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.

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JUDGMENT Final Written Decision Determining All Challenged Claims Unpatentable 35 U.S.C. § 318(a)

Denying In-Part and Dismissing In-Part as Moot Patent Owner's Motion to Exclude Evidence 37 C.F.R. § 42.64

I. INTRODUCTION

A. Background

Apple, Inc. ("Petitioner") filed a Petition for an *inter partes* review of claims 1–30 of U.S. Patent No. 10,595,731 B2 (Ex. 1001, "the '731 patent"). 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); Patent Owner filed a responsive Sur-reply (Paper 8). Taking into account the arguments and evidence presented, we determined the information presented in the Petition established that there was a reasonable likelihood that Petitioner would prevail in demonstrating unpatentability of at least one challenged claim of the '731 patent, and we instituted this *inter partes* review as to all challenged claims. Paper 10 ("DI").

After institution, Patent Owner filed a Patent Owner Response (Paper 26, "PO Resp."); Petitioner filed a Reply to the Patent Owner Response (Paper 29, "Reply"); Patent Owner filed a (corrected) Sur-reply (Paper 36, "PO Sur-reply").

Patent Owner also filed a motion to exclude (Paper 34, "Mot."); Petitioner opposed the motion (Paper 36, "Opp. Mot."); and Patent Owner filed a reply in support of its motion (Paper 38, "Reply Mot.").

An oral hearing was held on September 14, 2022, and a transcript of the hearing is included in the record. Paper 41 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. This decision is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of claims 1–30 of the '731 patent. For the reasons discussed below, we hold that

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Petitioner has demonstrated by a preponderance of the evidence that claims

1–30 are unpatentable.

B. 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 6, 2.

C. 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 6, 2; *see* Pet. 88. 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). As such, the '731 and '499 patents share substantially the same specification.

D. Priority Date of the '731 Patent

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 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

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provisional application No. 61/953,616. Pet. 2–3. Because Patent Owner does not contest this assertion, or the prior art status of any asserted reference, we need not determine whether the challenged claims are entitled to the benefit of the earliest filed provisional application. *See generally* Prelim. Resp. 4; PO Resp. 17, 19.

E. Asserted Grounds of Unpatentability

Ground	Claims Challenged	35 U.S.C § ¹	Reference(s)/Basis
1	1, 7, 12, 13, 16, 17, 23–26, 30	§ 103	Shmueli ²
2	1, 2, 4, 7, 12–14, 16–18, 20, 23–26, 30	§ 103	Shmueli, Osorio ³
3	3, 5, 6, 19, 21, 22	§ 103	Shmueli, Osorio, Li 2012 ⁴
4	8–11, 27–29	§ 103	Shmueli, Osorio, Kleiger ⁵
5	15	§ 103	Shmueli, Osorio, Chan ⁶

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

¹ The Leahy-Smith America Invents Act ("AIA") included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. Because we determine the priority date of the challenged claims is no earlier than the '731 patent's filing date of March 14, 2014 (*see infra*), we apply the AIA versions of the statutory bases for unpatentability.

² WO2012/140559, publ. Oct. 18, 2012. Ex. 1004.

³ U.S. 2014/0275840, publ. Sept. 18, 2014. Ex. 1005.

⁴ 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-2012") Ex. 1006.

⁵ Kleiger RE, Stein PK, "*Bigger JT Jr. Heart rate variability: measurement and clinical utility.*" 10(1) Ann Noninvasive Electrocardiol. 88–101 (2005). ("Kleiger") Ex. 1033.

⁶ U.S. Pat. No. 7,894,888, issued Feb. 22, 2011. Ex. 1048.

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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 Declarations of Dr. Igor Efimov, Ph.D. Ex. 2001; Ex. 2016.

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 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 [electrocardiogram] data or PPG [photoplethysmography] data." *Id.* ¶¶ 35–36. "An R-R interval represents a time elapsed between successive R-waves of a QRS complex⁷ of the ECG

⁷ "[E]lectrical activity of the heart based on depolarization and repolarization of the atria and ventricles . . . typically show[s] up as five distinct waves on [an] ECG readout – P-wave, Q-wave, R-wave, S-wave, and T-wave." Ex. 1003 ¶ 29. "A QRS complex is a combination of the Q, R, and S waves

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