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# Protect your heart: Purely diagnostic heart monitoring device found to be patent eligible subject matter

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On April 17, the Federal Circuit held that a purely diagnostic heart monitoring device is patent eligible subject matter—adding to the short list of precedents that have found claims covering an algorithm for monitoring and analyzing data to be patentable. The court reasoned that a device that detects a patient's cardiac events is patentable under 35 U.S.C. § 101 if the device is a technological improvement and does not merely automate longstanding techniques. *See* *Cardionet, LLC v. Infobionic Inc.*, Case No. 2019-1149 (Fed. Cir. 2020).

Cardionet's patent claimed a cardiac monitoring system for detecting and distinguishing atrial fibrillation and flutter from other arrhythmias. *Id.* at 3. Specifically, the patent claimed: (1) a "beat detector" to identify timing between beats and premature ventricular beats, (2) "logic" to determine variability in relevant beat timing (to distinguish ventricular tachycardic beats), and (3) an event generator for when atrial fibrillation or flutter is identified. *Id.* at 6-7. The Federal Circuit reversed the district court's grant of a motion to dismiss for patent ineligible subject matter.

The Federal Circuit determined that the claims focused on "a specific means or method that improves cardiac monitoring technology." *Id.* at 13 (internal quotations omitted). The improvement in technology cited by the court related specifically to the process for analyzing beat-to-beat timing in cardiac data to identify a type of atrial fibrillation more reliably. *Id.* The court confirmed that the claims could not have been an automation of known techniques because "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." *Id.* at 17 (internal quotation omitted).

The Federal Circuit further pointed to statements in the written description to support its conclusion that the claimed subject matter was an improvement in cardiac monitoring technology. First, the device was a technological improvement for effectively avoiding false positives and false negatives in correctly identifying atrial fibrillation and flutter. *Id.* Second, the device is able to identify "*sustained* episodes of atrial fibrillation and atrial flutter that have increased clinical significance." *Id.* at 14 (emphasis added) (internal quotation and citations omitted). These statements in the specification were "accepted as true and consider[ed] important in [the court's]

determination that the claims are drawn to a technological improvement." *Id.* at 15. Further, there was no evidence that the "claims merely computerized pre-existing techniques for diagnosing atrial fibrillation and atrial flutter" (*id.* at 16) or "merely collect[ed] information, display[ed] information, or embod[ied] mental processes." *Id.* at 18.

*Cardionet* may clear the way for increased patenting on purely diagnostic tools because it provides a roadmap for the types of claims focusing on data analysis that are likely to be considered patentable subject matter. *Cardionet's* finding that the patents claims to data processing techniques that improve diagnostic accuracy qualify as an improvement in technology under § 101 precedent may be viewed as an extension of prior eligibility case law that focused on improvements in computer technology.

## Practice Tips

*For patentees,* consider drafting claim language that distinguishes the claimed device's technique from mental or known processes, focusing on specific methods that improve a particular technology. In this case, for example, the Federal Circuit stated that "nothing in the record supports the district court's fact finding that doctors long used the claimed diagnostic processes." *Id.* at 16. The district court's assumption that the claims are directed to automating known techniques also seems incongruous with the claimed subject matter. For example, it is difficult to fathom how doctors mentally or manually could use "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." *Id.* at 17 (emphasis added); *see also id.* at 16. In addition, because "Step 1" of the *Alice* analysis requires the court to review not only the claims, but also the written description, patentees should further consider explaining how the invention improves the particular technology field. In this case, the written description "describe[d] a number of advantages achieved by the claimed cardiac monitoring device," including more accurate and precise diagnosis of particular arrhythmias as compared to human doctors. *Id.* at 16-17.

*For defendants*, consider pleading that the invention claims nothing more than long-known techniques in the Answer to the Complaint by attaching documents, declarations, or admissions to motions under Fed. R. Civ. P 12(b) or (c), or seeking judicial notice that the techniques practiced in the claimed invention are longstanding. *Id.* at 22, 29, 30. Otherwise, defendants are left to rely on an incomplete record that might not have sufficient evidence to mount an *Alice* defense based on automating longstanding practices.

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