic evidence, such as facts determined by judicial notice and party admissions. In Bilski, the Supreme Court cited to economics textbooks when finding "the basic concept of hedging" to be a long prevalent practice, and therefore an abstract idea. Bilski, 561 U.S. at 611, 130 S.Ct. 3218. In *Alice*, the Court cited to economics textbooks and articles in determining that "the concept intermediated settlement" "is of a fundamental economic practice long prevalent in our system of commerce," and therefore an abstract idea under step one. Alice, 573 U.S. at 221, 219-21, 134 S.Ct. 2347 (quoting Bilski, 561 U.S. at 611, 130 S.Ct. 3218).

Our cases have similarly not limited the analysis to the intrinsic record. For example, in *Capital One Bank*, in finding that claims directed to customizing marketing was ineligible, we relied on the fact that "newspaper inserts had often been tailored based on information known about the customer-for example. a newspaper might advertise based on the customer's location." 792 F.3d at 1369 (emphasis added). In Affinity Labs of Texas, LLC v. DIRECTV, LLC, 838 F.3d 1253 (Fed. Cir. 2016), we found claims for "providing out-of-region access to regional broadcast content" to be an abstract idea by relying on the fact that "[t]he practice of conveying regional content to out-of-region recipients has been employed by nearly every form of media that has a local distribution." Id. at 1258 (emphasis added). In Content Extraction & Transmission LLC v. Wells Fargo Bank, National Ass'n, 776 F.3d 1343 (Fed. Cir. 2014), we found claims to a method for recognizing images from hard copy documents to be abstract by considering that "banks have, for some time, reviewed checks, recognized relevant data such as the amount, account number, and identity of account holder, and stored that information in their records." Id. at 1347 (emphasis added). In Berkheimer v. HP Inc., 881 F.3d 1360 (Fed. Cir. 2018), we found that "the claims are directed to an abstract idea of parsing and comparing data" by considering patentee's "admi[ssion] that [the claimed] parsers had existed for years prior to his patent." Id. at 1366-67 (emphasis added). In In re Brown, 645 F. App'x 1014 (Fed. Cir. 2016), we found at step one that "the claims are drawn to the abstract idea of assigning hair designs to balance head shape" because the patent owner admitted "that the hair cutting step 'employ[ed] a well-known concept' [and] that the hair patterns applied are 'industry recognized.'" Id. at 1016 (emphasis added).⁴ In each of these cases, the court did not limit itself to intrinsic evidence, in each case relying on evidence outside of the patent itself.

Significantly, this approach has been recognized in the very cases on which the majority itself relies. Maj. Op. 1373–74. In *BASCOM Global Internet Services, Inc. v. AT&T Mobility LLC*, 827 F.3d 1341 (Fed. Cir. 2016), we found that "filtering content [wa]s an abstract idea because it is a longstanding, wellknown method of organizing human behavior," though the claims provided an inventive concept at step two by "carv[ing] out a specific location for the filtering system (a remote ISP server) and require[d]

⁴ In Intellectual Ventures I LLC v. Erie Indem. Co., 850 F.3d 1315 (Fed. Cir. 2017), we found claims to be directed to the abstract idea of "creating and using an index to search for and retrieve data." Id. at 1328. In the step one analysis, the court found it persuasive that "[t]his type of activity, i.e., organizing and accessing records through the creation of an indexsearchable database, includes longstanding conduct that existed well before the advent of computers and the Internet." Id. at 1327 (emphasis added). In In re TLI Communications LLC Patent Litigation, 823 F.3d 607 (Fed. Cir. 2016), we found that "attaching classification data, such as dates and times, to images for the purpose of storing those images in an organized manner is a well-established 'basic concept' sufficient to fall under Alice step 1." Id. at 613 (emphasis added); see also Finjan, Inc. v. Blue Coat Systems, Inc., 879 F.3d 1299, 1302, 1305-06 (Fed. Cir. 2018) (determining that "[b]y itself, virus screening [wa]s wellknown and constitutes an abstract idea," as was "performing the virus scan on an intermediary computer," though ultimately finding claims eligible because a "system and method for providing computer security by attaching a security profile to a downloadable" "employ[ed] a new kind of file that enable[d] a computer security system to do things it could not do before." (first alteration in original) (emphasis added) (first quote from Intellectual Ventures I LLC v. Symantec Corp., 838 F.3d 1307, 1319 (Fed. Cir. 2016))).

