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Paper 10
Date: December 8, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APPLE, INC.,
Petitioner,

v.

ALIVECOR, INC.,
Patent Owner.

IPR2021-00971
Patent 10,595,731 B2

Before ROBERT A. POLLOCK, ERIC C. JESCHKE, and DAVID COTTA, *Administrative Patent Judges*.

POLLOCK, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background

Apple, Inc. ("Petitioner") filed a Petition for an *inter partes* review of claims 1–15 of U.S. Patent No. 10,595,731 B2 ("the '731 patent," Ex. 1001). Paper 2 ("Pet."). AliveCor, Inc. ("Patent Owner") timely filed a Preliminary Response. Paper 6. ("Prelim. Resp."). Petitioner further filed an authorized Reply to the Preliminary Response (Paper 7, "Prelim. Reply"); Patent Owner filed a responsive Sur-reply (Paper 8, "Prelim. Sur-reply").

B. Summary of the Institution Decision

For the reasons provided below, Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has demonstrated a reasonable likelihood that at least one claim of the '731 patent is unpatentable, we institute an *inter partes* review of all challenged claims on each of the Grounds raised in the Petition. *See* 37 C.F.R. § 42.108(a) (2021) ("When instituting *inter partes* review, the Board will authorize the review to proceed on all of the challenged claims and on all grounds of unpatentability asserted for each claim.").

C. Real Parties-in-Interest

Petitioner identifies itself, Apple Inc., as the real party-in-interest. Pet. 88. Patent Owner, identifies itself, AliveCor, Inc., as the real party-in-interest. Paper 4, 2.

D. Related Matters

According to Patent Owner:

> U.S. Patent No. 10,595,731 has been asserted by Patent Owner against Petitioner in *AliveCor, Inc. v. Apple, Inc.*, Case No. 6:20-cv-01112-ADA, filed in the United States District

> Court for the Western District of Texas, and in Investigation No. 337-TA-1266 before the International Trade Commission, *In the Matter of Certain Wearable Electronic Devices with ECG Functionality and Components Thereof*. Apple also filed IPR petitions against the other patents asserted in those actions: IPR2021-00970 (USP 9,572,499) and IPR2021-00972 (USP 10,638,941).

Paper 4, 2; *see* Pet. 88. We refer to the above litigations as the "Texas Litigation" and the "ITC Investigation," respectively. *See* Pet. 81–82. We further note that the '731 patent at issue here is related by a chain of continuation applications to Application No. 14/730,122, which issued as U.S. Patent No. 9,572,499 ("the '499 patent), challenged in IPR2021-00970. *See* Ex. 1001, code (63); Prelim. Resp. 4. As such, the '731 and '499 patents share substantially the same specification.

The '731 patent claims priority to, *inter alia*, a series of provisional applications filed between December 12, 2013, and June 19, 2014. Ex. 1001, code (60); *see* Prelim. Resp. 4; Pet. 2 & nn. 1–3. Petitioner contends, and Patent Owner does not presently contest, that the claims of the '731 patent are not entitled the benefit of the earliest of those applications such that the critical date is March 14, 2014, the filing date of provisional application No. 61/953,616. Pet. 2–3; Prelim. Resp. 4. For the purpose of institution, we need not determine whether the challenged claims are entitled to the benefit of the earliest filed provisional application. Accordingly, and solely for purposes of this decision we apply March 14, 2014, as the critical date.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability (Pet. 1):

Ground	Claims Challenged	35 U.S.C §	Reference(s)/Basis
1	1, 7, 12, 13, 16, 17, 23–26, 30	§ 103	Shmueli[1]
2	1, 2, 4, 7, 12–14, 16–18, 20, 23–26, 30	§ 103	Shmueli, Osorio[2]
3	3, 5, 6, 19, 21, 22	§ 103	Shmueli, Osorio, Li[3]
4	8–11, 27–29	§ 103	Shmueli, Osorio, Kleiger[4]
5	15	§ 103	Shmueli, Osorio, Chan[5]

In support of its patentability challenge, Petitioner relies on, *inter alia*, the Declaration of Dr. Bernard R. Chaitman, M.D. Ex. 1003. Patent Owner similarly relies on the Declaration of Dr. Igor Efimov, Ph.D. Ex. 2001.

F. The '731 Patent and Relevant Background

The '731 patent relates to medical devices, systems, and methods for detecting cardiac conditions, including cardiac arrhythmias. Ex. 1001, 1:29–33, 2:17–25. In general:

> In response to the continuous measurement and recordation of the heart rate of the user, parameters such as heart rate (HR), heart rate variability (R-R variability or HRV), and heart rate

[1] WO2012/140559, publ. Oct. 18, 2012. Ex. 1004.
[2] U.S. 2014/0275840, publ. Sept. 18, 2014. Ex. 1005.
[3] Li Q, Clifford GD, "*Signal quality and data fusion for false alarm reduction in the intensive care unit*," 45(6) J Electrocardiol. 596-603 (2012). ("Li" or "Li-2005") Ex. 1006.
[4] Kleiger RE, Stein PK, "*Bigger JT Jr. Heart rate variability: measurement and clinical utility*." 10(1) Ann Noninvasive Electrocardiol. 88-101 (2005). ("Kleiger" or "Kleiger-2005") Ex. 1033.
[5] U.S. Pat. No. 7,894,888, publ. Feb. 22, 2011. Ex. 1048.

> turbulence (HRT) may be determined. These parameters and further parameters may be analyzed to detect and/or predict one or more of atrial fibrillation, tachycardia, bradycardia, bigeminy, trigeminy, or other cardiac conditions.

Id. at 2:57–64; *see id.* at 18:52–63 (Table 2, listing atrial fibrillation, sinus and supraventricular tachycardias, bradycardia, bigeminy, and trigemini among the types of arrhythmias).

According to Dr. Chaitman, "HRV analysis is an important tool in cardiology to help diagnose various types of arrhythmia." Ex. 1003 ¶ 35. "HRV is defined as the variation of RR intervals with respect to time and reflects beat-to-beat heart rate (HR) variability," and "can be accurately determined based on either ECG data or PPG data." *Id.* ¶¶ 35–36. With respect to the former, this involves measuring RR intervals. *Id.* ¶ 29. "An R-R interval represents a time elapsed between successive R-waves of a QRS complex of the ECG that occur between successive heart beats." *Id.* "If the RR intervals over a time period are close to each other in value, then ventricular rhythm is understood to be 'regular.' In contrast, if there are significant variations in the RR intervals over a time period, then the ventricular rhythm is understood to be 'irregular.'" *Id.* ¶ 37 (citations omitted).

The Specification explains that during cardiac arrhythmia, "the electrical activity of the heart is irregular or is faster (tachycardia) or slower (bradycardia) than normal," and in some forms, "can cause cardiac arrest and even sudden cardiac death." Ex. 1001, 1:40–44. According to the Specification, although the most common cardiac arrhythmia, atrial fibrillation, may cause no symptoms, it is associated with palpitations, shortness of breath, fainting, chest pain, congestive heart failure, as well as

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