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.

Decided: April 17, 2020

CHING-LEE FUKUDA, Sidley Austin LLP, New York, NY, argued for plaintiffs-appellants. Also represented by BRADFORD J. BADKE, TODD MATTHEW SIMPSON; NATHAN A. GREENBLATT, Palo Alto, CA.

GABRIEL BELL, Latham & Watkins LLP, Washington, DC, argued for defendant-appellee. Also represented by MAXIMILIAN A. GRANT; CHARLES SANDERS, Boston, MA.

Before DYK, PLAGER, and STOLL, Circuit Judges.

Opinion for the court filed by *Circuit Judge* STOLL.

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 life-threatening. 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,

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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 systems and techniques for 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 R-wave 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:



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

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fibrillation and atrial flutter, whereas it is indicative of V-TACH. *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 nonlinear 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

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).

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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 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

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.

Id. at col. 14 ll. 12–24.

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variability in the beat-to-beat timing caused by premature ventricular beats, the device can 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 "well-adapted 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 "welladapted 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 (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. Info-Bionic, 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 state a claim. Athena Diagnostics, Inc. v. Mayo 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 directed to patent-ineligible subject matter. *Berkheimer*, 881 F.3d at 1365.

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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 (quoting *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (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 (alteration in original) (quoting Gottschalk v. Benson, 409 U.S. 63, 67 (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 (alteration in original) (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 71 (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).

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 claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Alice*, 573 U.S. at 217 (quoting *Mayo*, 566 U.S. at 78–79). 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 (alteration in original) (quoting *Mayo*, 566 U.S. at 72–73).

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

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that the asserted claims of the '207 patent are directed to patent-eligible 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-tobeat timing of cardiac activity, detects premature ventricular beats, and determines the relevance of the beat-tobeat 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 beatto-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 patenteligible 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 Rwaves 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

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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 types of processors . . . without significantly 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.

Similarly, here, the '207 patent's 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-to-beat 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 three-dimensional 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 pre-existing 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)

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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 mat-For example, it is difficult to fathom how doctors ter. mentally or manually used "logic to identify the relevance of the variability [in the beat-to-beat timing] using a nonlinear 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 collecting, analyzing, 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. Al*ice* 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 (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, 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 (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 (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, 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 En*fish*, 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 self-referential 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. 9, 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—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 they claimed longstanding practices." Dissent Op. 7. 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

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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 patent-ineligible 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.

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.

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"). 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 patent-eligible 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

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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. 22 (citation omitted) (quoting Dissent Op. 9). 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

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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 longstanding. Indeed, the patentee repeatedly 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 nonlinear statistics to identify [atrial fibrillation and atrial flutter]. Nor did [the defendant] rely on an expert declaration demonstrating that either technique, individually or in combination with the other elements of the asserted claims, was known.").³ Moreover, the parties both

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 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

discussed a prior art document in their briefing as evidence 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 (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 (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 (2014), the Supreme Court explained that "the concept of intermediated settlement at issue" was "squarely within the realm of 'abstract ideas," id. at 221, because, "[l]ike the risk hedging in *Bilski*, the concept of intermediated settlement [in Alice] [wa]s "a fundamental economic practice long prevalent in our system of commerce,"" id. at 219 (emphasis added) (quoting Bilski v. Kappos, 561 U.S. 593, 611 (2010)). The Court

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

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emphasized that "hedging is a <u>longstanding</u> commercial practice," *id.* at 220 (emphasis added) and "that the mere recitation of a generic computer cannot transform [this] patent-ineligible abstract idea into a patent-eligible invention," *id.* at 223. 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. In *Alice*, the Court cited to economics textbooks and articles in determining that "the concept of intermediated settlement" "is 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 (quoting *Bilski*, 561 U.S. at 611).

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 data" considering and comparing by patentee's "admi[ssion] that [the claimed] parsers had existed for Id. at 1366–67 (emphasis years prior to his patent." 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

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 index-searchable 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

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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. 21– 22. 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, well-known 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] 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.

itself, virus screening [wa]s <u>well-known</u> 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 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. 22. 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 (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.

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