the filtering system to give users the ability to customize filtering for their individual network accounts." *Id.* at 1348, 1352. In *FairWarning IP, LLC v. Iatric Sys., Inc.*, 839 F.3d 1089 (Fed. Cir. 2016), we found ineligible claims "directed to collecting and analyzing information to detect misuse and notifying a user when misuse is detected." *Id.* at 1094. We noted, in finding the claims directed to an abstract idea at step one, that the claims ask "the same questions ... that humans in analogous situations detecting fraud have asked for decades, if not centuries" and thus "merely implement an old practice in a new environment." *Id.* at 1094–95. In making the step one determination, we thus have persistently looked outside the intrinsic evidence.

The majority, while recognizing the relevance of longstanding practice in the step one analysis, attempts to distinguish the above cases by suggesting undefined limits on the use of prior art to determine the "state of the art at the time of the invention." Maj. Op. 1374. The majority opinion cites to no authority to support any such limits. Determining whether something is a longstanding practice necessarily requires an analysis of whether the practice is part of a well-established "state of the art at the time of the invention." Id. "Evidence of the state of the art consists of proof of what was old and in general use at the time of the alleged invention. It is received ... to show what was then old, [and] to distinguish what was new" Brown v. Piper, 91 U.S. 37, 41, 23 L.Ed. 200 (1875).

The panel does not purport to overrule prior cases, nor could it. But the language of the panel opinion is likely to sow confusion for both the district court and the bar.

37a

I respectfully dissent from Part II.C of the majority opinion, and concur in the result.

38a

UNITED STATES DISTRICT CIRCUIT FOR THE DISTRICT OF MASSACHUSETTS

CARDIONET, LLC, and Braemar Manufacturing, LLC, Plaintiffs,

v.

INFOBIONIC, INC., Defendant.

Civil Action No. 17-cv-10445-IT

Signed 10/16/2018

348 F. Supp. 3d 87

MEMORANDUM AND ORDER

Indira Talwani, United States District Judge

Plaintiffs CardioNet, LLC ("CardioNet") and Braemar Manufacturing, LLC ("Braemar") allege that products manufactured and distributed by Defendant InfoBionic, Inc. ("InfoBionic") infringe on Plaintiffs' patent, U.S. Patent Number 7,941,207 ("the '207 patent"). Am. Compl. ("Complaint") [# 25]. InfoBionic moves to dismiss Plaintiffs' Complaint [# 25], arguing that the '270 patent is invalid under 35 U.S.C. § 101 as construed by Alice Corp. Pty. Ltd. v. CLS Bank Intern., 573 U.S. 208, 134 S.Ct. 2347, 2354, 189 L.Ed.2d 296 (2014), and its progeny, because the asserted claims are directed to an abstract idea and are patent-ineligible. Mot. to Dismiss 1 [# 36]. Finding that the claims at issue are directed at patent-ineligible concepts, and that the elements of each claim do not transform the claim into

a patent-eligible application, the court ALLOWS Defendant's <u>Motion to Dismiss</u> [# 36].

I. <u>Background</u>

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

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

urgent medical care," and "require minimal computational resources." <u>Id.</u> at col. 3:35-40.

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

II. Discussion

A. Standard

To survive a motion to dismiss, a plaintiff "must state a claim that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). In resolving the motion, the court must "begin by identifying and disregarding statements . . . that merely offer 'legal conclusion[s] couched as ... fact[].'" Occasion-Hernández v. Fortuño-Burset, 640 F.3d 1, 12 (1st Cir. 2011) (alteration in original) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 668, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009)). Nonconclusory factual statements contained in the pleadings must then be viewed as true, id., and the court must view these facts in the light most favorable to the nonmovant and draw all reasonable inferences therefrom to the nonmovant's behalf. Id. at 17.

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

Because the court accepts the factual allegations in the complaint and other allowable sources of information as true for purposes of a motion to dismiss, "[i]f there are claim construction disputes, ... the court [may] proceed by adopting the nonmoving party's construction," and construing the patent claims in a manner most favorable to the nonmoving party. <u>Aatrix Software</u>, 882 F.3d at 1125; <u>see also Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n</u>, 776 F.3d 1343, 1349 (Fed. Cir. 2014) (court applies the non-moving party's construction of the terms of the patent for purposes of the motion).

Section 101 states, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. The subject matter of a patent must be patentable under § 101; otherwise, the patent is invalid. <u>See Content Extraction</u>, 776 F.3d at 1346. The Supreme Court has held that this section contains an "implicit exception: [l]aws of nature, natural phenomena, and abstract ideas are not patentable." <u>Alice</u>, 134 S.Ct. at 2354 (quoting <u>Ass'n</u> <u>for Molecular Pathology v. Myriad Genetics, Inc.</u>, 569

U.S. 576, 133 S.Ct. 2107, 2116, 186 L.Ed.2d 124 Although "all inventions at some level (2013)). embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas," these three patent-ineligible exceptions prevent "monopolization" of the "basic tools of scientific and technological work," Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 132 S.Ct. 1289, 1293, 182 L.Ed.2d 321 (2012), and the "inhibit[ion of] further discovery by improperly tying up the future use of these building blocks of human ingenuity," Alice, 134 S.Ct. at 2354 (internal quotation marks omitted) (quoting Mayo, 132 S.Ct. at 1301).

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

First, the court must determine whether the claims at issue are directed to laws of nature, natural phenomena, or abstract ideas. <u>Id. at 2355.</u>¹ Claims are directed to an abstract idea if, "considered in light of the specification, . . . 'their character as a whole is directed to'" an abstract idea. <u>Enfish, LLC v.</u> <u>Microsoft Corp.</u>, 822 F.3d 1327, 1335 (Fed. Cir. 2016) (quoting <u>Internet Patents Corp. v. Active Network, Inc.</u>, 790 F.3d 1343, 1346 (Fed. Cir. 2015)). "The 'abstract ideas' category embodies 'the longstanding

 $^{^1\,}$ Because Defendant argues that the '207 patent is directed to an abstract idea, the court focuses its discussion on this exclusion.

rule that [a]n idea of itself is not patentable.'" <u>Alice</u>, 134 S.Ct. at 2355 (internal quotation marks omitted) (alteration in original) (quoting <u>Gottschalk v. Benson</u>, 409 U.S. 63, 67, 93 S.Ct. 253, 34 L.Ed.2d 273 (1972)). In <u>Benson</u>, for example, the court rejected claims involving an algorithm for "converting [binary-coded decimal] numerals to pure binary form," holding that the claimed patent was "in practical effect ... a patent on the algorithm itself." 409 U.S. at 71-72, 93 S.Ct. 253. Similarly, in <u>Parker v. Flook</u>, the court held a mathematical formula for computing 'alarm limits' in a catalytic conversion process was an abstract idea. 437 U.S. 584, 594-95, 98 S.Ct. 2522, 57 L.Ed.2d 451 (1978).

If the claims at issue are directed to laws of nature, natural phenomena, or abstract ideas, the court then considers the elements of each claim both "individually and 'as an ordered combination" to determine whether the additional elements "'transform the nature of the claim' into a patenteligible application." Alice, 134 S.Ct. at 2350 (quoting Mayo, 132 S.Ct. at 1298, 1297). The Supreme Court has "described step two of this analysis as a search for 'inventive concept' - i.e., an element or an combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." Id. (alteration in original) (quoting Mayo, 132 S.Ct. at 1294). "Purely 'conventional or obvious' '[pre]-solution activity' is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law." Mayo, 566 U.S. at 79, 132 S.Ct. 1289 (quoting Flook, 437 U.S. at 590, 98 S.Ct. 2522); see also Bilski v. Kappos 561 U.S. 593, 610-11, 130 S.Ct. 3218, 177 L.Ed.2d 792 (2010)

("[T]he prohibition against patenting abstract ideas 'cannot be circumvented by'... adding 'insignificant post-solution activity.'" (quoting <u>Diamond v. Diehr</u>, 450 U.S. 175, 191-92, 101 S.Ct. 1048, 67 L.Ed.2d 155 (1981))). To survive step two, the additional activity must "transform the claim into 'significantly more than a patent upon the' ineligible concept itself." <u>Rapid Litig. Mgmt., Ltd. v. CellzDirect, Inc.</u>, 827 F.3d 1042, 1047 (Fed. Cir. 2016) (quoting <u>Mayo</u>, 132 S.Ct. at 1294).

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

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

improvement in the signal processing and analysis capabilities of cardiac monitoring devices." <u>Id.</u> at 14.

To determine whether computerized technology is directed to an abstract idea, the court "asks whether the focus of the claims is on the specific asserted improvement in computer capabilities . . . or, instead, on a process that qualifies as an 'abstract idea' for which computers are merely invoked as a tool." Enfish, 822 F.3d at 1335-36. If "the plain focus of the an improvement to computer claims is on functionality itself," it is not directed to an abstract idea. <u>Id.</u> at 1336. However, if the "claims 'simply add[] conventional computer components to wellknown business practices,' . . . or 'a purely conventional computer implementation of а mathematical formula,' or 'generalized steps to be performed on a computer using conventional computer activity,'" it is directed to an abstract idea. In re TLI Commc'ns LLC Patent Litig., 823 F.3d 607, 612 (Fed. Cir. 2016) (quoting Enfish, 822 F.3d at 1338).

The Federal Circuit has found that computerimplemented claims for collecting and analyzing data to find specific events may be patent-ineligible abstract ideas. In <u>FairWarning IP, LLC v. Iatric Sys.</u>, <u>Inc.</u>, for example, the Federal Circuit considered a patent that "relate[d] to a system and method of detecting fraud and/or misuse in a computer environment based on analyzing data." 839 F.3d 1089, 1093 (Fed. Cir. 2016). The patented method "collect[ed] information regarding accesses of a patient's personal health information, analyze[d] the information according to one of several rules ... to determine if the activity indicates improper access, and provide[d] notification if it determine[d] that improper access ha[d] occurred." Id. In holding that the patent was an ineligible abstract idea, the court emphasized that "the 'realm of abstract ideas' includes 'collecting information, including when limited to particular content," and that "analyzing information by steps people go through in their minds, or by mathematical algorithms, without more, [are] essentially mental processes within the abstract-idea category." Id. (quoting Elec. Power Grp., LLC v. Alstom S.A., 830 F.3d 1350, 1353 (Fed. Cir. 2016)). The court also explained that "merely presenting the results of abstract processes of collecting and analyzing information, without more identifying particular (such \mathbf{as} а tool for presentation), is abstract as an ancillary part of such collection and analysis." Id. (quoting Elec. Power, 830 F.3d at 1353). The court concluded that because the claims at issue were "directed to collecting and analyzing information to detect misuse and notifying a user when misuse is detected," the claims were patent ineligible. Id. at 1094.

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

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

Plaintiffs respond that the '207 patent is not directed to an abstract idea because it "represents an improvement to the function of cardiac monitoring devices." Pls.' Opp'n 14 [# 40]. They argue that "[t]hrough the use of specifically programmed rules, termed 'determination logic,' coupled with beat detecting technology and an event generator, the invention improves a function specific to cardiac monitoring devices, namely the processing and analysis of cardiac signals to achieve more accurate and clinically significant AF detection." <u>Id.</u> (internal citation omitted).

Plaintiffs' response is more appropriately given at step 2. In any event, as InfoBionic argues, and as discussed more at step 2 *infra*, the claims that Plaintiffs assert do not recite any specific implementation or improvement in computerized

medical technology. See '207 Patent [# 25-1]; Def.'s Mem. 15 [# 37]. The idea of using a machine to monitor and analyze heart beat variability and interfering beats so as to alert the user of potential AF events may well improve the field of cardiac but Plaintiffs telemetry. do not identify computerized improvements particular to any technology. Thus, the '207 patent is directed to an abstract idea.

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

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

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

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

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

Plaintiffs also assert that the patent is analogous to the T wave filter claimed by U.S. Patent No. 7,009,715. In the earlier <u>CardioNet</u> litigation, this court found that the T wave filter claim recited an inventive concept because the patented process of "diminishing the intensity of the T wave while preserving or amplifying the R wave in an electrocardiogram ... cannot be performed in the human mind," and is therefore "tied to a machine" and meets the "machine-or-transformation test." <u>CardioNet, LLC v. InfoBionic, Inc.</u>, 2017 WL 1788650, at *9-10 (D. Mass. May 4, 2017) (order allowing in part and denying in part renewed motion for judgment on the pleadings).

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

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

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

InfoBionic argues that the '207 patent appears to recite "collecting cardiac data, determining its relevance, and then identifying a cardiac event," without identifying any specific "technical solutions or detailed software for performing the claimed functions."² Def.'s Mem. 17, 23 [# 37]. InfoBionic contends further that the patent recites only technological functions which "can be performed using conventional, off-the-shelf, cardiac monitoring equipment and conventional computer hardware and/or software."³ Def.'s Mem. 17-18 [# 37]. And, InfoBionic argues that the conventional components are not put together so as to add anything inventive by their combination. Rather, the claim elements "merely recite the conventional components that perform their usual functions put together in a standard way to perform a commonplace diagnostic method: collect data, analyze it, and identify medically significant events." Id. at 14. InfoBionic contends that the claims are therefore lacking an inventive concept and are patent ineligible. Id. at 15-16. For support, InfoBionic cites to FairWarning IP, 839 F.3d 1089, Intellectual Ventures I LLC v.

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

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

<u>Symantec Corp.</u>, 838 F.3d 1307 (Fed. Cir. 2016), and <u>Elec. Power</u>, 830 F.3d 1350.

In FairWarning IP, the Federal Circuit rejected the argument that the claims "solve technical problems unique to the computer environment and thus should be patent eligible" where the claims did not recite "technological advance relating to accessing" and combining disparate information sources," or otherwise "propose a solution or overcome a problem specifically arising in the realm of computer technology." 839 F.3d at 1091. Instead, the court found that the claims were rather "directed to the broad concept of monitoring audit log data." (quotation omitted). Similarly, in Intellectual Ventures, the Federal Circuit found no inventive concept where the claimed method of filtering emails to address computer viruses and spam did not "improve the functioning of the computer itself," but rather "use[d] generic computers to perform generic computer functions." 838 F.3d at 1315. And in Electric Power, the court found that claims which did not "require a new source or type of information, or new techniques for analyzing it" or "invoke any assertedly inventive programming" did not "require an arguably inventive set of components or methods, such as measurement devices or techniques[] that would generate new data." 830 F.3d at 1355. The Electric Power court emphasized that "[m]erely selection and manipulation requiring the of information ... by itself does not transform the otherwise-abstract processes of information collection and analysis." Id. (citations omitted).

The court finds InfoBionics's argument to be correct. Claim 1, the only claim quoted in the <u>Complaint [# 25]</u>, recites: A device, compromising:

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

a ventricular beat detector to identify ventricular beats⁴ in the cardiac activity;

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

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

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

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

2. The device of claim 1, wherein the relevance determination logic is to accommodate variability in the beat-to-beat timing caused by ventricular beats by weighting ventricular beats as being negatively indicative of the one of atrial fibrillation and atrial flutter.

3. The device of claim 1, wherein the variability determination logic is to compare times between

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

R-waves in three successive QRS complexes to determine the variability in the beat-to-beat timing.

. . .

7. The device of claim 1, wherein the event generator is to generate an event by performing operations comprising: collecting data associated with the collection of beats; and transmitting the data associated with the collection of beats to a remote receiver.

• • •

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

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

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

. . .

22. The article of claim $20,^5$ determining the relevance comprises: identifying a beat of the

⁵ Claim 20 asserts:

An article comprising one or more machine-readable media storing instructions operable to cause one or more machines to perform operations, the operations comprising: determining a beat-to-beat variability in cardiac electrical activity; determining a relevance of the variability over a collection of beats to one of atrial fibrillation and atrial flutter using a non-linear function of a beat-to-beat interval; and identifying one of an atrial fibrillation event and an

collection as a ventricular beat, and weighting the beat as being negatively indicative of the one of atrial fibrillation and atrial flutter.

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

Nothing in these claims imposes a meaningful limit on the abstract idea of identifying AF by looking at the variability in time between heartbeats and taking into account ventricular beats. Plaintiffs "specifically invention uses argue that the programmed rules, termed 'determination logic' " to improve the cardiac monitoring, Pls.' Opp'n 14 [# 40],⁶ and that "claims 2, 3, 10, and 22 (which is dependent upon claim 20) recite additional limitations to the determination logic described in the patent

atrial flutter event based on the determined relevance, the event being a period in time when the information content of the cardiac electrical activity is of increased relevance to the one of atrial fibrillation and atrial flutter."

^{&#}x27;207 Patent 17 [# 25-1].

See also id. at 6 (the '207 patent "uses determination logic to identify AF events"); id. at 16 (the '207 patent achieves solutions "through the claimed beat detectors and the event generators' application of the determination logic"); id. at 17 (the claims focus on a challenge to computer monitoring "by using determination logic to calculate beat-to-beat variability"); id. ("the limitations of the '207 patent . . . require[e] the rules to be applied in a specific way"); id. at 18 ("[t]he specificity of the decision logic in taking into account variability in the beat-tobeat timing ... provides ... limitation"); id. at 20 ("the beat detectors and event generator of the '207 patent work together with the determination logic"); id. ("specific programming is required to perform the claims' function"); id. at 21 ("[i]t is the combination of ... elements, together with the determination logic, that solves the prior art cardiac monitoring problem of incorrectly identifying AF events").

specification." <u>Id.</u> at 19. But, Plaintiffs do not identify what aspect of "the determination logic described in the patent specification" makes either the patent as a whole, or the specific claims asserted, patent-eligible.

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

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

[C]laims 2 and 22 specifically require that the determination logic weight premature ventricular beats 'as being negatively indicative,' claim 3 specifically requires analysis of 'three successive QRS complexes,' and claims 10 and 20 (not independently asserted) limit the determination logic to a non-linear function. Moreover, claim 7 provides for the additional advantage and monitoring system flexibility of the transmission of data associated with a collection of beats to a remote receiver – similar to the claims already found eligible by the Court in the Related Action.

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

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

Similarly, claim 7 simply provides that "the event generator collects and transmits data to a remote receiver," but "collecting, transmitting, and storing data is generic and conventional," Def.'s Mem. 20 [# 37], and therefore does not add an inventive limitation. <u>See In re TLI Comme'ns LLC Patent Litig.</u>, 823 F.3d at 613.⁷

 $^{^7}$ Claims 11 and 12 do not even include the reference to "determination logic," and instead simply limit the source and

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

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

type of data collected to a QRS detector and body surface sensors, both of which are conventional technology. <u>See In re TLI</u> <u>Commc'ns LLC Patent Litig.</u>, 823 F.3d at 613 (holding that, at step two of the <u>Alice</u> inquiry, "mere recitation of concrete, tangible components is insufficient to confer patent eligibility to an otherwise abstract idea. Rather, the components must involve more than performance of 'well-understood, routine, conventional activit[ies]' previously known to the industry." (quoting <u>Alice</u>, 134 S.Ct. at 2359).

 $\underline{Conclusion}$

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

IT IS SO ORDERED.

59a

60a

UNITED STATES COURT OF APPEALS, FOR THE FEDERAL CIRCUIT

CARDIONET, LLC, Braemar Manufacturing, LLC, Plaintiffs-Appellants

v.

INFOBIONIC, INC,

Defendant-Appellee

2019-1149

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

ON PETITION FOR PANEL REHEARING

Before DYK, PLAGER, and STOLL, *Circuit Judges*. PER CURIAM.

ORDER

Appellee InfoBionic, Inc. filed a petition for panel rehearing.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The mandate of the court will issue on June 11, 2020.

For the Court

<u>June 4, 2020</u> Date <u>/s/ Peter R. Marksteiner</u> Peter R. Marksteiner Clerk of the Court

35 U.S.C. § 101

§ 101. Inventions patentable

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.